A. Overview

1. Accomplishments (with significance/impact)

Major accomplishments in this third year of CTSI’s grant include continued development of several key local initiatives and inter-institutional and public-private consortia to promote clinical and translational research. The year also saw a transition in leadership with the CTSI PI, Clay Johnston, leaving to become the inaugural Dean of the Dell School of Medicine at UT Austin, and CTSI Co-Director, Deborah Grady, assuming leadership. Dr. Grady has been a part of the CTSI leadership team since the first days of the CTSI grant, leading the large and very successful training efforts. New leaders of the training program (Kirsten Bibbins-Domingo), Clinical Research Services (Henry Chambers) and consultation services (Alka Kanaya) were also named. To support expanded CTSI efforts, the CTSI board was expanded to include the Dean of the School of Medicine (joining the Deans of Dentistry, Nursing and Pharmacy) and the Chair of the Department of Pediatrics.

a. Increasing programmatic impact

i. **Continuing institutional growth in biomedical informatics.** In year 6, we described CTSI’s involvement in the preparation for launching the first academic home for biomedical informatics at UCSF. In year 7, the “Institute for Computational Health Sciences” (ICHS) was launched, and year 8 saw significant recruitment efforts for faculty and leadership. In year 8, CTSI also developed a strong partnership with the Center for Digital Health Innovation (led by Michael Blum, Director of the CTSI Biomedical Informatics program), which continued to fund and grow a pathway in the CTSI Catalyst program that focuses on development of digital health products (see Section 1.b.) Year 8 also saw the CTSI PI shepherding significant funding at UCSF to support the development of an Enterprise Data Warehouse (EDW), which will replace the current Integrated Data Repository (IDR), and enhance access to a wide range of clinical data for research. CTSI CIO Mini Kahlon joined the campus committee to oversee the development of the IDR and EDW, and reporting tools were rolled out in Spring 2014.

ii. **Expanding the Early Translational Research (ETR) program.** In Year 6, CTSI launched the ETR program with its flagship initiative, “Catalyst.” The Catalyst program is a novel approach to customizing consultation and providing funding to help early translational researchers advance their ideas and inventions to products with commercial potential. Year 7 saw the expansion of the program into 4 distinct tracks: therapeutics, diagnostics, devices, and digital health. Volunteer consultants (expanded to 140+) include senior executives in pharmaceutical or biotech companies, intellectual property lawyers, venture capitalists, clinical experts and more. Year 8 saw the Catalyst program attract significant support from two commercial sponsors, MedImmune and Quest Diagnostics.

iii. **Continuing to grow the online education program.** CTSI’s training and education programs are models of excellence, with greater reach established in the last few years through development of online education, including flagship courses on clinical research and research ethics. Year 8 saw the program mature with development of new courses in scientific writing and implementation and dissemination sciences.

iv. **Accelerating improvements in supporting clinical research.** CTSI continues to implement key improvements in the way clinical research services are delivered. Year 8 was the first year that the Clinical Research Service was led by Henry (Chip) Chambers, who has directed significant changes in operations, including establishing a “scatter bed” model in the adult and pediatric units. In addition, protocols that were exempt from contributing to recharge revenue are being phased out. The CTSI Board of institutional leaders helped craft and provided strong support for these strategies which are essential to bringing financial health to the program and allowing for continued innovation.

v. **Incentivizing and supporting cross-disciplinary teams.** A new cross-cutting initiative is under development to incentivize cross-disciplinary teams and to enable their success. New pilot
award categories were established that incentivize the formation of new teams across disciplines; a consulting service is being planned to support team development, organization and leadership; and work has begun to change promotion and advancement guidelines across campus to reward team participation.

vi. Expanding the use of research-enabling tools. Year 8 saw significant progress in the use of the research networking tool, “UCSF Profiles,” and in a UCSF-developed tool, “UCSF Open Proposals.” A publication, “The use and significance of a research networking system” (Journal of Medical Internet Research. 2014 Feb 7;16(2):e46), captured the tremendous success in increasing the use of Profiles, and conveyed the first evidence of research-enhancing outcomes, such as enabling collaborations and reducing inefficiencies in research administration. From across the university, UCSF Open Proposals gained users who deployed this open innovation tool to generate improved proposals and increase collaboration. The tool facilitated collaboration for efforts encompassing IT innovation in support of the academic mission, building next generation curriculum for medical students, and identifying the best investments in registry development. UCSF Open Proposals was described as a case study in how to inject innovation into the clinical and translational science mission in “Crowdsourcing the CTSA Innovation Mission” (Journal of Clinical and Translational Science. 2014 Mar 21. Doi:10.1111/cts.12147. PMCID in process.). Both tools formed the basis of cross-institutional collaboration as elaborated in Section 2.d.

vii. Implementing process improvement to improve efficiency and effectiveness of human subjects review. In Year 7, Lean Six Sigma approaches were used to provide analysis, data, and strategies that improved the timeliness and reduced the cost of sample handling and processing in the CRS. Year 8, saw a focus on UCSF Institutional Review Board (IRB) timelines, with the office of compliance and ethics participating with CTSI on a variety of process improvement exercises. Some of these were inspired by Lean Six Sigma while others were initiated through a solicitation of ideas from faculty across the university. Plans to reduce time spent in IRB have begun to be implemented and will be tracked in Year 9. Local efforts are also being coordinated with efforts across the UC system (see Section 2.a.)

b. Expanding the footprint of change
   i. Building diverse stakeholder partnerships to improve health in San Francisco. The San Francisco Bay Health Improvement Program (SFHIP), a flagship cross-cutting initiative for CTSI, continued to grow, enabled by its overall management working with the San Francisco Mayor’s Office and other City departments. Last year, brought advances in all initiatives including Dental Caries, Hepatitis and Physical Activity.

   ii. Leveraging the 5-member University of California (UC) CTSA network. In Year 6, the 5 UC CTSAs created a network to amplify individual campus efforts to improve research processes, and launched the UC Biomedical Research Acceleration Integration and Development program (UC BRAID). Another cross-campus effort was enabled by $5 million in funding from the UC Office of the President: UC Research Exchange (ReX) continues to make progress on integrating clinical data for research across the 5 UC CTSAs. Year 8, saw the launch of a data explorer tool, providing the first self-serve access to 12 million+ records from across the 5 UC medical campuses. The BRAID and ReX networks were leveraged to initiate several significant projects, including a NHLBI-funded drug development effort (Center for Accelerated Innovation) and several Patient and Clinical Data Research Networks funded by the Patient Centered Outcomes Research Institute (PCORI). BRAID also made progress on the IRB reliance initiative and master contracting.

   iii. Building a regional public-private consortium to accelerate the implementation of clinical trials. Year 7 saw the launch of a nascent network of institutions committed to reducing the hurdles to initiate clinical trials across institutions. Year 8 saw the Partnership for Accelerating Clinical Trials (PACT) formalized to include a large number of diverse institutions, ranging from academic (5 UC medical centers, Stanford, USC) to private (Sutter Health, Dignity Health). In addition, biotech and pharmaceutical partners (including Onyx pharmaceuticals and Genentech)
joined to help support the consortium. The UCSF CTSI PI led the formation of PACT and its transition to a formal organization. In Year 8, PACT adopted a joint leadership model, by the UC San Diego CTSA PI and the Director of Research at Sutter Health. In the future, leadership will rotate approximately every 2 years.

iv. Expanding impact of software that enables research. UCSF Profiles and UCSF Open Proposals (described above in Section 1.f.) formed the basis of cross-institutional collaborations. UCSF Profiles, built on the open source “Profiles Research Networking Software” from Harvard Catalyst, has been extensively customized and leveraged to increase usage and outcomes at UCSF. As a result, institutions have sought out UCSF CTSI to help them participate in the benefits of using a research networking tool. A pilot network, “Researcher to Researcher,” was launched, with UC San Diego and USC as founding members. The network was launched by UCSF CTSI and will be used to explore the benefits of researcher networking tools between institutions as the basis for further expansion. Similarly, UCSF Open Proposals has caught the imagination of other institutions and Year 8 saw its successful deployment at UC Merced and Harvard Medical School. Both external deployments will evolve into sustainable business models and will include a framework for the assessment of impact on research and other institutional processes.

2. Challenges encountered

a. Clinical Research Services (CRS) – The changes necessary to transform the previous GCRCs, now Clinical Research Services, continue to require culture change to enable movement to new models of efficient and cost-effective services. With a new Director (Henry “Chip” Chambers) on board, we have made key changes to the organization and function of CRS (see Section 1.d.), but much work remains to change the fundamental business model and to meet the changing needs of clinical research.

b. Planning, Evaluation, and Tracking (PET) – New tools have helped aggregate data across programs, and streamline aspects of program review and planning. A new focus on process improvement has been embraced across campus, stimulated in large part by CTSI efforts. However, the coordination and facilitation of program activities and organizational focus has room for improvement. In addition, there are a large number of clinical and translational research services where Lean Six Sigma-type process improvement could improve efficiency and timelines and reduced cost.

c. Early Translational Research (ETR). The ETR program is continuing to develop a proposal for a Gap fund to support innovation beyond the current capacity of Catalyst. Progress has been made with institutional leaders on developing this fund. In addition, ETR will continue to pursue external funding to support its mission.

3. Program integration & innovation

Program integration continues to be supported by on-going program evaluation, regular meetings of the senior leaders of CTSI, and periodic retreats of the broad CTSI community. Three major collaborations, SFHIP (Section 2.a), UC BRAID/ReX (Section 2.b), and PACT (Section 2.c) are essential components of CTSI’s efforts to advance research to improve health. In addition, UCSF CTSI and BRAID have begun to engage in the activities of national consortia on cohort identification, using electronic health records, and IRB reliance. As CTSI continues to expand its activities and impact in early translational research, it engaged various campus entities, from the University Innovation Technology and Alliances Office to the state-funded translational research “incubator: jointly established at UCSF, UC Berkeley, and UC Santa Cruz (“QB3”). These groups are now seamlessly integrated with the CTSI Early Translational Research (ETR) program to provide infrastructure and services across the continuum of product development. These partners participate in review panels for the Catalyst Program. The CTSI ETR Program reviews disclosures with the UCSF Technology Transfer office on a monthly basis to take a more proactive approach to assisting investigators. QB3 and CTSI make joint awards. And CTSI ETR investigators use the QB3 incubator. Finally, significant impact in biomedical informatics has occurred through campus-wide changes stimulated by CTSI as described in 1.A.1.a.
4. **Future Direction of CTSI**

Future areas of focus include:

- Changing the business model for clinical research services to create a sustainable system.
- Defining next generation clinical research and how Clinical Research Services and biomedical informatics can support these new initiatives.
- Continued expansion of Early Translational Research.
- Building on campus momentum to expand capabilities for leveraging clinical data to enable research at UCSF and across the five UC medical campuses.
- Ensuring that CTSI efforts on process improvement for core campus entities (such as the Office of Research, IRB, contracting) transitions over the next year to central campus efforts.
- Catalyzing the creation of a robust enterprise data warehouse across campus.

B. **Support received under Institutional commitments**

UCSF provides institutional support to almost every program component of CTSI. For the current year, the institution expended $6.08 million in cash support towards CTSI programs. The four schools contributed a total of $4.33 million in cash support, which was distributed to the programs as follows: $1.67 million to augment the NIH-funded activities in the CTSI Training Program; $325,000 to Community Engagement and Health Policy; $525,000 to fund additional pilot grant awards; $70,000 for Biomedical Informatics initiatives; $125,000 to Consultation Services; $90,000 for Career Development; $411,000 for administration; $615,000 for Early Translational Research; and $493,000 to develop new initiatives. In addition, the Chancellor’s Office contributed $750,000 to augment the activities of the Community Engagement and Health Policy, Biomedical Informatics and Virtual Home programs, and to co-fund administration for CTSI. The UC system provided $1M to fund the UC Research Exchange program, which is a multi-campus project that is affiliated with the CTSI BMI program.

C. **Collaborations and National CTSA contribution**

CTSI continues to work on several national projects, participating actively, or leading. These include:

- Co-Chairing SGC#1 – CTSI PI Dr. Clay Johnston.
- Co-Director, Translational KFC – Early Translational Research Program Director Dr. June Lee.
- Co-leading the new Policy Working Group – Community Engagement and Health Policy Co-Director Dr. Laura Schmidt.
- Presenting Workshops on Profiles, the VIVO ontology and Eagle-I enhancements – Virtual Home Director, Leslie Yuan, MPH
- Leading the Human Subjects Database project (HSDB) – BMI Co-Director Dr. Ida Sim

In addition, the CTSI PI and CIO both participate extensively in UC BRAID activities, the regional network of 5 UC CTSA’s, and in PACT. Further collaborations are described in Section 1.A.2.

D. **Contributions to significant scientific clinical and translational advances**

Sixty-five articles citing the services of CTSI were published in journals with an Impact Factor >5 during the reporting period. We selected a few with an impact factor of 10 or more to illustrate how the work of CTSI is contributing to advance all aspects of clinical and translational sciences.

A. Moran, “Interleukin-1 antagonism in type 1 diabetes of recent onset: two multicentre, randomised, double-blind, placebo-controlled trials,” *The Lancet*. 2013 Jun 1; 381(9881):1905-15. Canakinumab and anakinra were safe but were not effective as single immunomodulatory drugs in recent-onset type 1 diabetes. Interleukin-1 blockade might be more effective in combination with treatments that target adaptive immunity in organ-specific autoimmune disorders.

R.Apps, “Influence of HLA-C expression level on HIV control,” *Science*. 2013 Apr 5; 340(6128):87-91. A variant upstream of human leukocyte antigen C (HLA-C) shows the most significant genome-wide effect on HIV control in European Americans and is also associated with the level of HLA-C expression. We characterized the differential cell surface expression levels of all common HLA-C allotypes and tested directly for effects of HLA-C expression on outcomes of HIV infection in 5243 individuals.
This study sought to identify loci for coronary artery calcification (CAC) in patients with chronic kidney disease (CKD). We identified several loci associated with CAC in CKD that also relate to MI in a general population sample. CKD imparts a high risk of CHD and may provide a useful setting for discovery of novel CHD genes and pathways.

The etiology of biliary atresia (BA) is unknown. Given that patterns of anomalies might provide etiopathogenetic clues, we used data from the North American Childhood Liver Disease Research and Education Network to analyze patterns of anomalies in infants with BA. Careful phenotyping of the patterns of anomalies may be critical to the interpretation of both genetic and environmental risk factors associated with BA, allowing new insight into pathogenesis and/or outcome.

Clinical asthma studies across different age groups (i.e., cross-age studies) can potentially offer insight into the similarities, differences, and relationships between childhood and adult asthma. The National Institutes of Health's Asthma Research Network (AsthmaNet) is unique and innovative in that it has merged pediatric and adult asthma research into a single clinical research network.

To assess a causal relationship between air pollution and childhood asthma using data that address temporality by estimating air pollution exposures before the development of asthma and to establish the generalizability of the association by studying diverse racial/ethnic populations in different geographic regions. Early-life NO₂ exposure is associated with childhood asthma in Latinos and African Americans. These results add to a growing body of evidence that traffic-related pollutants may be causally related to childhood asthma.

This study is the largest to examine composition of the lower respiratory tract microbiome in healthy individuals and the first to use the neutral model to compare the lung to the mouth. Specific bacteria appear in significantly higher abundance in the lungs than would be expected if they originated from the mouth, demonstrating that the lung microbiome does not derive entirely from the mouth. The mouth microbiome differs in nonsmokers and smokers, but lung communities were not significantly altered by smoking.

Plasma biomarkers such as Ang-2 can improve clinical prediction scores and identify patients at high risk for ALI. In addition, the early rise of Ang-2 emphasizes the importance of endothelial injury in the early pathogenesis of ALI.

A phenotype-based screen of 320 compounds identifies a US Food and Drug Administration-approved compound (clemizole) that inhibits convulsive behaviors and electrographic seizures. This approach represents a new direction in modelling pediatric epilepsy and could be used to identify novel therapeutics for any monogenic epilepsy disorder.
Self-Evaluation Report

Evaluation Objectives to Be Addressed:

In year 8, UCSF CTSI self-evaluation focused on five areas:

1. **Delivery of innovative services to the UCSF research enterprise.** CTSI is constantly seeking to understand the evolving needs of researchers at UCSF and to develop innovative tools and services for meeting those needs.

2. **Institutionalization of mature services and technologies.** CTSI strives to develop sustainable partnerships with UCSF campus to assess and implement the transfer of mature services to the appropriate UCSF structures or external organizations.

3. **Improvement of clinical and translational research processes.** CTSI partners closely with campus partners to analyze and improve clinical and translational research processes to improve the cost, quality, and speed of translating research while developing a robust C&T workforce.

4. **Maximization of impact of CTSI on its stakeholders, including UCSF and the broader CTSA.** CTSI is using its balanced scorecard and ROI methodologies to ensure good stewardship of NIH dollars while delivering measurable impact on health, developing sustainable partnerships, and offering a great place to work.

5. **Promotion of translational research at UCSF and beyond.** CTSI promotes the development of biomedical products, in partnership with industry, and new technologies, such as digital and wireless health.

Framework for CTSI Self Evaluation and Findings:

UCSF CTSI continued the implementation of the Balanced Scorecard approach as the key methodology to assess programs and CTSI’s overall performance. Each program was requested to identify key objectives and associated metrics in three categories: 1) CTSI customers (community, UCSF, national research environment), 2) internal processes, and 3) sustainable business models. Within this framework, each program generated a list of projects or initiatives to deliver on its objectives. Each program then presented a budget broken down by initiatives to the CTSI Operating Committee (OC) and the Board.

Objectives and budget initiatives are maintained in a web-based scorecard management system – Process Based Leadership (PBL). Progress and updates on individual programs are reported directly into PBL, thereby streamlining communication around program management and allowing for greater transparency. PBL also features detailed program management functions (meeting and task management) that will be rolled out in Year 9. This will further centralize and structure communication around goals and objectives, cutting down on many emails, spreadsheets attachments, and so on.

The output of PBL is used to generate a dashboard posted on CTSIs’ web site, showing the performance of CTSI against the target it sets for itself. The main purpose of this dashboard is to demonstrate transparency and accountability.

Here are findings related to the 5 key evaluations objectives

1. **Delivery of innovative services to the UCSF Clinical Research Enterprise**

   Innovative new services included team science initiatives, data that enables clinical and translational research and research administration, and online education. CTSI is laying the foundation to promote and reward team sciences in the context of biomedical research. A program has been put in place to award pilot money to projects that meet specific team sciences criteria. In addition, innovative ways of reporting authorship are being tested. Finally, efforts are being taken in collaboration with UCSF Departments to include team participation in promotional criteria and provide more transparency around them.
CTSI continues to leverage its data “Shoebox”, i.e., its home-grown solution to integrating data from central human resources, papers and grants, and information from CTSI services. Shoebox is being utilized extensively to identify how investigators have benefited from CTSI services, and to generate custom utilization reports to key stakeholders. For instance, School Deans receive personalized information on publications generated by their department, and will receive broader personalized dashboards from CTSI. In addition, Shoebox continues to be used in conjunction with other technologies to automate the APR report generation process.

CTSI has also taken active and significant steps to re-structure its Biomedical Informatics program by nominating a key stakeholder as Co-Director: Michael Blum, CMIO of the Medical Center. While further work needs to be done to strengthen the strategic direction of the program, this appointment was a positive step in aligning CTSI with the overall informatics effort at UCSF to ensure that the specific needs of clinical researchers are being taken into account in the design of the overall “UCSF Enterprise Data Warehouse”.

Finally CTSI has grown its online education offering for students with courses on Designing Research for Clinical Trainees and Responsible Conduct for Research. This offering has been particularly well-received by the trainees for both its quality and cost-effectiveness. Further expansion is planned, notably in the area of early translational research where there is a significant unmet need.

Although NIH funding is adequate to fund the development of new C&T solutions, it may generate less value when used to operate mature tools and programs. While not always possible, CTSI aims to have clear technology and program transfer plans in place from the beginning, with a clear and willing recipient identified.

2. **Institutionalization of mature services and technologies**

CTSI is continuing the strategic re-alignment of the Clinical Research Services (CRS) program started in Year 07, with three goals: 1) Understand and quantify the needs of the rich pool of C&T researchers at UCSF, 2) Develop a set of agreed-upon guidelines through which CRS will operate, and 3) Design services to meet PI needs while developing a sustainable business model. As a result, underperforming cores were closed after extensive consultation with the PI community. Contracts with the Medical Center for space and nursing services are being re-negotiated on sound business plans. The program is also actively developing technology solutions to streamline its budgeting, billing, and scheduling services to better serve the PI community.

CTSI continues to be successful in deploying a novel ‘Open Proposals’ platform. Open Proposals is an effective tool and process to solicit, screen, approve, and implement project proposals to solve scientific and technical issues. It was initially implemented in Year 7 for CTSI needs but is now being used by multiple departments on campus to enhance the quality of proposals and the teams that work on them. Open Proposals has also been used by other institutions, UC Merced and Harvard Medical School, with an evolving business model for this extra-institutional activity.

3. **Improvement of clinical and translational research processes**

Internally, CTSI continues to expand its focus on efficiency, in which Program Evaluation and Tracking (PET) plays an active role. In Year 8, the Community Engagement and Health Policy (CE&HP) program significantly improved the planning and execution of its activities to better leverage its modest investment for increased impact on the community. CRS and PET have also collaborated to better map and understand budgeting and billing processes prior to designing and selecting technology solutions. In addition, PET is initiating two new projects for CTSI: 1) Improving the financial reporting data of the CRS program, and 2) Mapping the underlying processes that need to be followed to support the efficient functioning of the UCSF Enterprise Data Warehouse (EDW) to which the BMI program contributes.
Working closely with central campus administration, PET has improved the following three processes through Lean Six Sigma and other process improvement tools: 1) the IRB approval process for both expedited and full committee reviews, 2) the post-award set-up process, and 3) inpatient clinical research processes. In all three cases, the focus is on speed while maintaining a high quality of execution.

Collaborations with Campus and the Medical Center allow CTSI to gain direct access to a wide range of data necessary for assessing and measuring the impact of its activities on Campus. These activities also align with the goal of institutionalizing C&T research at UCSF by presenting CTSI as a key partner in all aspects of C&T operations. CTSI plans on expanding these process improvement efforts to a more strategic level after getting tactical results in FY09.

4. **Maximization of impact of CTSI on its stakeholders, including UCSF and the broader CTSA**

CTSI intends to be the best steward of NIH money by: 1) Showing how NCATs dollars generate value to UCSF through new ROI calculations, 2) Increasing its revenues from operations and 3) Investing in programs/projects with cross-cutting reach at a national level.

CTSI is now measuring the ROI from a UCSF point of view, i.e., it is estimating the return to UCSF per dollar of institutional funding. In terms of indirect costs, UCSF receives $0.97 for each dollar invested. In terms of follow-on funding, such as grants received by CTSI and CTSI grant awardees, the return is $9.81 per dollar. CTSI will continue to measure this return on a yearly basis to demonstrate the value it generates to one of its key strategic partners, with the purpose of diversifying its funding sources beyond NIH. We recognize that this is a limited approach to measuring the true value that CTSI brings to the institution, but we believe it is a starting point.

In Year 08, CSTI generated 3.5% of its total operating budget (NIH + non-NIH funding) from income from its operations (revenues from the CRS and Consultation Services and other programs). With an aggressive re-structuring of the CRS program and strong incentives for all CTSI programs to strive for self-sustainability, CTSI plans to significantly increase this proportion in the coming year.

CTSI continues to play a leading role in the implementation of the UC Biomedical Research Acceleration, Integration and Development program (UC BRAID) across the 5 UC Health Campuses. This collaboration offers substantial value to all five UCs by jointly reducing barriers to translation. UC BRAID, along with substantial funding from the Office of the President of the University of California, supports the UC Research Exchange (UC ReX), which is creating an integrated data repository across the 5 UC campuses. This system includes governance, IRB reciprocity, master contracting and cohort identification. In addition, CTSI is participating in the CTSA consortium activity to develop a common set of metrics and a process to harmonize IRB and contract procedures across all 61 sites. A two-stage program is being implemented, starting with a pilot at 10 test universities to be followed by a scale-up based on the results.

In parallel, CTSI led the development of the Partnership to Accelerate Clinical Trials (PACT). This is a consortium of 20 Institutions (including the 5 UC Medical Centers, Stanford, USC, Sutter Health, and Dignity Health) that have agreed to implement a centralized IRB system and to accelerate the pace of clinical trials. This year, CTSI PI Clay Johnston turned over leadership of PACT to the CTSA PI from UC San Diego and the Director of Research at California Pacific Medical Center/Sutter Health, but UCSF continues to serve on the Steering Committee and support project management.

In another effort to join forces with other Campuses, UCSF CTSI together with UCLA have taken leadership to create UC Engage, a 5-campus project involving an inter-disciplinary team to develop and implement guidelines for biorepository collection and operations at University of California (UC) outpatient clinics. UC Engage has partnered with the UC BRAID Biobank Working Group to aid in the creation of best practices and governance for biospecimens for the five UC medical campuses. This group has agreed on vision, goals, and milestones needed to develop Standard Operating Procedures (SOP), has developed half of the operations SOPs, and has agreed upon an outline for overall governance.
5. **Promotion of translational research at UCSF and beyond.**

The Early Translational Research (ETR) Catalyst program is a key vehicle for this goal, and the program continued to perform strongly in Year 08 after its inception in Year 06. The program provides rich consultation and financial awards in a broad spectrum of translational research, including therapeutics, diagnostics, devices, and now digital health in collaboration with the Center for Digital Health Innovation led by Michael Blum, CTSI BMI program Co-Director. Disclosing inventions is a requirement for any applicants to receive awards and ETR generates significantly more disclosures per dollar invested compared to the broader UC system. In addition, ETR is now receiving funding from industry sponsors such as Quest and Medimmune.

Other activities that have helped in the promotion of translational research at UCSF and beyond include a model project for translating science into best practices for the public. With external funding, the CE&HP program designed a model for scientific review and creative representation of key concepts around sugar and impact on health was designed. This ‘sugar science’ project will be released next year. Finally, the San Francisco Health Improvement Project (SFHIP) continues to evolve its model for translating science into improved health and plans on disseminating its learning next year.

**Variables being measured in program reviews**

As reported in prior NIH APRs, the assessment criteria address four categories:

- **Performance Management:** How has each program progressed against its objectives and how has it managed its portfolio of initiatives?
- **Return on Investment:** What return did programs achieve for CTSI or UCSF, whether monetary or strategic?
- **Impact:** What is the contribution of the program to CTSI’s mission?
- **Leadership and Management effectiveness:** What leadership and management practices best meet the needs of the program?

During program reviews for each program, the CTSI Executive Committee critically assessed how well the program has performed toward stated goals and whether the program is well-positioned for future success in terms of having key leadership and staff, proper organization, and efficient functions. A wide range of measures is reported by programs, including the number of consultation hours, number of linkages established, number of proposals submitted and funding awarded, number of scholars/trainees trained, number of mentors trained, and number of community partnerships established or under development. These measures are addressed in the individual program reports included in this APR.

**Budget-by-initiative**

To assess the cost-effectiveness of a program’s activities, CTSI compares program’s annual budget with its portfolio of initiatives, which represent priorities and projects.

**Data Collection Methods Employed:**

In Year 8, programs continued to use quantitative and qualitative data collection methods. As mentioned above, the Shoebox now provides a single “source of truth” from which various data can be pulled by manual or automated queries. PBL is also now becoming a key source of data for both program review and APR needs.

**Confidentiality and Human Subjects Protection Activities:**

CTSI programs continue to pursue confidentiality and human subjects’ protection activities where appropriate. During Year 8, they focused on the following:
• **Pilot funding for studies involving human subjects and animals.** Our pilot funding program, SOS, requires that all recipients of funding provide IRB and IACUC approval numbers as a condition of accepting the funding. All IRB and IACUC approval numbers are reflected in the IRB and IACUC approval table attached to this APR.

• **Studies conducted by Scholars and Trainees.** Our training programs require that trainees and scholars conducting clinical studies comply with Human Subjects Training (HST) requirements and that all studies are fully compliant with IRB regulations. A list of all scholars and trainees who have taken human subjects research training, HIPPA training, and/or responsible conduct of research (TICR) courses is appended.

• **Confidentiality of research subjects.** The UCSF and affiliate IRBs ensure Human Subjects’ confidentiality and protection. Clinical researchers follow GCP protocols and SOPs. Data reports are presented in aggregate form rather than reporting by individual program participant. A list of all IRB approvals from UCSF and affiliates that fall within the CTSI scope is attached to this APR and marked “IRB Approval Report.” In addition, all CRC sites ensure that all new staff involved in the design and conduct of clinical studies complete human subjects training. This list is attached. CTSI programs with staff that may have access to patient health information (PHI) through database integration or development ensure that staff receive HST and appropriate certification that is verified by CTSI central office.

• **Community Partner Interaction.** All studies conducted by UCSF/affiliate investigators with community partners require Human Subjects Protection approval. The Community Engagement program provides informational guides to investigators and community partners who are contemplating research projects. These guides not only include information on Human Subjects Protection, they also direct researchers to online Human Subjects Protection training. In addition, the guides and training assist community partners in understanding the nature of collaborative interactions with USCF researchers and the associated requirements.

**Timeline for Future Activities**

• In Y09, we will continue to execute on program plans. We will actively reach out to investigators and the community to translate more research into products that improve health.

• We will further embed the use of PBL in day-to-day program management. We will merge the generation of APR and program review materials through PBL, and we will train all Programs on how up to create, maintain, and update scorecards on their own.

• We will evaluate new cross-cutting initiatives within UCSF and among CTSAs to collaborate actively and share knowledge on our respective areas of excellence, continuing with the UC system in California.

• We will continue to find innovative ways to measure and improve CTSI performance.
CTS I External Advisory Board

The CTSI External Advisory Board (EAB) plans to meet in the summer 2014. The EAB report will be sent in to NCATS to summarize progress at the meeting. As in past years, attendees at this meeting will include selected members of the current external advisory board, CTSI board and CTSI operations committee members as well as invited guests, based on the topic.

Last year, the meeting focused on our burgeoning efforts in planning for online education in early translational research and obtaining high-level guidance on challenges and opportunities for our third renewal application.

This year, we will focus on the opportunities and challenges in redesigning clinical research services, both traditional patient-centered efforts as well as new “next-generation” clinical research approaches that leverage electronic platforms.

UCSF Clinical and Translational Science Institute External Advisory Board Members 2014

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President and CEO, California HealthCare Foundation

UCSF Clinical and Translational Science Institute
Operations Committee and Board Members who will be present include:

Henry F. Chambers, MD
Professor, Medicine
Chief, Division of Infectious Diseases, SFGH
Director, Clinical Research Services
Clinical and Translational Science Institute (CTSI)

Deborah Grady, MD, MPH, Professor of Medicine
Associate Dean for Clinical and Translational Research
Director of the UCSF Women's Health Clinical Research Center
Co-Director, UCSF Clinical and Translational Science Institute

Maninder Kahlon, PhD
Assistant Professor of Neurology
Executive Director & CIO
UCSF Clinical and Translational Science Institute

June H. Lee, MD
Professor, Division of Pulmonary Medicine and Critical Care Medicine
Director, Early Translational Research
UCSF Clinical and Translational Science Institute

Sally Mead
Chief Administrative Officer
UCSF Clinical and Translational Science Institute
Biomedical Informatics (BMI)

A. Personnel
1. Co-Directors: Ida Sim, MD, PhD and Michael Blum, MD
2. Campus Lead, Cross-institutional Data Initiatives: Maninder Kahlon, PhD
3. Associate Director Digital Health: Aenor Sawyer, MD
4. Program Manager: Angela Rizk-Jackson, PhD

B. Goals of Program
1. Enhance capacity for access and use of data resources for the purpose of scientific research
2. Foster digital health innovation
3. Facilitate cross-institutional data collaborations

C. Program Characteristics
1. Process
   CTSI’s Biomedical Informatics (BMI) program is led by two co-directors, Blum (Associate vice Chancellor for Informatics, Director of the Center for Digital Health Innovation, and Chief Medical Information Officer of the UCSF Medical Center) and Sim (Co-Founder of Open mHealth, Project Leader of the national Human Subjects Database - HSDB). Under this Program, the CTSI facilitates development of resources to access health data from campus and affiliates by performing needs assessments and outreach in collaboration with the head of Academic Research Services, Douglas Berman, as well as by providing representation on campus-wide steering committees with Blum, Sim & Kahlon on the Enterprise Data Warehouse and Research Technologies Committees. Additionally, Blum and Sim serve on the Executive Committee of the newly formed Institute for Computational Health Sciences (ICHS), which will drive academic informatics activities on campus. Sim also chairs the Clinical Informatics Subcommittee of ICHS, and both Blum and Sim will be serving on the search committee for the ICHS Director/Co-Director.

   Blum and Sim help facilitate a digital health track in both the CTSI SOS and Catalyst programs to support digital health projects with potential commercial applications. Sim leads the faculty consultants supporting the Digital Health offerings of CTSI Consultation Services. Aenor Sawyer, faculty in Orthopaedic Surgery, plays a key role in facilitating digital health in both awards programs, as the Associate Director of Strategic Relations for the Center for Digital Health Innovation, and liaison to external partner programs such as the Center for Information Technology Research in the Interest of Society (CITRIS) and Rock Health. Kahlon is the Campus Lead for a number of cross-institutional data collaborations, serving as Executive Committee member for the UC Research Exchange (UC ReX) effort which helps coordinate research data sharing of health records data from all five UC biomedical campuses, and also as Co-investigator on two PCORI-sponsored data networks (one Clinical Data Research Network, CDRN, and one Patient-Powered Research Network, PPRN) which will feed into the larger PCORnet initiative, all described below.

   Both Sim and Blum are co-investigators of another PPRN, the Health eHeart Alliance. Sim is the Health eHeart Alliance’s informatics faculty lead. She serves on the national PCORnet Data Standards, Security, and Network Infrastructure Task Force and is working with the Task Force on a “common pipeline for PPRNs to handle their mHealth data.” Finally, Rizk-Jackson provides general programmatic support as well as lending research perspective and academic outreach expertise to campus teams developing data resources and services.

2. Progress
   a. Opportunities and challenges in implementing relevant program activities
   UCSF has launched a cross-cutting initiative to foster Precision Medicine, and accordingly has demonstrated a commitment to supporting campus informatics efforts with the establishment of the Institute for Computational Health Sciences (ICHS), a new informatics academic unit, and the Center for Digital Health Innovation (CDHI), which supports faculty, staff, and students as well as external partners to develop, incubate, and validate digital health technologies. The CTSI is
committed to working with these groups in collaboration with other campus leadership to ensure that informatics efforts are informed by the needs of translational researchers. While some planned BMI Program activities have been delayed for a variety of reasons, other opportunities have arisen in connection with these campus groups (see C.2.b below).

b. Modifications made to original plan, activities, or focus with rationale
A planned effort to convene partner institutions to identify digital health pilot projects had intended to leverage the CTSA Telehealth group. However, this effort was delayed due to inactivity of this group and reorganization of the CTSA structure. The funds budgeted for these activities were repurposed to support an event co-sponsored by the ICHS and UCSF Institute for Human Genetics aimed at informing the campus community about the available clinical data resources and related services, as well as to engage participants on plans for future direction of these resources. This event arose from conversations between leadership of the BMI Program and ICHS, and aligns well with Program goal B.1.

D. Major Accomplishments
1. Enhance capacity for access and use of data resources for the purpose of scientific research
The BMI program is co-funding a programmer to build features into the UCSF Electronic Health Records (HER) system that will support scientific research. UCSF EHR data is currently accessible to the research community through an i2b2 based Integrated Data Repository (IDR) and the EHR data environment. Cohort counts are available directly to investigators via the IDR as well as via data extraction requests through the Academic Research Services (ARS) team. The ARS team can also deliver complete de-identified data sets, and, with IRB approval, identified data sets from the EHR environment. The BMI Program has mapped out further improvements for the discovery and access of these data resources, and begun implementing this plan by harmonizing resource information and taking part in outreach efforts including a campus-wide IT ‘ShareCase’ and an informational workshop event highlighting these clinical and financial data resources.

Additionally, the EHR data will be compiled with other non-EHR campus data sources and external data in the Enterprise Data Warehouse (EDW) that is currently in development. The BMI Program has established a working group to help drive development of the EDW with scientific research use cases and associated requirements. Recognizing that there still exists a gap between a researcher gaining access to a data source and subsequently making good use of what is available, the BMI Program set out to understand the existing landscape of personnel fulfilling the role of data concierge. The Program Manager completed an assessment of current clinical data utilization, highlighting who is accessing the data, how they are accessing it, and for what purpose. This report was shared with the EDW Committee and we will continue to work with appropriate groups on campus to develop data concierges. Finally, data security is a critical concern to all at UCSF. BMI will continue to work with ARS and Information Technology Services (ITS) to ensure that the secure MyResearch platform meets investigators needs and provides a secure, usable environment for all protected data.

2. Foster digital health innovation
The BMI Program has led two efforts to improve the resources available for supporting digital health projects. Acting on feedback from research teams, the BMI Program Directors met with Directors of the SOS & Catalyst Programs to enact changes to the digital health awards (grants) structures on campus that will clarify the appropriate awards mechanisms and better address the needs of the investigators and projects. The BMI Program has also set out to construct a more effective consultation process for digital health research by completing an initial evaluation of current consultation mechanisms and working with appropriate campus groups to develop a centralized, sustainable process for digital health consultations that allows tracking, evaluation, and recharge for services. The BMI Program will support digital health training for faculty by producing a short web-based tutorial aimed at informing prospective researchers about the processes associated with digital application development in the context of research. We are also building a partnership with the online learning team to develop a series of these web-based tutorials. Educational opportunities and UCSF visibility in Digital Health were expanded internally and externally by frequent speaking engagements by the BMI Program leadership. In
addition, interprofessional education was expanded to include HeathTech electives in the Fall, Winter and Spring quarters for the first time.

The ontology modeling and data sharing work done under the HSDB project is being adapted for digital health sciences as follows: the ontology will inform the core data model for a U2C proposal on “Mobilizing Research: A Research Resource to Enhance mHealth Research.” This will allow more sophisticated computational support for digital health study design and more efficient and accurate participant recruitment.

3. **Facilitate cross-institutional data collaborations**
The BMI Program supports CTSI leadership efforts related to a number of cross-institutional data initiatives including the University of California Research eXchange (UC ReX), which recently expanded access to its initial tool, Data Explorer. Data Explorer is a shared University of California (UC) resource that allows UC investigators and quality administrators to search the collective 12 million de-identified clinical patient records of UC. UC ReX is currently developing a proposal assessment model to ensure proposed projects are aligned with the mission and technology strategy of UC ReX, and a data quality plan to ensure that it remains a valid and trusted resource.

Additionally, we have been awarded support from the Patient-Centered Outcomes Research Institute (PCORI) for two proposed data networks. The Clinical Data Research Network (CDRN) will bring together data from existing EHR systems at 7 institutions and the Patient-Powered Research Network (PPRN) will leverage data available at 2 academic medical centers as well as existing Disease Advocacy Organization-based patient networks to drive research participation and engagement. These networks are part of the larger vision of PCORI to support a national patient-centered clinical research network (PCORnet), whose ultimate goal is to enable research activities to be performed across multiple CDRNs and PPRNs.

E. **CTSA Consortium, Activities and Contributions**
   1. UC ReX (see d.3)
   2. HSDB (see d.2)
   3. Telehealth TSIG (see d.2)
   4. CTSI BMI also participates in: (1) Ontology Affinity Group, Informatics KFC; (2) Resource Representation and Discovery Group, Informatics KFC; (3) Integrated Data Repository Affinity Group, Informatics KFC; and (4) Comparative Effectiveness Research -- Informatics Working Group (joint CER and Informatics KFC WG)

F. **Plans for Coming Year**
   1. Align CTSI biomedical informatics program leadership with evolving campus leadership structure to promote biomedical informatics on campus
   2. Advocate for research needs in the development of campus enterprise data warehouse
   3. Expand and mature services available to support the use of electronic data resources for research
   4. Continue to grow the campus digital and mobile health community and academic offerings
   5. Collaborate with CDHI in building a cross disciplinary online curriculum in digital health
   6. Expand and harmonize services available to support the campus digital health community
   7. Align campus data strategies with those of PCORnet and demonstrate the validity and utility of cross-institutional data networks
   8. Co-host the Evaluation of Digital Health Technology conference at UCSF in late Fall 2014 to focus on challenges in evaluating digital technologies in healthcare, including study design, research methodology, rapid timelines, data management, and lack of common vocabulary across disciplines. This event is co-sponsored by BMI, CDHI, and CITRIS partners.
Career Development (CD) Program

A. Personnel
1. Director, CD Program: Renee Navarro, PharmD, MD
2. Co-Directors, CTSI Comprehensive Mentoring Program: Mitchell Feldman, MD, MPhil & Jeanette Brown, MD
3. Director, UCSF Office of Career and Professional Development: Bill Lindstaedt, MS
4. Program Manager: Angela Rizk-Jackson, PhD

B. Goals of Program
1. To provide outstanding research mentoring and career advice.
2. To promote career advancement for clinical and translational researchers.
3. To improve recruitment and retention of under-represented minorities (URM) and women clinical and translational researchers.

C. Program Characteristics
1. Process:
   The CD Program is led by Dr. Renee Navarro (Vice Chancellor of Diversity and Outreach, Professor of Anesthesia and Perioperative Care), who directs career advancement, mentoring and minority recruitment and retention activities. Drs. Jeanette Brown and Mitchell Feldman lead the Comprehensive Mentoring initiative, which includes faculty representatives from all 4 UCSF professional schools. Mr. Bill Lindstaedt leads our professional skills seminar series. The initiative to support team science is led by Dr. Deborah Grady (CTSI Interim Director) with key input from Dr. Daniel Lowenstein (CTSI Associate Director), Dr. Mike McCune (Professor of Medicine, Experimental Medicine Division Chief, and previous CTSI Director), and other campus leadership. The program is supported by Angela Rizk-Jackson, program manager.

2. Progress:
   The CD Program has multiple initiatives intended to improve career development for clinical and translational researchers. This complexity is managed by close collaboration among the program leaders and senior staff, as well as via automated systems for reviewing and tracking. Additionally, a number of program activities have broader support from the campus as well as external organizations. For example, the effort to promote team science activities is supported by a campus-wide initiative to foster “precision medicine,” an effort that necessitates interdisciplinary collaboration. Also, activities focused on increasing diversity are supported by aligned efforts of the campus Diversity and Outreach Office and Academic Affairs, as well as partnerships with the Physician’s Medical Forum.

D. Major Accomplishments
1. To provide outstanding research mentoring and career advice.
   The Mentor Development Program (MDP) is a case-based seminar series begun in 2007. The 8th annual series is in progress. By June 2014, the MDP will have trained 91 mentors from all 4 UCSF professional schools and affiliated programs such as the Kaiser Division of Research. The program has enrolled about an equal number of men and women. Tools were developed for evaluation of the program with overall ratings in the upper 4s on a scale of 1 to 5 (best).

   One of the best measures of the success of the MDP is that graduates have now become leaders of the program and of several new pilot programs, including the Mentoring Consultation Unit, the Mentor Profile, and a newly developed electronic mentor evaluation system.

   Based on suggestions from MDP graduates to provide more leadership training, the MDP was expanded to include a 2-day leadership program entitled: “Scientific Leadership and Management.” In November 2013, we conducted the 6th Annual MDP Graduate Retreat, an interactive meeting to discuss mentoring issues, cases, challenges and lessons learned as a mentor, and suggestions for program improvement.
To provide more uniform mentor evaluations, the Comprehensive Mentoring Program developed a standardized, electronic mentor evaluation system that is currently undergoing a validation study with IRB approval. The School of Dentistry is pilot-testing the electronic mentor evaluation system using the E-value server, which is integrated with teaching evaluations. The electronic mentor evaluation system will request the evaluation from the mentee at the completion of a research project, on an annual basis, or at the time of preparing a mentor's packet for advancement or promotion. In the past year, we continued to train the UCSF Departmental Mentor Facilitators through the MDP and included instruction in using UCSF Profiles to link mentees with appropriate mentors. Finally, we also developed and implemented a month-long K Scholar Early Mentor Development Program.

2. To promote career advancement for clinical and translational researchers.

In collaboration with the UCSF Office of Career Development, CD has supported 12 workshops emphasizing the needs of the clinical researcher. In YR8, the following workshops will be implemented and evaluated by participants for content and format. All continue to receive exceptionally positive evaluation ratings.

<table>
<thead>
<tr>
<th>Course Titles (June 1, 2013 – July 1, 2014)</th>
<th>Period</th>
<th>Number of Participants (C&amp;T / Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tackling Difficult Professional Conversations</td>
<td>Oct 6, 2013</td>
<td>17/33</td>
</tr>
<tr>
<td>Research Talk Clinic</td>
<td>Jan 13, 2014</td>
<td>0/3</td>
</tr>
<tr>
<td>Research Talk Clinic</td>
<td>Feb 10 2014</td>
<td>0/5</td>
</tr>
<tr>
<td>Creating Figures in Adobe Illustrator (Parnassus campus)</td>
<td>Feb 20, 2014</td>
<td>3/46</td>
</tr>
<tr>
<td>Writing Qualitative Research</td>
<td>Feb 21, 2014</td>
<td>19/19</td>
</tr>
<tr>
<td>Creating Figures in Adobe Illustrator (Mission Bay campus)</td>
<td>Feb 26, 2014</td>
<td>8/57</td>
</tr>
<tr>
<td>myIDP-How to Choose Your Ideal Career</td>
<td>Mar 20, 2014</td>
<td>21/69</td>
</tr>
<tr>
<td>Strategies for the Visual Communication of Science (3 sessions)</td>
<td>Mar 5, 12, 19, 2014</td>
<td>10/40</td>
</tr>
<tr>
<td>Funding Your Research: Navigating the NIH Application Process</td>
<td>Apr 14, 2014</td>
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</tr>
<tr>
<td>Funding Your Research: Preparing a K99/R00</td>
<td>Apr 28, 2014</td>
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<tr>
<td>Funding Your Research: Getting a Postdoctoral Fellowship (F32)</td>
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<tr>
<td>Funding Your Research: Fellowship Opportunities for International Postdocs and Fellows</td>
<td>May 5, 2014</td>
<td>N/A</td>
</tr>
<tr>
<td>Funding Your Research: Writing Specific Aims</td>
<td>May 19, 2014</td>
<td>N/A</td>
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</tbody>
</table>

In a separate effort to highlight the growing importance of interdisciplinary teams to the understanding of human biology and the translation of research discoveries into clinical applications and population health, the CTSI has initiated efforts aimed at supporting team science. The CTSI pilot award program (Strategic Opportunity Support) is offering a new award for team science, and the CD Program will complement these monetary awards with a series of consultations aimed at developing the selected teams and team leaders. CD is facilitating discussions with campus leaders to advocate for appropriate recognition of team science activities in faculty promotion considerations.

3. To improve recruitment and retention of URM and women clinical and translational researchers.

CD supports the Visiting Elective Scholarship Program (VESP), which sponsors URM advanced professional students interested in clinical and translational research at the residency level to complete a clinical elective at UCSF. This year, the VESP partnered with the Physicians Medical Forum to offer three additional scholarships for African American medical students, bringing the total number of scholarships to 5. In an effort to expand support for writing NIH Midcareer Investigator Awards in Patient-Oriented Research (K24), the CD Program has identified 3 URM clinical and translational faculty with R01 grants who are candidates for submitting a K24 grant. CD will provide support for these faculty in positioning themselves as high-caliber candidates for future proposal submissions.
This year, the CD Program sponsored four URM and women faculty to attend Association of American Medical Colleges (AAMC) career development seminars. Post-seminar evaluations indicate that attendees find the workshops very useful, and follow-up on past attendee career advancement show eligible attendees have gone on to receive promotions. Past sponsored attendees have also gone on to form campus peer mentoring groups, such as the Women's Advancement and Recognition in Medicine (W.A.R.M.) Hearts group based at San Francisco General Hospital.

To increase awareness of unconscious bias at UCSF, the CD Program has supported a workgroup of three faculty to develop an unconscious bias training program. In the previous fund year, CD sponsored these faculty to attend the three-day Unconscious Bias Learning Lab for Health Professionals (AAMC/Cook Ross). Since then, they have completed an asset mapping of existing unconscious bias modules and training programs at UCSF, done an extensive literature search of existing unconscious bias programs at other institutions, and provided education and training to over 250 faculty and staff at various retreats, leadership meetings, and workshops.

**E. CTSA Consortium, Activities and Contributions**

Mitchell Feldman and Jeanette Brown have been actively involved in the national CTSA Education and Career Development Key Function Mentoring Program, working with other CTSA leaders to develop uniform definitions of types of mentors and to develop mentor evaluation resources.

**F. Plans for Coming Year**

1. **To provide outstanding research mentoring and career advice.**
   
   We plan to continue to expand training of the UCSF Faculty Mentor Facilitators (faculty in each department who are charged with ensuring that each junior faculty member in the department has optimal mentoring) in the Mentor Development Program, and to encourage more faculty to complete their Mentoring Profile on UCSF Profiles. We will continue the K Scholar Early Mentor Development Program with a yearly seminar. The Mentor Consultation Service is now jointly run by the CTSI and the Faculty Mentoring Program, and will continue to offer free and confidential consultation related to mentoring issues. The web-based electronic mentor evaluation system is scheduled to launch campus-wide early in the next fund year. We are developing an online Mentoring Program that will be completed in the next fund year and made available to UCSF and others across the nation.

2. **To promote career advancement for clinical and translational researchers.**
   
   We will continue the Career Development Workshops and the two-day Scientific Leadership and Management seminar with ongoing evaluation and revisions. We will expand support of the team science initiatives, funding up to 3 teams, and include sponsorship of consultations to complement awards granted through the CTSI SOS Program.

3. **To improve recruitment and retention of URM and women clinical and translational researchers.**
   
   We will expand the URM Visiting Elective Scholarship Program by including a larger number of departments from which students can select electives (we are currently in discussions with two additional departments to support this program) and expand the UCSF Traveling Ambassadors by hosting diversity receptions at two to three national meetings that will provide ambassadors the opportunity to foster relationships with URM faculty in a focused format. We will continue developing unconscious bias training programs at UCSF, including educational seminars at campus events as well as an online course utilizing the Moodle platform in collaboration with the CTSI online learning team. We also plan to continue expansion of our initiative to increase the number of NIH Minority Supplements at UCSF and to support the AAMC Professional Development Seminars. Finally, we plan to improve the demonstration of diversity through the CTSI website continually.
Clinical Research Services

A. Personnel
1. Program Director: Henry F. Chambers, MD
2. CRS Site Medical Directors: Ron Clyman, MD, Professor of Pediatrics (NCCU); Lynda Frassetto, MD, Professor of Medicine (Moffitt-Adult); Mark Jacobson, MD, Professor of Medicine (SFGH); Ron Krauss, MD, Associate Professor of Medicine (CHORI); Margot Kushel, MD, Associate Professor of Medicine (Tenderloin); Harry Lampiris, MD, Professor of Medicine (VAMC); Joan Lo, MD, Associate Professor of Medicine (Oakland Kaiser Permanente); Pamela Munster, MD, Associate Professor of Medicine (Mount Zion); Barbara Moscicki, MD, Professor of Pediatrics (Moffitt-Pediatrics) (replacing Jennifer Puck, MD, PhD)
3. CRS Advisory Committee Chairs: Morris Schambelan, MD, Professor Emeritus of Medicine (SFGH, CHORI/Kaiser/Tenderloin) Jay Tureen, Professor of Pediatrics (Moffitt-Pediatrics)

B. Program Characteristics
Clinical Research Services (CRS) includes 9 sites with both inpatient and outpatient facilities: Moffitt-adult (12M), Moffitt-pediatrics (PCRC), Moffitt-neonatal (NCCU), SFGH-adult, Mount Zion-adult, SF Veteran’s Administration-adult (VAMC), Children’s Hospital Oakland-adult & pediatrics (CHORI), Kaiser Permanente-adult (Oakland) and the Tenderloin-adult (TCRC) located in an inner city neighborhood in downtown San Francisco. Each site is led by a medical director. In addition, CRS provides 4 core research services including: Bio-nutrition, Body Composition/Exercise Physiology, Specialized Research Nursing, and Sample Processing Laboratories. CRS is supported by two (formerly three) Scientific Advisory Committees, including representation from all CRC sites, that provide quality overview of research protocols utilizing CRS services.

Administration across all sites and services is coordinated by the CRS Director and facilitated by the Administrative Director. Henry F. Chambers, MD was hired as the new CRS Director as of July 1 in YR8 and Eunice Stephens, who had been the Assistant Director of Operations, assumed position of Administrative Director (a position which combines the duties of Assistant Director of Operations with those of Assistant Director of Finance).

C. Progress
1. UCSF Facilities
   - In YR8, CRS supported 325 studies: 34 inpatient and 291 outpatient protocols, serving 198 UCSF principal investigators.
   - Strategic conversations with the UCSF Medical Center were conducted that have resulted in an overhaul of the operational model for the pediatrics and adult inpatient sites at UCSF’s main hospital on Parnassus. A scatter bed model has been adopted for the pediatric research units and negotiations are underway with the UCSF Medical Center to adopt a similar model for adult inpatient research subjects.
   - Recharge rates were finalized and a recharge program was implemented in September of 2013.
   - Approximately a quarter of protocols are fully subsidized (i.e., “grandfathered”). A financial analysis was conducted to define the cost of these subsidies in lost recharge revenue. A plan to end full subsidies is being developed that will balance cost recovery with investigator needs and resources, allowing full subsidies to be phased out.
   - An administrative reorganization was completed to realize cost savings in YR8 with a reduction in Central Administration of 3 FTE.
   - A Lean Six Sigma operational efficiency project was completed. Based on the findings of this project the scientific review process has been streamlined, the number of review committees reduced from three to two, and the representation modified such that proposals for pediatric and adult research can be reviewed by either committee, permitting a 2-week turnaround time.
   - A survey of investigators, both users and non-users of CRS services, has been developed to ascertain current needs, to identify barriers to accessing services, and to identify new services that will expand the user base.
- Plans have been developed to transition the CRS pediatrics research services from the Parnassus/Moffitt Hospital campus to the new children’s hospital at Mission Bay.
- Plans have been developed to establish a sample processing laboratory to meet pediatric and cancer center research needs at Mission Bay.
- Lack of scalability, inefficiencies and underutilization of the Participant Recruitment and Clinical Coordinator Services prompted the closure of these cores. Participant Recruitment services been transferred to Consultation Services to maintain the most frequently used services.

2. Children’s Hospital Oakland Research Institute (CHORI)
   - CHORI’s Family Heart and Nutrition Center (FHNC) continues to support family-based community outreach programming for cardiovascular health.
   - Clinical studies of rare diseases are ongoing and include research in lysosomal storage diseases and Neurodegeneration with Brain Iron Accumulation (NBIA). Enrollment of subjects in a randomized clinical trial of elosulfase alfa was completed.
   - CHORI CRS supported 78 active protocols in 13 pediatric departments for 42 clinical investigators. Outpatient visit census was 3,104. The CTSI research-processing laboratory processed 4000 samples.

3. Oakland Kaiser Permanente Division of Research (DOR)
   - DOR completed renovations/upgrade with consolidation of services to a single 10,000 square foot floor unit (7 participant exam rooms, 8 interview rooms, 2 procedure rooms, 2 labs, 1 freezer room and 1 bone densitometry room).
   - The DOR clinic remained strong with 570 visits during the first 8 months of Year 8 across multiple large population-based studies.
   - Several large NIH-funded cohort studies supported by the UCSF DOR CTSI have been highly productive, including numerous publications that have received media attention.
   - A centralized web-based IRB submission system was successfully launched, enabling more efficient tracking of IRB renewals for CTSI-supported protocols.

D. Challenges

1. UCSF Facilities
   - Budgeting and recharge billing continue to be challenges. CRS is exploring an open source partnership with the CTSI of the Medical University of South Carolina to develop software that investigators can use for budget planning for CRS services.
   - Utilization of inpatient support services has declined and maintaining these inpatient services comes at high cost.
   - Access to “low touch,” outpatient services is limited.

2. Children’s Hospital Oakland Research Institute (CHORI)
   - Children’s Oakland has implemented a new electronic medical record system (EPIC) in 2013-2014. The training of research staff to use EPIC for research purposes and research billing is a significant work effort.
   - Children’s Oakland has entered into a formal affiliation agreement with UCSF and the demand for services has increased and improved capacity will be needed to support additional studies.

3. Oakland Kaiser Permanente Division of Research (DOR)
   - Consolidation of research space at Kaiser DOR has presented challenges in coordinating study visits and study protocols across CRC staff and space and in meeting demand phlebotomy services, which remains high.
   - Changes in the NIH and external funding climate have limited the size, capacity and cost-sharing of ongoing cohort studies and the number of newly funded studies that focus on patient-oriented research. Several large cohort studies are currently completing or awaiting news on additional funding.
E. Plans for the Coming Year

- Complete analysis of a survey of service needs of users and non-users to identify gaps in support of clinical and translational research at UCSF that could be served by the CRS.
- Reorganize CRS operations and services to better serve a larger percentage of UCSF investigators in Basic, Clinical, and Behavioral departments.
- Engage the medical directors and stakeholders in strategizing how best to deploy CRS resources to meet investigator needs.
- Rebuild the Clinical Coordinator Core in a cost-efficient model.
- Democratize CRS services by expanding the user base and access.
- Implement the plan for clinical and translational research services at the new Mission Bay campus at UCSF, including the new women’s, children’s and cancer hospital that will begin operations in 2015.
- Phase out support for fully subsidized research projects.
- Implement and expand billing and recharge operations.
- Plan for relocation of TCRC-based services as the lease for this space expires in 2015 and will not be renewed.
- Under the leadership of CHORI investigators Mark Walters and Elliott Vichinsky, develop a grant, in conjunction with UCSF, for the CIRM Alpha Stem Cell Clinics Network – Alpha Clinic Award. The Alpha Stem Cell Clinics will provide critical operational support for the conduct of clinical trials for investigational stem cell therapies and will operate as a center of excellence for approved stem cell therapies.
- Develop innovative strategies by Kaiser DOR for cost-sharing of staff and resources to enhance greater outpatient volume and number of studies supported.
- Expand the DOR integrated research model to benefit senior and junior investigators, as well as trainees and explore ways to support additional pediatric research within the DOR clinic.
Clinical and Translational Science Training (CTST) Program

Note that the Annual Progress Report (APR) includes separate narrative reports for the KL2 and TL1 programs that are an integral part of the CTST, but not included in this narrative.

A. Personnel
1. Deborah Grady MD, MPH, CTST Director; Christine Ireland MA, MPH, CTST Deputy Director
2. Douglas Bauer MD, Director, Resident Research Training Program (RRTP)
   Kirsten Bibbins-Domingo, MD, PhD, MAS, Director, CTSI K Scholars Program (KL2)
   Peter Chin-Hong, MD, Director, Pre-health Undergraduate Program (PuP)
   Ralph Gonzales, MD, MSPH, Director, Implementation Science Program (IS)
   Jeffrey Martin MD, MPH, Director, Training in Clinical Research (TICR) Program
   Joel Palefsky MD, Director, Clinical and Translational Research Fellowship Program (TL1)
   Shuvo Roy PhD, UCSF Co-Director, Master of Translational Medicine (MTM) Program

B. Goals of Program
1. To sustain and expand our research education program (Training in Clinical Research "TICR") to provide didactic training for learners at all levels.
2. To sustain and expand research training programs that provide level-specific training and mentoring.
3. To sustain and expand discipline-specific research training and mentoring programs for investigators translating “laboratory to human subjects” and “evidence into practice”.
4. To integrate our extensive array of research education and training activities.

C. Program Characteristics
CTST is comprised of 7 integrated education and training programs administered with the help of 4.7 FTE Program Coordinators: Clair Dunne for research education (TICR); Kim Woodhouse for the Clinical and Translational Research Fellowship (TL1); Christine Ireland for the K Scholar Program (KL2); Christian Leiva, for the RRTP and PuP programs, Aria Yow and Cecil Hunter for Implementation Science, and Olivia DeLeon, logistics and classroom coordinator. Senior faculty members direct each of the educational and training programs, and are members of the CTST Steering Committee. Dr. Grady chairs the Committee, which meets the first Monday of the month with frequent email and personal communication between meetings. This structure assures that program directors are aware of and contribute to all CTST activities, and fosters collaboration and cross-cutting endeavors.

1. Aim 1: To sustain, expand and further develop the research education program (TICR)
   a. Process: Jeffrey Martin MD, MPH is Director of the TICR Program. The TICR Advisory Committee, consists of senior faculty stakeholders and advises the Director on curriculum, program policies and procedures. The TICR Program consists of 44 individual courses and 3 major educational programs that are progressively staged in didactic content, intensity of mentoring, and research product requirements to meet the needs of scholars with varying professional objectives: a 7-week Summer Clinical Research Workshop; a 1-year Advanced Training in Clinical Research (ATCR) Certificate Program; and a 2-year Master’s Degree Program in Clinical Research.

   b. Progress
      • Joint MD, MAS: We have had a combined MD, MAS degree program for medical students to complete the Master's in Clinical Research and their MD degree in a 5-year period since 2010, and the first student matriculated in 2012-13. We see this program growing in popularity as another student matriculated in 2013-14, and two students have been accepted for 2014-15.
      • Remote learners: In 2013-14, we offered more online options for our most popular courses, including high quality lecture recordings and both synchronous and asynchronous online small group experiences.
      • Instructors: To meet the demand for instructors to lead small group sections of our courses, we have used both CTSI K scholars and doctoral students in the PhD Program in Epidemiology and Translational Science. This mutually beneficial arrangement provides the scholars and doctoral students with teaching experience relevant to their careers and is at least a partial solution to
the challenge of finding enough small group section leaders for our ever increasing numbers of courses and students.

2. Aim 2: To sustain and expand research training programs that provide level-specific training and mentoring.
   a. Process: In addition to the TL1 and KL2 programs (described separately), the UCSF CTSI sponsors the Pre-health Undergraduate Program (PuP) and the Resident Research Training Program (RRTP) with funding from the UCSF School of Medicine. PuP, targets underrepresented minority and disadvantaged undergraduate students and provides didactic training and mentoring during August. RRTP is a comprehensive program for clinical residents to promote investigative careers through didactic training, small funding for research projects and mentoring.
   b. Progress
      • *PuP Recruitment*: 18 undergraduate students were selected from among 55 applicants, 6 of whom were underrepresented minorities. Students selected were from Johns Hopkins University; New College of Florida; San Francisco State University; University of California, Berkeley; University of California, Davis; and University of Puerto Rico. For 2014, PuP had a record number of admissions.
      • *RRTP Schedules, Mentors*. There continues to be vigorous participation in the RRTP from all Departments, but some Departments provide few trained mentors and little elective time for research training. We have addressed these challenges by direct recruitment of mentors through our Ambassador program and expanded flexible scheduling of courses, including an online option. To improve the quality of resident-initiated research, we require completion of didactic coursework as a prerequisite to pilot funding.

3. Aim 3: To support and expand discipline-specific research training and mentoring programs for investigators translating “laboratory to human subjects” and “evidence into practice”.
   a. Process. CTST fosters early translational research by launching the Master of Translational Medicine. To foster late translational research, CTST supports the Implementation Science Program, with a specialized track in the Masters in Clinical Research, a Certificate for advanced health professionals, and an Action Research Program provided an experience in implementation science to improve health systems, and mentoring for students, residents, fellows and junior faculty.
   b. Progress
      • *Master’s degree for early-stage engineers, scientists, clinicians*. MTM provides a MS degree jointly administered by the bioengineering departments of UCB and UCSF, for a unique combination of engineering, business, and clinical expertise.
      • *Implementation Science track in Master’s in Clinical Research*. This is an increasingly popular option. 25% of students are expected to graduate with a specialized focus in implementation science in May 2014.
      • *Certificate Program in Implementation Science*. A one-year Certificate Program for health professionals that provides education and training in implementing evidence-based health practices. Enrollment in the program soared from 1 in 2012-13 to 12 in 2013-14, all of whom are UCSF Assistant Professors.
      • *New Action Research Program*. Developing skills in implementation science requires immersion into the community in which the translational activity takes place. The new ARP is a 4-month, hands-on training program where UCSF professional students join an interdisciplinary team of researchers to design and implement an intervention targeted at a “hot spot” with the overall goal of improving access and outcomes for patients while reducing unnecessary follow-up visits and improving patient satisfaction.

4. Aim 4: To integrate our extensive array of research education and training activities.
   a. Process: The UCSF Pathways to Discovery Program (PTD) includes a Clinical and Translational Research (CTR) Pathway. CTST has worked with UCSF PTD to fully integrate each level of training so that learners at any level who enter the “pipeline” will have a clear and shortened path to a career in clinical and translational research.
   b. Progress
Organizational challenges. Integration of CTST programs with the CTR Pathway was further improved this past year with the appointment of Dr Peter Chin-Hong as CTR Pathway Director.

D. Major Accomplishments

- **New Classrooms (Aim 1).** Completed our participation in the planning and design of new state-of-the-art classrooms at the new Mission Hall on the UCSF Mission Bay Campus.
- **Migrated Courses to UCSF Collaborative Learning Environment (Aim 1).** Migrated all 44 TICR courses to the UCSF Collaborative Learning Environment, which uses the Moodle platform. This web-based internet platform provides a flexible environment for holding course syllabus materials, recorded lectures, student forums, grading, and course evaluations.
- **Curricular enhancements (Aim 1).** Methodologic advances in causal inference have been permeating many core and advanced courses in the TICR Program. New courses in Chronic Disease Epidemiology and Cancer Epidemiology were started.
- **First PhD student graduated (Aim 1).** The first student graduated with a PhD in Epidemiology and Translational Science in Fall 2013.
- **PuP trainees admitted to UCSF professional schools (Aim 2).** Two participants in PUP have been admitted to dental school and two to medical school at UCSF. One PuP graduate was recently matched in a surgical residency program.
- **Residents present research results (Aim 2).** 31 residents in the RRTP presented their research findings at the annual Resident Research Symposium and 14 presented their research at national specialty meetings supported by RRTP travel awards. 7 residents have first author peer-reviewed publications.
- **Residents enroll in CTR Pathway to Discovery (Aims 2 and 4).** 5 residents have enrolled in the CTR Pathways to Discovery Program.
- **Action Research program system based implementation science (Aim 3).** Six medical students participated in an intervention with UCSF’s Cardiology clinic to improve the patient experience. Students contribute to the team by making pre-visit phone calls, conducting check-in procedures, reviewing after visit summaries with patients, and conducting follow-up phone calls to reinforce behavior change and medication adherence, and in evaluating the program on delivery system metrics, patient satisfaction and provider attitudes.
- **MTM Graduates (Aim 3).** MTM graduates are working at major pharmaceutical, biotechnology, and scientific consulting companies in positions as senior level engineers, researchers, scientists, analysts, and managers. One graduate received two 510(k) clearances from the FDA within two years of completing the MTM capstone project.
- **Modified the TL1 application process to accommodate MTM students (Aims 3 and 4).** Since MTM students are selected later than TL1 selection process, we needed to modify the process to allow MTM students to apply for the year-long experience.

E. CTSA Consortium, Activities and Contributions

Dr. Grady was a member of the CTSA Key Function Committee on Education and Career Development until it was disbanded earlier this year. Christine Ireland is a member of the California CTSA Education Consortium. Dr. Bibbins-Domingo, TL1 trainees and KL2 scholars attend the annual Translational Science Meeting in Washington, DC.

F. Plans for Coming Year

Effective July 1, 2014, Dr Kirsten Bibbins-Domingo will direct the CTST (taking over from Dr Grady as Dr Grady is interim PI of CTSI) and Dr Douglas Bauer will direct the KL2 program. We will sustain our educational programs and individual courses as the TICR Program moves to the UCSF Mission Bay Campus in Fall 2014. In the newly built Mission Hall, the TICR Program will be more closely integrated with clinicians and global health scientists and have access to over a 50% increase in modern classroom space. We will sustain the RRTP and seek cost-sharing funding from the residency programs for the residents to take Designing Clinical Research. PuP will expand to a multiyear program for selected students and we will conduct a pilot program with Morehouse College and Oakwood University (HBCUs). We will complete an evaluation of the ARP in Cardiology, and will implement the 2nd team at SFGH. The ARP will be incorporated into UCSF School of Medicine’s new curriculum for expansion and ongoing support.
CTSI K Scholar Program  
KL2 TR000143

A. Personnel  
1. Kirsten Bibbins-Domingo, PhD, MD, MAS, Director; Christine Ireland, MPH, Deputy Director  
2. Louise Walter, MD Associate Director

B. Goals of Program  
1. Recruit and annually support 20 outstanding KL2-funded faculty scholars and at least 35 K12 and individual K awardees, diverse in discipline, academic home and ethnicity;  
2. Continue to provide career development, mentoring and infrastructure for K scholars including Master's level education; 75% protected time for research; pilot research funds (KL2 scholars only); weekly work-in-progress and methodology seminars and career development advice.  
3. Enhance career development, mentoring and infrastructure by providing regular individual meetings with statisticians and grant/manuscript-writing advisors, statistical programming, database expertise, financial advice and experience teaching clinical and translational science, and  
4. Create new K Program components including: Early Mentor Development program; K to R transition support; informal instruction in responsible conduct of research during weekly works-in-progress; alumni scholars participating as faculty in weekly works-in-progress sessions.

C. Program Characteristics  
1. Process  
The program leaders provide direction and oversight of the program, participate in weekly works-in-progress seminars, and serve as career mentors for K scholars. Two other epidemiology faculty (M Pletcher, R Grant) attend works-in-progress and serve as career mentors. In addition, 5 senior biostatistics faculty (C McCulloch, J Neuhaus, S Shiboski, J Boscardin, S Sen) attend weekly works-in-progress seminars and provide individual biostatistical expertise to K scholars. Experts in grant writing (T Mitchell) and manuscript writing (A Markowitz) provide one-on-one tutorials for K scholars writing R01 grants or manuscripts for publication. K faculty (T Mitchell and A Kanaya) provide a month long didactic instruction in research grantwriting in January and lead small groups of scholars actively preparing R01 and equivalent grants in February-April. A senior faculty member with specific expertise in clinical trials (S Cummings) is also available to scholars and participates in works-in-progress and didactic sessions. The K program faculty meets monthly, including 2-hour sessions in the winter and spring where individual scholars’ progress is discussed.

Each year, 6-8 KL2 Scholars at the junior faculty level are selected to enter the K Program July 1. Scholars receive 4-5 years (depending on level of training upon entering the program) of salary support at $85,000 per year for 75% effort to pursue multidisciplinary clinical and translational research with training and mentoring provided by the Program. Scholars obtain a Master's Degree in Clinical Research, or in some cases an Advanced Training in Clinical Research Certificate unless they already have such education, and are provided a supportive environment, start-up research funds, and access to core faculty (as described above).

Program is located at China Basin Landing, adjacent to the UCSF Mission Bay Campus and home to the UCSF CTSI Training Program, classrooms, program administrators and faculty. Scholars may occupy a "hotel" cubicle or office while at the facility and also have office space, computer and administrative support in their home department.

New scholars join senior scholars and core faculty at a two-day retreat in late July to introduce new scholars and their research, and to provide orientation and socialization into the program. Beginning in August, scholars and core faculty attend 1 3/4 hour Friday morning works-in-progress seminars (WIPS) each with 10 scholars led by 2 senior program faculty who rotate across WIPS during the year and who are drawn from a pool of 4 experts in clinical research who run the seminars and 5 biostatisticians who add technical rigor. The WIPS are followed by a program-wide hour-long seminar led by UCSF faculty or senior administrators on a variety of topics each week that during the reporting period faculty led
seminars on advanced biostatistics and epidemiologic methods, non-NIH research funding opportunities, research ethics, mentoring, team science, how to build a T1 career, building collaborations between bench and clinical scientists, among others. A lunch for scholars and faculty follows the seminar and provides an informal networking opportunity for scholars at different stages of career development. Scholars prepare individual Career Development Plans that are reviewed with program faculty and updated yearly, and receive individual advice on their relationships with their departments and mentors.

2. Progress
   a. Opportunities and challenges in implementing relevant program activities
      • **Fees for non KL2 Scholars.** In 2013, 35 non-KL2 scholars chose to participate in our program’s infrastructure and pay the nominal fee, which is similar to the number on non-KL2 scholars who participated when no fee was charged.

      • **Training in Responsible Conduct of Research.** In this reporting period, we featured “ethical quick hits” during works-in-progress led by senior research faculty. These short discussions (10-15 minutes) were popular with scholars and senior faculty alike and were based on the scholars’ research or issues highlighted in journals or media. Quick hits topics during the reporting period included discussion of the ethics of: open access, pay for publication journals; crowd-sourced scientific/clinical research; industry of on-line scholarship; and oxygen for premature infant consent, among others. One of our KL2 scholar alumni, Alex Smith, who regularly blogs about ethical issues (including in the NY Times), presented a one hour interactive seminar involving the question of compensating a patient for his potentially valuable tissue from a genetically unique tumor that was based on an actual case at UCSF; scholars were assigned to take a side and present to the whole group and then hold an “eyes closed” vote on whether or not they felt compensation was ethical in this situation.

      • **Mentoring.** K Scholars receive extensive mentoring, but they are also emerging mentors. During the reporting period senior faculty at UCSF led two sessions on mentoring: one focused on the mentoring resources available at UCSF and one highly interactive session on how to be an effective mentor and mentee.

      • **K to R Transition.** This is the second year the program has emphasized transitioning from the K to independent funding for research for our senior K scholars. In 2013-14, Tom Mitchell led 4 one-hour didactic sessions on R grantwriting attended by 15-20 scholars. Nine scholars who are in the active stages of writing an R01 grant subsequently participated in 8 2-hour sessions with the focus is on preparing the Specific Aims, Significance, and Innovation sections of an R01. This year the program offered scholars the opportunity to have their R01 grant reviewed by senior program faculty. Two R01s were reviewed during the reporting period.

   b. Modifications made to original plan, activities, or focus with rationale
      We decreased the number of KL2 funded scholars we originally planned to support from 25 to 20 during the reporting period due to an increase in scholars’ salaries that we instituted in 2011 and the CTSI re-budgeting of funds from the KL2 to the UL1 to support new initiatives.

D. Major Accomplishments
   1. **Recruitment of a superb group of KL2 Scholars,** diverse in discipline, race and ethnicity, and gender (Aim 1). The individuals who received a new KL2 award beginning in July 2013 represented our most diverse group of scholars in terms of discipline and training background with 4 PhDs (33%). 67% of awardees are female and 2 are Asian. We continue to be challenged by the relative lack of underrepresented minority junior faculty at UCSF who are eligible for the award.

   2. **Successful expansion of the program to include other NIH-funded K Scholars (Aims 1, 2 and 3).** During the reporting period, the Program included a total of 67 faculty-level scholars: 20 funded by the KL2 program and 36 funded by other K mechanisms. The value of our program’s infrastructure for these
otherwise isolated beginning faculty with individual NIH K awards is demonstrated by the fact that even though we now charge a nominal fee to participate, 36 non-KL2 scholars chose to do so - a considerable time commitment in addition to the cost. Of the 36 non-KL2 scholars, 5 have with institutional K12 awards, 29 have K awards from 12 NIH institutes/centers and AHRQ and 2 have other career development awards.

3. **Increased the number of senior K scholars who submit R01 grants (Aim 3 and 4).** Since we began offering instruction (both didactic and tutorial) in R01 grantwriting in 2012-13, the number of senior scholars who submitted R01 or equivalent grants increased from 47% in 2012-13 to 64% in 2013-14.

4. **K Scholar Alumni Continuing Involvement in Program (Aim 4).** During the reporting period, 4 K scholar alumni spent Friday mornings for 8 weeks leading the K scholar works-in-progress sessions. They each led a one-hour faculty seminar on a variety of topics: industry funding opportunities; building a career as a T1 researcher; team science. These alumni scholars now at Associate Professor (and one, Professor) level provide a pipeline for succeeding K program faculty and leadership in the future. In January the K program sponsored its first K Scholar Alumni event, a half-day attended by 21 alumni scholars with peer discussions on topics identified by alumni, including: funding; balancing research, clinical and operational professional activities; and mentoring

5. **Alumni Survey of Career Outcomes.** During the reporting period, we surveyed 67 alumni K scholars (both KL2 and non-KL2 participants in the program) and received 63 (94%) responses thus far. The success of our alumni is demonstrated by the fact that 92% hold positions in academic institutions, 82% conduct clinical and translational research at least 40% of their professional effort, 30% have obtained an R01 (rising to 44% of those who entered in 2005-2008) and 90% have obtained any research grant funding. The median number of first or last author publications reported since leaving the K program was 8, ranging from 2.5 – 14 depending on how long they had been out of the program. In addition to these traditional metrics for success, 47% reported having collaborated with another K scholar (that would not have occurred in the absence of the K program) and of those collaborations, 40% resulted in a funded research grant. 75% of alumni reported having mentees included on a publication. Alumni scholars were asked to rate how the K affected their current skills and expertise, ability to get a desired position and ability to get grants, using a scale of 1-5 with 5 being of the greatest value. Each of the 3 factors received the highest median rating of 5.

6. **Current Scholar Progress.** Some of the metrics demonstrating the current scholars’ progress:
   - 7 KL2 scholars terminated their KL2 funding during the past year when they received NIH K awards, and all but one of these continued to participate in the program.
   - Scholars in years 3-5 of the program published a median of 3 publications per year

E. **CTSA Consortium, Activities and Contributions**
Dr Grady served on the Education and Career Development Key Function Committee until the disbanding earlier in the reporting period.

F. **Plans for Coming Year**
The K Scholars program will be under new leadership in the next year. Douglas Bauer MD will become the Director of the program, Louise Walter will stay on as Associate Director and Charles McCulloch PhD will come on as Associate Director. Kirsten Bibbins-Domingo who led the K program since 2012 will become CTST Director, replacing Dr. Deborah Grady who is interim CTSI Principal Investigator. This leadership plan includes faculty who have been with the K program for several years (Walter and McCulloch) and a new director who will bring fresh ideas. We will recruit and support additional scholars to replace those who are leaving, and continue to provide them with career development, mentoring and infrastructure. We also plan to conduct an analysis comparing individuals at UCSF who have an individual K award but who do not participate in the CTSI K Scholar Program to those who have participated in the program using measures of grants, publications, collaborations.
Clinical and Translational Research Fellows Program (TL1)
TL1 TR000144

A. Personnel
1. Program Director: Joel Palefsky, M.D.
   Program Co-Director: Peter Chin-Hong M.D.
2. Joel Palefsky, M.D., Professor of Medicine, TL1 Program Director, Director, Clinical and Translational Research Fellowship Program, Co-director, Clinical and Translational Research Pathway, UCSF
   Peter Chin-Hong, M.D., Professor of Medicine, TL1 Program Co-Director, Director of Designing Clinical Research course for pre-doctoral students and Director of the Pre-health Undergraduate Program (PUP) and the Clinical and Translational Research Pathway, UCSF.
   Kim Woodhouse, Analyst III, TL1 Program Administrator

B. Goals of Program
1. Sustain and continue to develop our highly successful TL1 program to train pre-doctoral students and stimulate them to pursue careers as clinical and translational researchers;
2. Sustain and expand the Pre-health Undergraduate Program (PUP) to train undergraduate students from underrepresented groups who aim to pursue careers in clinical and translational research;
3. Enhance the core curriculum in clinical research for all pre-doctoral students at UCSF;
4. Encourage appropriate TL1 trainees to enroll in the UCSF Catalyst program, which combines customized expert feedback and advice with funding to help drive promising early-stage research through the complex process of translating ideas into products and patient benefit;
5. Enroll students in the Masters in Clinical Research program into the TL1 program;
6. Expand TL1 programmatic activities to include students in the Masters in Translational Medicine (MTM) program into the TL1 program and students in the other four Pathways programs at UCSF.

C. Program Characteristics
1. Process: The TL1 program at UCSF was originally funded in 2005 as a Roadmap T32 predoctoral training program to train predoctoral fellows in clinical and translational research. This T32 program, subsequently converted to a TL1 program with funding of the CTSA grant, was combined with the UCSF Doris Duke Charitable Foundation (DDCF) Clinical Research Training Program for medical students to form the umbrella program, Pathways to Careers in Clinical and Translational Research (PACCTR). The PACCTR program was then reorganized into the Clinical and Translational Research Fellowship Program (CTRFP) as it was integrated into the UCSF Clinical and Translational Research (CTR) Pathway. The CTR Pathway is the largest of 5 Pathways in the new UCSF Pathways to Discovery Program, which also includes Global Health, Health and Society, Health Professions Education and Molecular Medicine. The goal of the Pathways program is to support learners at all levels, including predoctoral students, toward leadership and innovation via mentored projects, coursework and career development. Our ultimate goal is to stimulate predoctoral students to choose a career path that emphasizes clinical and translational research; leadership and team science.

Under the continuing leadership of Dr. Palefsky, the CTRFP is the year-long research program that forms the core of the CTR Pathway (to which Dr. Palefsky was appointed as Co-Director in 2011). UCSF’s institutional commitment to the TL1 program includes funding for up to 8 additional year-long fellows and other activities including works-in-progress sessions, the annual UCSF Inter-school Research and Scholarly Activities Festival and Clinical and Translational Research journal clubs.

Recruiting TL1 fellows begins with extensive outreach campaigns by TL1 leadership to predoctoral students from all 4 UCSF schools (Dentistry, Medicine, Nursing, Pharmacy). Applications are rigorous (modeled after NIH R01 applications) and a valuable learning experience for the student. Mentors play an active role in helping students prepare the application and are evaluated as part of the application review process. Applications are reviewed by a panel of distinguished faculty from all 4 schools and ranked using current NIH scoring criteria. All CTRFP fellows complete a rigorous curriculum that provides theoretical knowledge of clinical research methods and ethics combined with practical experience. The fellows customize their program and participate in an intense program of activities.
They are required to produce a legacy product (thesis or first-authored original peer-reviewed publication based on their work) and graduate with a MD with Distinction designation. Legacy product work is supervised by a 3-member faculty committee appointed by the Pathways to Discovery program.

As a key part of the program, each CTRFP fellow receives mentorship from a variety of sources:

- **Mentoring Team** - composed of a lead mentor and one or two co-mentors from different disciplines. Lead mentors advise students on didactic courses; help identify colleagues; ensure that projects are moving satisfactorily toward presentations and publications and provide career advice. Co-mentors provide particular guidance in their areas of expertise. Students meet weekly with the lead mentor and at least monthly with co-mentors. Mentors attend the student’s work-in-progress seminars and local research presentations.

- **CTRFP leaders** - Dr. Palefsky or Dr. Chin-Hong meet with students as a group every 2 weeks and meet one on one formally with each student at least three times per year; more often as needed.

- **Program-specific mentoring** - research methodologists and biostatisticians provide research advice to CTRFP fellows taking the Designing Clinical Research for Students and Residents, the ATCR certificate and the Masters degree program.

- **CTRFP trainees** begin the process of learning mentorship skills through didactic training provided by the CTSI Mentor Development Program, and the PUP program, in which they are paired with a mentor an undergraduate student interested in the health sciences.

Numerous other enrichment activities are available to TL1 fellows. These include the annual TL1 spring meeting, conferences in their own academic field locally, nationally and internationally, and oral and poster presentations at the UCSF-wide annual research symposium. Students also meet regularly with their mentors, TL1 program leadership and their PUPs. They participate in, organize and run the quarterly UCSF-wide pre-doctoral journal club. They attend a TL1 faculty presentation every other week as part of their works-in-progress session.

A meticulous evaluation process permits students to report on the experience they are having with their mentors, and for mentors to report on the CTRFP program. Students meet regularly with each other and with CTRFP faculty to present their work, critique the work of their peers, learn skills in research design and ethics, and oral and written research presentation.

Inter-school CTRFP Curriculum Committee: One of the goals of the TL1 program is to provide enrichment of clinical research curriculum to all UCSF pre-doctoral students to promote inter-professional communication, promotion of the TL1 and other structured research training programs, and enhancement of knowledge of clinical research. This is accomplished by providing annual small-group sessions in case-based clinical research methodology for predoctoral students in each school, led by an inter-professional faculty. Additional learning opportunities include online modules in clinical research methodology created by the committee, the annual UCSF Inter-school Research and Scholarly Activities Festival and quarterly inter-school clinical research journal club led by the students with support from the committee faculty.

2. Progress:

   Opportunities and challenges in implementing relevant program activities: Recruiting students from all 4 schools for the entire range of CTRFP fellowships has been challenging. While there is strong demand for one-year fellowships from students in the School of Medicine and substantial interest from Nursing and Pharmacy, we have had relatively few applicants for 1-year fellowships from Dentistry. The curriculum structure in the School of Dentistry does not easily allow a full year research experience. We are continuing to work closely with leadership in all the schools to more effectively recruit students with diverse backgrounds, and this year we plan to offer a fellowship position to a dental student who has applied and whose application was ranked very highly.

D. Major Accomplishments

Goal 1: CTRFP continues to grow in number of applicants, and, based on anonymous online surveys and face to face meetings with students and mentors, we continue to have a high level of satisfaction. We are
continuing to develop new programmatic activities to enhance the learning experience for our trainees. This year we have required that trainees participate in leadership of at least one CTRFP journal club in addition to requiring attendance. We have continued to expand the UCSF Inter-school Research and Scholarly Activities Festival, with a record number of registrants this year (more than 120) signed up to present a poster. This year we will be holding our poster session with digital posters, and each student presents their poster orally to a group of 6-8 students and 2 faculty. The e-posters will be archived online and be available after the session and will be an additional legacy product beyond their required published papers or thesis. The Festival and Posterpalooza in particular have become very prominent on campus, and garner substantial attention, including from campus media.

Goal 2: The objectives of PUP are to inspire students who have an interest in a career in clinical and translational research from UC Berkeley and other universities to pursue a career in the health professions, public health, epidemiology and translational science, health policy, and other academic programs after graduation. Led by TL1 program Co-Director Dr. Peter Chin-Hong, PUP has been successful in preparing senior undergraduate students for admission to graduate programs by offering a summer clinical research training program for up to 20 undergraduate students. In 2013, 33% (6 of 18) PUP students were from populations underrepresented in the health sciences.

Goal 3: The Core Curriculum Committee has been very active in promoting a clinical research agenda to the entire predoctoral student body of all 4 schools. Committee activities, particularly the small group sessions, have been highly rated by the students.

Goal 4: Last year, one TL1 trainee participated in the Catalyst program. We will continue to offer participation in the program to the 2014-2015 class of students.

Goal 5: This year, we will be admitting pre-doctoral medical students enrolled in the Masters of Clinical Research program, with the one-year TL1 CTRFP providing the core of their didactic training and practicum research experience.

Goal 6. This year, two students in the Master of Translational Medicine program participated in our CTRFP programmatic activities. Created with the support of the CTSI, the MTM degree was approved in 2012. The program links the Department of Bioengineering at UC Berkeley with the Department of Bioengineering and Therapeutic Sciences at UCSF. It is designed to train students in applying translational research and engineering approaches to solve fundamental problems in health and healthcare delivery. The goals of the program are to prepare engineers and clinicians to bring innovative treatments and devices into clinical use; to participate in an interdisciplinary team design project co-advised by an engineering faculty member and a clinical researcher; and provide students with the skills to integrate the necessary scientific, technological, and business expertise required to drive scientific discoveries into public use for the improvement of health.

E. CTSA Consortium, Activities and Contributions
UCSF TL1 leadership participates in each of the consortia conference calls. UCSF students attend and actively participate in the national TL1 meetings and will do so again at the 2014 meeting.

F. Plans for Coming Year
We will continue to focus on providing the highest quality program possible to enrich the clinical research training of our TL1 students by addressing each of the goals described above. We will continue to assess our application process, solicit feedback on all aspects from the program from our stakeholders, and make improvements as needed based on this feedback. Several initiatives are planned for the coming year: 1) Actively promote the Catalyst program to our students; 2) Assess the success of integrating Masters of Clinical Research students into the TL1 program; 3) Expansion of the PUP program.
Community Engagement and Health Policy (CE&HP)

A. Personnel
1. Co-Directors Kevin Grumbach, MD, Laura Schmidt, PhD, MPH, MSW
2. Faculty: Margaret Handley, Carmen Portillo, Tung Nguyen, , Rena Pasick, Eliseo Peres-Stable, Dean Schillinger, David Thom, Dean Schillinger, Robin Corelli, Kristen Madsen, Baharak Amanzadeh, George Taylor, James G, Kahn, Daniel Dohan, Lisa Chung, Michael Potter. Staff: Paula Fleisher, Juliana Fung, Roberto Ariel Vargas, James Rouse, Wylie Liu, Sharon Rose

B. Goals of Program
The goals for Year 8 were: 1. Improve health and decrease health disparities in San Francisco for targeted populations and health conditions; 2. Support practice-based research partnerships that improve health outcomes for patients in diverse practice settings. 3. Provide opportunities for UCSF faculty, staff, and students to translate their work. 4. Improve Operations and Finance.

C. Program Characteristics
1. Process: CE&HP organizes faculty and staff with expertise in community-based participatory research, practice-based research, implementation science, and health policy to partner with civic agencies, community-based organizations, and policymakers to promote participatory and community-engaged models of translational research to improve the health of the public and promote health equity. Key processes include Consultations and Training, Linkages and Convenings to facilitate match-making between UCSF investigators and community-based partners, and translational research Resources, which include technical assistance, pilot grants, databases, and toolkits.

2. Progress: All proposed objectives and goals for Year 8 of CE&HP are on track.
   a. Opportunities and challenges in implementing relevant program activities:
      San Francisco Health Improvement Partnerships (SFHIP) is a community-engaged translational science and population health initiative organized to:
      • Support focused, working partnerships between UCSF researchers and community stakeholders with shared interests, assets, and expertise in several of the most compelling health issues in San Francisco;
      • Collaboratively plan and prioritize a set of aligned community interventions informed by scientific evidence and community expertise and experience to address these health issues;
      • Implement a well-coordinated set of community-based health improvement interventions; and
      • Evaluate the process and outcomes of SF HIP and disseminate the lessons from this evaluation.

      A key milestone for SFHIP in Year 8 was to transition the program to greater shared leadership with the San Francisco Department of Public Health and the San Francisco Hospital Council, along with broader engagement of more community-based stakeholders. The Bay Area Health Funders Group, consisting of local philanthropies, is also moving to align its funding priorities with the programmatic objectives of SFHIP.

      The San Francisco Bay Area Collaborative Research Network (CRN) has 27 institutional partners, including clinic systems, large medical groups, and private pharmacies, and aims to support interest in practice-based research. CRN provides linkages as well as consultations to researchers. CRN has collaborated with the CTSI CRS in an effort to transform clinical research services from the traditional, hospital-based CRC model to a new model that emphasizes more flexible functionality and that extends beyond the walls of the traditional CRC to link with community clinicians, medical groups, and community clinics.

   b. Modifications made to original plan, activities, or focus with rationale: Although the CRN and CRS have partnered on a small grants program, joint community visits, and participant recruitment strategies, it became clear that most CRS-based investigators do not perceive that their research programs are conducive to being conducted in community practice settings or designs focusing on
“applied” implementation science. As a result, the CRN is reassessing how to reach UCSF investigators outside the CRS program who have not traditionally engaged in practice-based research.

D. Major Accomplishments

Accomplishments are listed to align with the Goals in section B. One of the most visible accomplishments of CE&HP was a commentary authored by CE&HP co-director Kevin Grumbach, CTSI director Clay Johnston, and UCSF Vice Dean of Education Catherine Lucey, articulating a strategy for academic health centers to integrate translational research, practice-based education, and patient care so that academic health centers can fulfill the Institute of Medicine vision of learning health systems: “Transforming From Centers of Learning to Learning Health Systems: The Challenge for Academic Health Centers,” JAMA. 2014;311(11):1109-1110. doi:10.1001/jama.2014.705.

Goal 1: SF HIP has five well-established and successful partnership working groups in the areas of physical activity and healthy eating, Hepatitis B, high utilizers of multiple services, alcohol policy, and children’s oral health. 225 individuals from UCSF and the community are participating in these groups, including representatives from the San Francisco Departments of Public Health, Police, Parks and Recreation, District Attorney, Housing and Homeless Services; and YMCA, Community Clinic Consortium, ethnic health equity coalitions, and many other CBOs.

Accomplishments include: Engaged 3 community organizations that represent Tenderloin, Mission, Chinatown and Bayview Hunters Point neighborhoods to launch a CBPR study of community attitudes towards public policy on sugary beverages and retail sale of alcohol; produced a menu of evidence-based sugar sweetened beverage policy options for policymakers, including the SF Board of Supervisors; provided evidence-based materials for a media campaign on health aspects of sugary beverages; expanded children’s oral health promotoras project to three sites in the SF Unified School District; 139 physicians from the 4 largest medical groups in SF completed surveys assessing Hep B knowledge and attitudes and developed clinical registries of patients with chronic Hepatitis B.

We are evaluating community health outcomes for these projects on an ongoing basis. Key findings in Year 8 include: among patients with chronic Hepatitis B cared for at SF county primary care clinics, rates of confirming Hepatitis A immunity and vaccinating non-immune patients range from 43-96% across clinics, and rates of up to date liver function tests, from 75-85%; for studies evaluating community-based interventions to address obesity risk factors in children and youth, we found that by including community organizations in the data source search we could identify an expanded set of databases and measures at the neighborhood level, making them feasible to use for evaluation of local interventions; for alcohol related projects, we have institutionalized inclusion of blood alcohol measurement into the SF trauma center registry, and preliminary analyses show a statistically significant relationship between violence and alcohol outlet density and unemployment rate across census tracts.

Goal 2: A CRN survey of individual clinician members yielded responses from 1,600, and the information about their practice and interest in research was turned into a searchable database to facilitate linkage with appropriate community clinicians for practice-based research studies. More than 17 consultations/linkages have been performed to date in year 8, and $10,000 in small grants awarded through CRS partnership. 15 CRN studies with extramural funding were active in year 8, including R01 and R21 studies funded by the NIH, AHRQ, Philanthropy, and PCORI. There has been new or ongoing translation of at least 3 successful CRN intervention studies into practice at a local, regional or national level: flu shot-colon cancer screening linkage (featured by AHRQ as a best practice on its Health Care Innovations Exchange), E-Referrals (spread to several major health care delivery systems), and smoking cessation counseling by pharmacists in Safeway Pharmacies.

The preliminary findings of the "Ask, Advise, Refer: Promoting Brief Smoking Cessation Interventions in Safeway Community Pharmacies" study at 20 pilot sites provided data to justify further dissemination of a brief community pharmacy-based smoking cessation intervention to 74 additional pharmacies in California in December 2013. The practice model is slated for national roll-out (n=1,200 pharmacies) in late 2014.
In Year 8, 40 consultations requests have been submitted to CE&HP (23 for community engagement and 17 for practice-based research). Two requests led to full consultations involving substantial technical assistance and linkage activities, and the remainder were addressed with more focused guidance.

**Goal 3:** A CE&HP faculty member is co-directing a new 5-UC campus CTSA project on ethics and policies for biorepository research, featuring a strong community-engagement component to identify feasible ways to obtain informed consent and handle research specimens to guide implementation of policies and procedures to create an exemplary, culturally respectful system for biorepository research at UC.

CE&HP faculty and staff taught 4 CTST courses: Community Engagement (15 students), Implementation Through Systems Change (16 students), Qualitative Methods (14 students), and Cost-effectiveness Analysis (23 students). All 4 courses achieved student satisfaction ratings of 4 or 5 on a 1-5 scale. CE&HP faculty and staff were also extensively involved in teaching community engagement for core curricula in health professions schools at UCSF in Year 8, teaching 168 medical students, 88 family medicine, pediatrics, and medicine residents, 4 graduate nursing students, and 2 dental students. CE&HP also taught 19 high school students pursuing careers in public health, and conducted several training workshops on research, evaluation and craftsmanship that included community members.

**Goal 4:** CE&HP has absorbed a 5% annual reduction in funding from the NIH CTSA award, in addition to sequestration cuts, and increased non-CTSA sources of funding for CE&HP program projects by more than 20%, resulting in more than a 20% increase in total budget for CE&HP activities relative to year 5.

**E. CTSA Consortium, Activities and Contributions**

For the Strategic Goal 4 Workgroup within NCATS, CE&HP co-founded the National Health Policy Consortium with collaborators at the George Washington University CTSA. The Health Policy Consortium has provided a “home” within NCATS for training, dissemination and the promotion of evidence-based policymaking. The Workgroup also serves as a nexus for creating and sustaining cross-CTSA partnerships, the most active one involving UCSF, George Washington University, Harvard, Wisconsin and the University of Washington. With the restructuring of NCATS Strategic Goals and KFCs, the Policy Consortium will disband as a formal NCATS workgroup but maintain collaborations.

**F. Plans for Coming Year**

SFHIP will complete its reorganization as it becomes institutionalized under the joint management of CTSI, SFDPH, and Hospital Council, with Dr. Grumbach continuing to co-chair the Steering Committee. SFHIP projects will begin to yield population-health outcome findings on targeted community health metrics, with a continued emphasis on policy-level interventions. We will achieve greater alignment of SFHIP and the CRN for SFHIP projects engaging community clinicians, using the model of the SFHIP Hepatitis B Quality Improvement Collaborative for additional projects such as disseminating best practices in integration of oral health into routine primary care of children.

The CRN will also develop a strategic plan on how to engage more UCSF investigators in practice-based research and fully transition to a recharge method for billing for consultations. We plan to work with the CTSI PET to strengthen inclusion of social network research methods for CE&HP program evaluation, as well as metrics for assessing sustainability. CE&HP will also be including within its portfolio a half-million dollar grant from the Laura and John Arnold Foundation to develop a multi-media translational medicine campaign around new research findings on the health harms of sugar overconsumption, called SugarScience. This project will serve as a pilot effort in building web-based and social media-based platforms for promoting direct dialogues between the public and medical researchers on specific health concerns. It is our hope that this project will catalyze new strategies for engaging and translating science in ways that are meaningful to the public. Finally, CE&HP is reaching out to the UCSF Center for Digital Health to explore opportunities for collaboration in community-engaged research in the arenas of e-health and m-health.
Consultation Services (CS) Program

A. Personnel (3/1/13-2/28/14)
   1. Program Director: Mark Pletcher (Program Director)
   2. Unit Directors: Peter Bacchetti (Biostatistics), Alka Kanaya (Research Design), Jennifer Creasman (Data Management)
   3. Salaried Consultants: Nancy Hills (Biostatistics), Barbara Grimes (Biostatistics), Chengshi Jin (Biostatistics), Michael Kohn (Research Design), Joel Simon (Research Design), Elaine Allen (Biostatistics)
   4. Staff: Alice Fishman (Senior Program Manager), Katherine Nelson (Program Manager), Erin Breed (Program Coordinator)

B. Goals of Program
   1. To improve the quality and quantity of science at UCSF and affiliated CTSI institutions by providing easily accessible, comprehensive, and integrated consultations in the areas of clinical and translational research
   2. To determine whether extensive free research consultation is effective at improving priority scores and likelihood of funding among junior faculty applying for K awards by conducting a randomized controlled trial
   3. To advance methodological research by providing CTSI consultants the support required to develop new methodology that supports and transforms our ability to conduct translational research.

C. Program Characteristics
   1. Structure/function and Administration
      Consultation Services continues to provide quality consultation services by expanding the breadth of services and recruiting new consultants. Currently there are 18 CTSI consulting units that Consultation Services supports by enabling online access, triaging consult requests, and supporting use of a shared professional services automation tool (OpenAir) that tracks requests and consulting time. The Administrative Core provides centralized leadership, general program oversight, and support for the consultation units and special project teams by managing the use of OpenAir, the administrative and financial arrangements of consulting engagements, administration and analysis of program evaluations, oversight of methodology work, and the development of policies and practices.

   2. Consulting Units
      Consultation Services continues to expand by adding consultants in ClinicalTrials.Gov, Bio-behavioral Measurement, Recruitment Services, Scientific Writing, DSMB and Practice Based Research Network. To address increased demand for services, we continue to recruit new consultants in the Design and Biostatistics Unit. We have also consolidated leadership of Bioinformatics consulting with Biostatistics consulting, which resulted in a decrease in overhead.

      Consultation Services has continued the “Tandem Consulting” program in which Epidemiology and Translational Science PhD students participate in the consultations. So far, the five “tandem” consultations in which a PhD student has participated in a consultation along with a faculty consultant have all been reviewed positively.

      As of February 28, 2014 the units supported directly by Consultation Services (Biostatistics, Data Management, Research Design and Recruitment (effective November 1, 2013)) have served 604 new projects and 480 unique Principal Investigators and delivered 3,298 hours of direct consulting services.

   3. Special Projects
      Mark Pletcher MD MPH
      RCT Extensive Consultation Services 5/08 -- Current
This project aims to evaluate whether extensive CTSI consulting services increase client scores on K-grant applications and proportion of applications funded. The study is also a means of delivering services to junior investigators with the most need.

Peter Bacchetti PhD
BCU Infrastructure Investment 7/08 -- Current
This project has aimed to increase productivity and enhance the products that our analysts provide to clients and consultants. A large library of SAS macros now automates many common tasks and includes enhancements such as model checking in the standard output. Some output contains color-coding of results and hyperlinks to online explanatory material at CTSpedia, making it easier to understand for clients and quicker to assimilate for consultants.

Michael Kohn MD
Study Design Methodology Project 7/13-6/14
This project supports the development of a sample size website including online sample size calculators. The site will provide online calculators for the standard sample-size problem types and, depending on the time required for the standard calculators, several additional problem types. These calculators will be fully documented and referenced, and each will have an accompanying online training video/demonstration. The site will also prominently discuss the flaws in common expectations and conventions concerning sample size and may provide alternative online calculators based on both Bayesian principles and a simplified cost efficiency approach. This site will make it easy for design consultants to help investigators with their sample size calculations and allow investigators to repeat the calculations themselves with different parameters and assumptions.

Sean Thomas PhD
Biostatistics/Next Generation Sequencing (Deep Sequencing) 7/11 – 6/14
This project ensures efficient bioinformatics pipelines are in place at UCSF by having dedicated and specialized bioinformaticians to meet these needs.

Janet Coffman PhD
Comparative Effectiveness Large Data Analysis Core (CELDAC) 7/13-6/14
This one year project will allow us to understand the potential demand for a multi-campus data concierge service. A cross-institutional approach to implementing a data concierge would leverage the talents of a larger group of faculty and staff with pertinent expertise.

Stuart Gansky, MS, DrPH
CT.Gov 7/13-6/14
The one year project is focused on developing a cadre of staff with expertise in CT.Gov results reporting, who would allow expanding those macros, and developing other tools to meet the needs of UCSF investigators to comply with federal law. The CT.Gov system is frequently updated and expanded, so this support would allow the tools to stay current with both required and optional reporting elements.

D. Major Accomplishments
1. Administrative Accomplishments:
   • We have expanded our outreach strategy and developed a more precise method for identifying the faculty and trainees who may be interested in specific services we offer. We create low-cost marketing materials for all new services and actively promote new and existing services.
   • With the closure of the Participant Recruitment Service, Consultation Services initiated new services in cohort identification and direct mailing.

2. Consultation Accomplishments:
   • Received 604 new requests for services from over 480 Principal Investigators.
   • Consultation Services saw an increase in compliance of citation during FY8. 302 publications were identified from researchers that benefited from consultation services and cited CTSI, a 20% increase over the 251 citations from the previous year. An additional 2,950 publications arose during 2013-2014 from researchers who received Consultation Services who did not cite CTSI. CS performed a manual review of a random sample of 100 of these publications and found that 15 pertained to the same topic as the consultation request. Based on this review, CS estimates that an additional 443 publications were influenced.
3. Special Projects Accomplishments:
   • We have screened 205 clients requesting to participate in the randomized trial of extensive consultations, enrolling 104 participants since inception (15 in the last 12 months), towards a total goal of 150.
   • Provided 66 hours of subsidized consultation services to junior faculty participating in the intervention arm of the randomized trial of extensive consultations.
   • The Data Management Network project has provided a portal of communication for data managers across the UCSF campus. We have partnered with the UCSF library to invite the broader community to R-programming seminars, begun a REDCap chatter group for users to post questions and/or issues with REDCap and created a listserv to post and inform about data management events and/or job postings. One member, excited about this new community has taken the initiative to have UCSF host a Bay Area SAS Users Group meeting.
   • We evaluated the Study Design Categorizer and determined that the increased time it required by clients to complete the process wouldn’t result in better triage outcomes so we decided not to implement.

E. CTSA Consortium, Activities and Contributions
Consultation Services continues to evaluate opportunities for cross-institution consultation, and has focused recently on the five University of California CTSAs. In particular, we are identifying options for cross-campus consultation for the Center for Large Data Set Analysis Core and are currently surveying expertise. Once we understand where the expertise lies and where the potential need is, we will convene a meeting of the BERD directors to further develop these opportunities.

Consultation Services has contributed to 5 articles and entries on CTSpedia. Representatives from Consultation Services at UCSF also participated in the BERD online journal club and in monthly BERD Key Function Committee (KFC) calls. During this reporting period, there were over 12,000 page views of the documents UCSF posted on CTSPedia.

F. Plans for Coming Year
   • Mark Pletcher will step down as Program Director effective March 31st, 2014, to be replaced by Alka Kanaya, the former Research Design Unit Director.
   • We are in the process of recruiting a new Research Design Unit Director to replace Dr. Kanaya.
   • Consultation Services will continue its focus on meeting faculty members’ needs for consultation in an ever expanding array of services, engaging our clients and consultants in identifying potential new units.
   • We will monitor our efforts to ensure we are providing consultation efficiently.
   • We also anticipate formalizing a needs assessment with the goal of potentially expanding our array of recruitment services.
   • We plan to continue supporting our current special projects by recruiting and enrolling participants into the randomized trial of extensive consultations, enhance biostatistics consulting services by developing statistical tools and templates which will be shared on CTSpedia and produce manuscripts in research methodology.
   • We will continue to identify the best methods for providing cross-campus consultation across the five UC CTSAs.
Early Translational Research (ETR) Program

A. Personnel
   1. Director: June Lee, MD, FACC
   2. Personnel: Irina Gitlin, PhD., Ruben Rathnasingham, Ph.D., Aenor Sawyer, MD, MS, Catherine Tralau-Stewart, PhD., Kirsten Hutchinson, Terry O’Donnell, Erin Forman

B. Goals of Program
   The primary goal of the ETR program is to provide customized support for the early development of therapeutics, diagnostics, and devices by researchers at UCSF and CTSI affiliate institutions. We focus on the following key initiatives to achieve this goal:
   1. education
   2. research team development
   3. clinical and market assessment
   4. facilitating public and private partnerships and funding
   5. consultation with industry experts, and
   6. research funding.

C. Program Characteristics
   1. Process
      The ETR program is supported by an internal team and an advisory panel made up of more than 140 industry and academic experts. The Director of the program, Dr. June Lee, is an experienced physician and industry leader. Prior to CTSI, she worked at Genentech as the therapeutic area head, leading early clinical development programs in Infectious Diseases, Cardiovascular/Metabolic Diseases, and Respiratory Diseases. The ETR program is also supported by two program managers with industry experience in early translational research and development, and two program coordinators who oversee program operations.

Catalyst Awards Program
   As a primary focus of CTSI’s efforts to support early translational research, the Catalyst Award is designed to help translate early-stage research ideas into marketable products. The award facilitates partnerships and provides essential support services as well as pilot funds. It includes:
   • Review of proposal and written feedback and recommendations by an expert panel of experienced pharmaceutical and academic scientists, venture capitalists, and commercial experts.
   • One-on-one consultation with an expert to address issues related to technology management, commercialization, strategic plan development and funding/partnership strategy
   • Funds of up to $100,000 to be applied toward practical validation steps required to secure outside funding or licensing including facilitation of critical pilot experiments.

UC BRAID D4
   The Drug, Device, Discovery and Development (D4) workgroup is a new component of UC BRAID. D4 is chaired by ETR Director, Dr. June Lee, and is focused on the early translation of academic discovery research into valuable and impactful therapies. D4 is leveraging the combined strengths and resources of the five campuses to accelerate this translation process:
   • To improve competitiveness of UC researchers for translational funding opportunities
   • To develop cross-campus collaborations for early translational projects
   • To facilitate access to translational resources and infrastructure on each campus
   • To share successful programs and services that support translational researchers

LaunchPad (launchpad.ucsf.edu)
   Interactions with Catalyst Awards Program participants highlighted the need to provide a venue for translational researchers at UCSF to both share and benefit from insights into the tools and resources offered by the program. LaunchPad is an online education platform designed to highlight the experiences and accomplishments of UCSF’s translational researchers, and to support them in their efforts to develop beneficial medical products. This online resource features videos of
investigators, administrators and industry experts sharing their experiences working through five keys to successful translational research—unmet needs, target product profile, collaboration, development plan and organizational support—as well as other resources for researchers. LaunchPad was conceived by the ETR team and developed through a pilot CTSI award.

2. **Progress**

   a. Opportunities and challenges in implementing relevant program activities:

   - **Product Development Consultation:** Investigators whose research may lead to positive clinical impact are often unfamiliar with the hurdles along the path to commercialization beyond scientific and technical challenges. Clinical need, competitive landscape, intellectual property, manufacturing, regulatory and clinical strategy play crucial roles in the development of any healthcare product. By leveraging the expertise of the ETR program personnel and our consultation panel, we have been able to provide early input on potential product development pathways to help many investigators better design research plans and identify strategic partners.

   - **Pilot grants:** Applicants to the Catalyst Award Program often propose compelling research projects but lack sufficient proof of concept data to garner support. We have found that providing pilot grants (of less than $15,000) to investigators not only helps with their likelihood for follow-on funding, but also aids in the development of a translational-focused research plan.

   - **Identification of promising innovations:** In our effort to expand our reach across UCSF, we continue to face challenges in increasing awareness among researchers and identifying those who will most benefit from our support. We have implemented targeted marketing campaigns that have significantly increased awareness and are continuing to collaborate with ITA, QB3 and other UCSF institutions to improve our reach.

   b. Modifications made to original plan, activities, or focus with rationale

   - **Facilitating access to Contract Research Organization (CRO) services for translational work:** The ETR program has identified gaps in UCSF’s capabilities to move development of therapeutics, medical devices, and diagnostics tools beyond the early discovery stage towards clinical trials. These gaps include activities such as custom synthesis of chemical entities with promising biological effects, structure-activity optimization of hit molecules for improved biological functionality, ADME/PK/Toxicology testing of compounds, biocompatibility testing of materials and devices, and others. These types of activities can be conducted by CROs with appropriate expertise on a fee-for-service basis. The ETR program has successfully assessed and signed master agreements with 5 CROs. Initial marketing efforts have produced growing interest in the program. We believe that removing the barriers to identifying appropriate CROs and negotiating contracts will substantially simplify utilization of these services, allowing translational projects to move forward more rapidly. This effort has also expanded to the broader UC community through our participation in the UC BRAID Drug Discovery and Development Program (D4), where we are working to develop a mechanism to provide other campuses access to these CROs.

   - **Consultation services for early translational activities:** The ETR group has expanded the Consultation Services program offered by CTSI to include consultations in early translational/preclinical subjects relevant for drug/device/diagnostics development process. The subjects include: i) design and implementation of high-throughput screening experiments, ii) hit/lead optimization and custom synthesis, iii) evaluation of hits in biological (ADME/PK/Tox) assays, and iv) animal model selection and study design. This program provides researchers with access to experts in the aforementioned subjects and will help guide their translational research programs.

   - **Education efforts in translational research:** As part of the efforts to increase awareness and encourage student participation in translational research, the ETR staff is contributing to the courses and educational programs on ongoing basis. Specifically, the ETR staff contributes to the course design, and helps to identify speakers, both academic (with basic research or clinical expertise) or with industry affiliations, to conduct lectures in those courses. Examples of courses include Master in translational Medicine, Graduate Education in Medical Science (GEMS), and Training in Clinical Research. In addition, a select number of students have been invited to
observe the discussions and outcome of the Catalyst Program to gain insights in technology assessment and product development.

- **Building collaborations within academia and between industry and academia:** The ETR group is continuously identifying potential partnering opportunities within the academic community or between academia and industry to strengthen the research teams, to broaden access to resources, and to increase competitiveness for funding opportunities.

**D. Major Accomplishments**

1. An assessment of the Catalyst Awards Program advisory panel revealed a lack of diagnostics and regulatory expertise. We have addressed this gap through the enrollment of industry leaders in both. The panel has now expanded to more than 140 industry and academic experts,

2. The Catalyst Awards Student Internship Program has grown rapidly. Students receive first hand insights into how translational projects are gauged for their clinical and commercial viability by observing the panel discussions and consultation sessions with industry experts. Applications are oversubscribed and the feedback from student participants is overwhelmingly positive.

3. Successfully completed 2 industry partnerships in the Catalyst Awards program: Quest Diagnostics in the diagnostics track and MedImmune in the therapeutics track. Both partnerships include upfront payments for program management and potential funding of awards for projects of interest to the partners.

4. Collaborated and successfully garnered a $12M NHLBI Center for Accelerated Innovation Award to fund promising translational research within the 5 UC medical campuses (UC Irvine, UC Davis, UC San Diego, UCLA and UCSF).

5. Garnered approximately $170,000 in additional non-CTSI revenue, and $185,000 in in-kind consulting.

6. Catalyst Awards projects returned a 6-fold increase in funding following initial support from the Catalyst Program,

7. Projects that were supported by the Catalyst Awards program have progressed to garner 6 strategic partnerships, and more than 40 invention disclosures and patent applications.

**E. CTSA Consortium, Activities and Contributions**

We have increased our engagement with the CTSA Consortium through participation in multiple presentations and workshops as well as one-on-one engagement with other CTSA members who have expressed interest in replicating our initiatives. ETR Director, Dr. June Lee has participated in several CTSA-member meetings to discuss ETR programs and support the development of our most successful initiatives at other institutions.

**F. Plans for Coming Year**

1. Create a robust strategy for the long term growth and sustainability of ETR by:
   a. Establishing a board of advisors focused on growth
   b. Increasing industry and not-for-profit partnerships

2. Collaborate with CTSI education/training programs to design and develop a translational research education platform focused on engaging faculty and senior students and fellows.

3. Identify collaborative opportunities and facilitate research team building to enhance research outcomes.
Global Health Program

A. Personnel
1. Director of Program: Paul Volberding, MD; Director of Research, UCSF Global Health Sciences (GHS); Director, AIDS Research Institute; Director CTSI-GH
2. Program staff: Georgina Lopez, research administration and management training; Teresa Moeller, data manager and international programs analyst; Alma Yates and Terry O'Donnell, project analysts, Kristen Newhouse, program assistant

B. Goals of Program
1. Attract new resources
2. Attract support for new investigators
3. Create cohesiveness within the community of global health scientists
4. Increase activity with basic sciences
5. Increase administrative efficiencies
6. Stay competitive nationally

C. Program Characteristics
1. Process: The CTSI Global Health (GH) program builds on efforts by the UCSF Global Health Sciences (GHS) to facilitate and accelerate global health research across the campus. GH faculty and staff (1.6 FTEs) manage and support program activities. In addition to CTSI-GH funded positions, the GHP leverages the support of a number of central campus and departmental personnel through working committees as well as additional staff support provided through key partnerships with Global Health Sciences (GHS), AIDS Research Institute (ARI), and the Center for AIDS Research (CFAR). Significant support for issues of concern to the global health researchers is provided by personnel in Risk Management, Office of Legal Affairs, Office of Sponsored Research, the Controller’s Office, and the Ethics and Compliance Office. GH has initiated several programs which specifically address the needs of the UCSF community involved in international projects. To maximize impact, new programs are aimed at facilitating international research at all levels and for all UCSF investigators regardless of where they perform their research. The International Research Advisory Council (IRAC) provides a platform for open communication including identifying issues of concern with solutions often provided from amongst experienced investigators. The East Africa Interest Group, co-funded and supported by CFAR and GHS, provides a platform for UCSF researchers working and conducting research in East African settings. The program focuses on improving information exchange and fostering collaborations; lowering regulatory and informational barriers to performing international research; and providing opportunities to stimulate young investigators to enter the field of international research.
2. Progress
   a. Opportunities and challenges in implementing relevant program activities:
      CTSI and GH uniquely span the disciplines of all four UCSF schools, allowing them to address challenges and develop solutions for effective international projects support and administration across the entire UCSF enterprise. Issues in conducting international research range from the specifics of the research project itself to international regulatory compliance, budgetary restrictions, travel and safety of UCSF personnel, risk management for the University, etc. GH developed a collaboration between administration and faculty to institutionalize the sharing of expertise and resources in support of international research projects and training that has been lauded as a model for effective engagement across the UC campuses. GH has prioritized systemic changes in policy and administration to better support international research, so that the system is fixed, rather than the short term issue being addressed. This long view to change ensures that the activity does not devalue into ongoing navigational aid activities. The earliest challenge in the program has been identification and communication among the researchers involved in global work, which was addressed in 2012 and 2013 with the development of the database, newsletter, forum and HUB. Going forward our perceived challenge will be to continue to refine these tools, integrate them into the UCSF structures, both existent and being built. With that in mind- GH has positioned itself in many of the University planning activities, to better advocate for uptake of the tools developed by CTSI.
b. Modifications made to original plan, activities, or focus with rationale:
   i. Develop training materials and information packets for UCSF faculty and staff on international research administration and management. While we did not create formal training materials for faculty, we have worked to develop consensus across the schools and departments on the content that applies widely. These consensus materials make up the bulk of the content of the GlobalResearchHub, which is poised to become the home for global tools and resources that apply across UCSF. As we complete the buy-in process, it may be more appropriate to spin out training from the HUB in the future. We did develop materials and provided formal training to the campus Pre-Award RMS teams, on the specific requirements of setting up accounting and grant compliance structures in an international context.
   
   ii. Develop training materials and information for clinical researchers from limited resource settings. Rather than developing specific training materials for our collaborators from limited resource settings; we focused on refining content for the Global Research HUB an online resource that is available to our colleagues to facilitate UCSF global research activities.
   
   iii. Support International scholars through the campus Resource Allocation Program (RAP). Rather than directly funding support of international scholars, we continued to offer support for the logistics of bringing scholars to UCSF via our consultation services, and provided a centralized compendium of steps and advice for bringing a scholar to UCSF within the HUB. In addition, we leveraged our connections within the GH community to ensure that 2 new GH related funding opportunities were offered through RAP to the UCSF community.
   
   iv. Community building for early career faculty with an interest in global health. Bowing to the “over booked” status of early career academics and the need to offer a tangible contribution to this community, we transitioned this ‘convening’ activity into providing an online home for global interest groups, and working with the participants to manage their listservs and advertise their activities to their peers in the Global Research News. This has been very effective in growing grassroots networks that bridge traditional UCSF pillars.

D. Major Accomplishments

1. Partnered with CTSI Regulatory Knowledge, Virtual Home, and Communications, officially launched the Global Research HUB and transitioned this activity to GHS. The Global Research Hub provides a central resource for the campus on research administration; information on training opportunities available at UCSF to global health researchers, regulatory and other compliance information of relevance to the global health researchers.

2. With the launch of the GR-HUB and Database, we reconfigured the GlobalResearch Community forum to function as a true forum rather than as a combination website/forum. Redirecting participants to the GR-HUB for specific information and maintaining the community exchange features including:
   a. UCSF researchers in Africa, Asia, Oceania, and Latin America
   b. Interest group interfaces to foster junior faculty interactions with their peers across UCSF
   c. Where appropriate, redirecting traffic from the G-RES portal to the GR-HUB
   d. Expand the reach of the newsletter and moderated forum to global health researchers from other CTSA institutions as well as other UC campuses.

3. Held quarterly meetings and support the activities of the International Research Advisory Council (IRAC) to continue to effect improvements to the administration, management, and oversight of funded global activities at UCSF. Transitioned this activity to GHS.

4. With the increased usability of the international projects database working with CTSI VH and GHS and CTSI Communications to re-launch the improved “Global Research Database”.interface on Profiles.

5. Convened a major symposium to focus on global implementation science in partnership and collaboration with ARI, CFAR, and GHS.


8. Manage the GH consulting, recruiting appropriate faculty and reporting activities and resolution to CTSI.
9. Work with CTSI Program Planning as it develops new tools to track activities in order to ensure our program metrics are defined and tracked appropriately part of our program planning activities.
10. Partnered with ARI and GHS to foster Global Health Early Investigator community building through four “junior” global events.

E. CTSA Consortium, Activities and Contributions

The monthly UCSF Global Research Newsletter with its linked moderated online forum are distributed to more than 4200 people who share an interest in UCSF Global Research, over 3100 of these are UCSF faculty, trainees, and staff, while the remainder are alum or collaborators at other universities, here or abroad. Averaging an open rate of 32%, (excellent for an academic newsletter), more than 400 people click through to access the resources housed within. The Global Research forum averages 730 hits per month, and generates enquiries from within UCSF and across academia. We see these as a cornerstone for building out a broader academic community of global researchers, with activities spanning the UC’s and the CTSA’s

F. Plans for Coming Year
Collaborate with ARI, CFAR, and GHS to achieve the following objectives:

1. Partnering with GHS, build on current support for convening stakeholders to identify new opportunities for research and policy creation regarding HCV, this project will develop a model for how economic elements: cost, cost effectiveness, behavioral economics, and implementation science can be integrated into research on health topics in order to strengthen overall research and policy implications. Advising the process of conducting multidisciplinary research across several sites focused on the scale-up of new HCV drug therapy and treatment plans. This project includes staff time for advising on the process of managing these complex research teams as well as funding to complete baseline projects that will serve as the basis (and in many cases data) for future grant applications.

2. Based on the knowledge and expertise developed in creating the UCSF Global Research Hub (http://globalresearchhub.ucsf.edu/) and building on a UCOP funded project to work across the UC system to aggregate resources and best practices into a similar structure (i.e., Drupal based, modular system which can be propagated across UC sites), we will facilitate integration of these resources into a cross institutional aggregation system being developed for Global Health academic institutions. The Global Health Hub (http://www.globalhealthhub.org) is self-funded and voluntarily managed by academics from UCSF and Harvard to aggregate content from around the web, including blogs, twitter feeds, resource pages, calendars, journals etc., pulling headlines and excerpts for content from other sites and providing links back to the original for full content. We will coordinate activities between the three efforts: UCOP, the Global Hub, and UCSF (HUB and GHS) in global health to maximize efficiency, so that the systems speak with and mutually reinforce one another.

3. Partnering with GHS, ARI, CFAR, CTSI and leaders of the Clinical and Translational Symposium to create a one-day UCSF research symposium. This event will provide an opportunity to disseminate findings on both global health and translational research to the university.

4. Partner with various CTSI programs in order to identify projects of mutual interest, which support the focus on rare and neglected diseases.
Online Education (OLE) Program

A. Personnel (3/1/13-2/28/14)
1. Faculty Director: Deborah Grady, MD, MPH
2. Other personnel
   • Senior Program Manager: Lisa Schoonerman
   • Course Director, Designing Clinical Research: Vanessa Jacoby, MD
   • Course Director, Responsible Conduct of Research: Barbara Koenig, PhD
   • Course Director, Translating Evidence to Practice: Audrey Lyndon, RN, PhD
   • Course Director, Writing Clinical Research Reports: Deborah Grady, MD, MPH
   • Course Director, Mentor Training: Mitchell Feldman, MD
   • Course Director, Unconscious Bias: Renee Navarro, MD
   • Course Director, Early Translational Research: Charles Craik, PhD, and June Lee, MD
   • Online Learning Director: Chrisanne Garrett
   • Online Learning Technical Analyst: Deila Caballero
   • Online Learning Administrative Analyst: Asha Robertson

B. Goals of Program
The primary goal of the Online Education program is to develop and deliver high quality online and blended training programs in basic clinical and translational research methods. The program introduces clinicians to core research methods to initiate them to a career in clinical research. The Online Education program directly aligns with CTSI’s mission to provide training to support clinical and translational research for learners at all levels across a spectrum of settings including distance learning.

C. Program Characteristics
1. Structure/function
   Online Education is directed by Deborah Grady with content support from faculty directors for each of the primary course offerings (see above) and technical support from a CTSI technical and administrative team including instructional design direction from Chrisanne Garrett, video capture, editing, and other technical support from Deila Caballero, and business and administrative support from Lisa Schoonerman and Asha Robertson. The OLE team also collaborates with and leverages campus-wide resources from the UCSF Library’s Learning Technology & Education team. For example, the OLE participated in vendor evaluation and selection of a campus-wide video hosting service and is now utilizing Kaltura for course video components.

2. Progress
   CTSI Online Learning is a relatively new initiative that began in 2010 as a part of the CTSI Training Program (CTST), and delivered the first fully asynchronous online course - Designing Clinical Research (DCR) for Students and Residents in summer 2011. Subsequently, DCR online has been successfully delivered for trainees including undergraduates, professional students, residents, fellows and faculty. A second core course - Responsible Conduct of Research (RCR) – was converted to a fully online asynchronous course in fall of 2011. In 2013, RCR was delivered to 114 trainees and faculty at UCSF and forms the didactic platform for research ethics education at UCSF.

   In 2013, because of the ability to deliver courses to learners external to UCSF, as well as the unique production requirements associated with creation of the online courses, program reporting and tracking was separated from the CTST programs. Financial reporting continues to be incorporated within the larger CTST budget.

   Development and delivery of these courses provided valuable learning experience related to the unique requirements of online educational design for professional adult learners, but also provided important lessons with regard to necessary expertise, staff, administrative support and technical issues.
At the same time, the Online Education group developed internal capacity to independently develop new courses, upgrade existing courses, and provide technical support to groups outside UCSF.

D. Major Accomplishments
Between March 1st, 2013 and February 28th, 2014, the OLE program delivered courses to a total of 307 trainees including undergraduates, professional students, residents, fellows and faculty. We are also in the process of developing 2 additional online courses that should near completion by the end of FY08: "Writing Clinical Research Reports" and "Translating Evidence to Practice". Writing Clinical Research Reports provides readings, video lectures, editing exercises and demonstrations of editing clinical and translational research manuscripts. Translating Evidence to Practice provides readings, video lectures and discussions, exercises and product development focused on research in implementation sciences.

E. CTSA Consortium, Activities and Contributions
N/A

F. Plans for Coming Year
1. The OLE team will continue to pursue the aim to be a premier developer and provider of online clinical research training by expansion of course portfolio. Courses planned for development in FY09 include:
   • Introduction to Clinical Trials
   • Advanced Clinical Trials
   • Mentor Training
   • Conflict of Interest
   • Early Translational Research Education Program
2. Development of partnerships to provide training in clinical research methods and responsible conduct of research with smaller medical schools, focusing on centers without robust research training, and those with a high proportion of under-represented minority trainees.
3. Development of a sustainable business model in which fees for course delivery support development of new courses and initiatives.
Planning, Evaluation, Tracking (PET)

A. Personnel
   1. Fabrice Beretta, MS, MBA, Director, Planning, Evaluation and Tracking (PET)
   2. Greg Tong, MPP, Sr. Program Manager (PET)
   3. Sandra Flores, Assistant, Administration
   4. Anirvan Chatterjee, Data Director, Virtual Home program (VH)

B. Aims of Program
   1. Measure and communicate CTSI performance and impact
   2. Improve Clinical and Translational processes in CTSI and at UCSF
   3. Develop a center of excellence in performance management and improvement at UCSF within the broader CTSA
   4. Implement program review and APR processes

C. Program Characteristics
   PET is composed of 2.6 FTEs: Fabrice Beretta (1 FTE), Greg Tong (1 FTE). It also gets the assistance of 0.15 FTE from Administration and the Virtual Home programs: 10% from Sandra Flores, and 5% FTE from Anirvan Chatterjee.

1. Measure and communicate CTSI performance and impact
   a. Process: PET has continued the implementation of its performance management process centered on program reviews. The process combines the use of Balanced Scorecards and the management of Initiatives (projects) portfolios by CTSI programs, as described in the YR7 APR.

   b. Progress
      Process Based Leadership (PBL): PBL is the name of a web-based performance management system used by PET to help programs manage their scorecards, initiatives, and key documentation. This year, PET used PBL as the central system for program planning and APR preparation workflows, streamlining document storage and creating custom manuals in support.

      Return On Investment: In collaboration with expert consultants (Social Venture Technology Consulting), PET developed and piloted an sROI (Social Return on Investment) methodology for the children’s oral hygiene initiative of CTSI’s Community Engagement and Health Policy (CEHP) program. That initiative tests the use of community resources to deliver the proven benefits of fluoride varnishes to pre-school children. By carefully quantifying resources (dollars, people, time) and health outcomes in economic terms, and documenting qualitative changes in behavior and knowledge, the model enabled an evaluation of the delivery mechanism as well as the return on investment. Current data indicates that each $1 invested in the project returns $0.8 and that the key to breakeven is to expand the program to serve at least 120 children a year. The PET program plans to broaden use of the sROI methodology to other programs and eventually the whole organization to prepare for the competing renewal.

      Dashboards: PET developed a dashboard for CTSI overall that relies on data from PBL (see Aim 2 following). Key results were posted at http://ctsi.ucsf.edu/impact

2. Improve Clinical and Translational processes in CTSI and on Campus
   a. Process: PET uses Lean Six Sigma and Project/Portfolio management tools in consulting engagements to improve processes that CTSI and Campus rely on to deliver clinical and translational research.

   b. Progress
      CTSI support: PET has developed and implemented a comprehensive organizational scorecard to reflect CTSI’s long-term strategy of developing innovative services, transferring mature services to campus, improving clinical and translation processes, maximizing the impact of its activities for itself
and its stakeholders, and promoting C&T research at UCSF. Metrics were developed for each aim, with particular attention to the number of PIs CTSI supports at UCSF, return on investment for stakeholders, and the total amount of resources deployed to support C&T research.

In FY09, PET plans to start two new projects for CTSI: 1) improving financial data reporting in the Clinical Research Services program, and 2) mapping the underlying processes needed to support the efficient functioning of the UCSF Enterprise Data Warehouse (EDW) to which the BMI program contributes.

**UCSF support:** PET has been actively engaged with UCSF to improve the following processes.

- **IRB approval** for both expedited and full committee reviews. The target is to reduce the Time to Approval from 73 to 43 days in average for full review, and 21 days for expedited. All processes have been mapped, gaps identified, and a detailed improvement plan put in place. A newly trained Lean Six Sigma Green Belt has been named project leader to implement the improvement plan.
- **Post-Award process** for UCSF. Following a similar methodology, an improvement plan and team have been put in place to reduce the Time to Award set-up from 60 days on average to 30 days.
- **In-patient clinical research.** This project is being implemented in partnership with the Medical Center and Rona Consulting, which is leading a comprehensive Lean methodology deployment at UCSF. The objective is to reduce the overall duration from protocol submission to first patient discharged from 229 to ~100 days. The methodology used is Value Stream Mapping. Certified Lean Leaders by Rona are leading the workshops and analysis with local support from Campus and CTSI. PET plans on continuing to support all projects in FY09, mostly on a consultative basis and to ensure that implementation plan, and project objectives are met.

**Training:** PET has formally trained 7 Lean Six Sigma Green Belts from CTSI and UCSF in partnership with Motorola University, a leader in Lean Six Sigma certification. As a follow up, PET has created a Lean Six Sigma community with the intent of fostering ideas from new trainees and implementing improvement projects that can generate real value for CTSI and UCSF.

3. **Develop a center of excellence in performance management at UCSF and within the broader CTSA**
   a. **Process:** This aim is targeted at leveraging and deploying established performance management and improvement methodologies at UCSF and within the CTSA. From a CTSA standpoint, the first step is to partner with smaller CTSAs with less PET resources than UCSF and for whom such partnerships would add value.

   b. **Progress**

   **Global Health services:** PET has engaged in small consulting efforts with Global Health Sciences that have generated revenues for the program. PET facilitated multiple strategic planning retreat sessions for Global Strategic Information and the Private Health Sector initiatives with the objective of laying the foundation for a scorecard management system for both groups.

   **Scripps:** PET has established a value-added partnership with Scripps Translational Sciences Institute to deploy the balanced scorecard approach and PBL in collaboration with Dr. Eric Topol and Mike Alcorn, and have built simple, concise and well-structured scorecards.

   **Epidemiology & Statistics:** In FY09 PET will collaborate with the Epidemiology Department at UCSF to lay the foundation for a scorecard management system. PET will first implement a Strength, Weakness, Opportunities, and Threat (SWOP) exercise.

4. **Implement Program Review and Annual Progress Report process**
   a. **Process:** The main objective here is to approve the yearly budget of programs by 1) reviewing the performance against scorecards target and objectives, 2) providing strategic guidance, and 3) providing operational/tactical recommendations to programs. This review process is in turn used to
b. **Progress**

PET has stayed up-to-date on developments in KFC evaluation subgroups, especially community engagement and social network analysis. In addition, it revised, planned, and implemented a new Program Review process compared to FY07. The main improvements include 1) clearly mapping the review process and documenting all inputs/outputs and requirements, 2) developing templates to facilitate the review process and 3) changing the timing to enable program review to inform planning and budgeting. The review process now occurs in February before APR preparation to ensure that the budget and APR are thoroughly assessed. The timing generates efficiencies as CTSI programs can use the outcome of reviews for the APR and limit redundant work.

In FY09, PET plans on transitioning full management of scorecards to programs. PET will then be involved only on a consultative basis to ensure that information is compliant and consistent with internal standards and policies. PET will focus on improving the overall organizational scorecard and strategy for the competing renewal. It will also use its resources to expand into the development of Social Network Analysis/Team Science-based metrics. And it will mine some of the new data that is generated by the Medical Center Health Electronic Records (HER) and Clinical Trials Management systems, such as Oncore, to understand better the performance of Clinical Research at UCSF in terms of cost, quality, and speed.

**Opportunities and challenges in implementing relevant program activities**

PET continues to engage successfully in many partnerships within and outside CTSI. The transition to PBL 3.0 addressed many of the gaps experienced by Programs in their workflows and review processes. By changing the timing of program reviews, PET was able also to improve budgeting and APR preparation. The key challenge for PET in the coming year is to balance its growing portfolio of activities with UCSF and the Medical Center with its internal activities within the limited resources available to the Program.

**D. Major Accomplishments**

1. Implementation of PBL 3.0 (Aim 1): PBL 3.0 successfully addressed the shortcomings of the previous version. The current system is user-friendly and offers the opportunity to integrate APR reporting and Program Reviews.
2. Initiation of three major process improvement projects in collaboration the Central Administration of the Clinical Research Enterprise at UCSF (Aim 2). This partnership allows CTSI to access data and gather knowledge on the clinical research landscape at UCSF, and provides resources to UCSF to deal with critical issues that affect its competitiveness.
3. Development of the organizational scorecard (Aim 2): It has become useful for understanding how CTSI balances its resources to deliver on its mission.
4. Implementation of sROI (Aim 1). The model adds value to CE&HP and has generated interest from the San Francisco Department of Public Health.

**E. CTSA Consortium, Activities and Contributions**

Fabrice Beretta and Greg Tong were members of the Evaluation KFC before its dissolution. Greg Tong is also involved in Evaluation activities undertaken by five University of California campuses, “UC BRAID.”

**F. Plans for the coming year**

1. Continue adoption of Process Based Leadership by program directors and management so that they assume accountability for their own reporting with consulting support from PET.
2. Develop new metrics in the area of team sciences and research networks.
3. Ensure that process improvement projects started in FY09 meet their stated goals.
4. Expand the relationship with Campus to further improve the efficiency of clinical research at UCSF.
Regulatory Knowledge and Support (RKS) Program

A. Personnel
1. Elizabeth Boyd, PhD, Associate Vice Chancellor and Director, RKS, Associate Adjunct Professor
2. Dan Dohan, PhD, Associate Professor
3. Barbara Koenig, PhD, Professor
4. Vanessa Jacoby, MD Assistant Professor

B. Strategic Goals of Program
1. Provide resources to researchers to meet regulatory requirements and increase knowledge and skills
2. Evaluate and improve quality of existing systems to reduce undue administrative and regulatory barriers to clinical and translational research
3. Identify new regulatory issues and barriers to effective clinical and translational research

C. Program Characteristics
1. Process
Dr. Boyd is the Associate Vice Chancellor and Chief Ethics and Compliance Officer at UCSF and has been Program Director for RKS since February 2012. Under Dr. Boyd’s direction, the program has successfully focused on creating and distributing new tools, templates, and guidance in key regulatory areas and has begun implementing critical improvements to IRB processes and clinicaltrials.gov activities.

2. Progress
a. Provide Resources to Researchers
   
   CT.Gov
   Improving CT.GOV compliance is an ongoing effort. We have developed tools and macros and provided consulting services to support faculty, resulting in a decrease in reporting errors. By the end of this grant year, we intend to disseminate the tools to other University of California CTSAs.

   IND/IDE
   Training about onboarding investigators and regulatory compliance has been developed and shared with the research community. A series of webinars will be completed by June 2014. Consulting in excess of 200 hours has been provided to faculty about IND/IDE approvals and compliance. Going forward, funding for this service will be supported by the Vice Chancellor’s Office.

   Responsible Conduct of Research (RCR)
   One hundred and twenty students were trained in this in this highly rated on-line course.

   Regulatory Binder Toolkit
   The Toolkit, designed to assist research sites in maintaining compliance with human subject research policies, was posted for all researchers.

   Global Health Hub
   RKS implemented a comprehensive website that provides tools, templates, guidance and contacts for international researchers who need assistance with regulatory and contractual matters.

b. Evaluate and Improve Quality of Existing Systems
   
   CHR Efficiencies
   The goal for this year has been to evaluate options for reducing the time between CHR application submission and review by the Full Committee. Based on the evaluation, we are in the process of implementing two changes to the CHR review process: Developing solutions
that address common errors in the application and consent form and removing the requirement for all applications to address stipulations prior to committee review. We identified two processes for decreasing this pre-committee approval time: 1) improve the quality of the application by making changes in application sections with the highest number of errors/stipulations and, 2) remove the requirement for all applications to address stipulations prior to committee review.

We have also begun the development of new CHR applications for Social and Behavioral Research and for Biomedical research and are setting minimum preparation standards for submissions to permit CHR analysts to focus on well-prepared and complete applications.

IRBs
We have entered into a contract with Western IRB and are in negotiations with several other external IRBs to facilitate review of multi-campus clinical trials. The five University of California CTSAs have established reciprocity between the UC IRBs; from July through December 2013, UCSF relied on another campus approval 53 times and another campus has relied on UCSF’s approval 110 times. Efforts continue to identify additional multi-site studies that can utilize this mechanism.

We are also participating in the establishment of Pacific Alliance for Clinical Trials (PACT), along with other California-based CTSAs, and providers. PACT is a non-profit entity created by clinical trial sites from academia and the community with input from a variety of trial sponsors, investigators, and other experts. It will strive to simplify and streamline multicenter clinical trial initiation at sites within the PACT Consortium by establishing a system that offers solutions to major sources of inefficiency for a multicenter trial: review by multiple Institutional Review Boards (IRBs) and negotiation of multiple clinical trial agreements.

c. Identify New Regulatory Issues
Dosimetry Database
Based on input from the Radiation Safety Committee, we are in the initial stages of developing a prototype for an on-line database of radiation doses from various machines that will estimate the dose range and generate protocol-specific consent language. The final tool will be designed to be shared with other CTSAs.

D. Major Accomplishments
1. Decreased errors and increased reporting compliance with CT.Gov.
2. Completed IND/IDE training.
3. Produced a Regulatory Binder
4. Posted an on-line Global Health Hub
5. Continued to expand IRB reciprocity
6. Participated in the establishment of PACT
7. Initiated planning for a tool to improve reviews by the Radiation Safety Committee

E. CTSA Consortium, Activities and Contributions
RKS participated in the monthly RKS CTSA Consortium conference call meetings and had representation on the following groups:
1. IND/IDE taskforce
2. GLP subgroup
3. ClinicalTrials.gov taskforce
4. Monitoring/DSMB affinity group
5. Electronic submission working group

F. Plans for Coming Year
1. Continue to expand the use of reciprocal IRB approvals through PACT and other universities.
2. Develop on-line Conflict of Interest course content.
3. In partnership with UC Davis and UC San Diego, implement a centralized multi-campus IRB for approval of stem cell research applications funded by the California Institute of Regenerative Medicine (CIRM).

4. Implement new applications for biomedical and social-behavioral research and test impact of these changes on time to approval.

5. Develop and implement an on-line dosimetry database that can be utilized by other CTSAs.
Strategic Opportunities Support (SOS) Program

A. Personnel
1. Director: Daniel Lowenstein, MD
2. SOS Steering Committee: Daniel Lowenstein, MD, Christine Miaskowski, RN, PhD, FAAN, Peter Sargent, PhD, Lisa Bero, PhD

B. Goals of Program
The primary goal of the SOS program is to stimulate career development and provide financial support for early stage research to young faculty, under-represented in health sciences (URHS) faculty, mid- and senior-level faculty who are pursuing new research directions, and teams of scientists planning multidisciplinary projects. SOS accomplishes this by selectively and competitively awarding resources in the form of grants and, when appropriate, mentorship in these grant applications. SOS support is directly aligned with the CTSI goals and provides crucial funds for a number of specific CTSI programs. SOS participates in the UCSF Resource Allocation Program (RAP), which provides a single application and review process for a wide variety of granting programs, utilizing NIH-style specialized review committees that review and score applications regardless of the final funding source. SOS conducts two grant cycles annually and unsuccessful applicants in a given cycle are urged to reapply using the feedback and mentorship offered by RAP.

C. Program Characteristics
1. Structure/function:
   SOS is directed by Dr. Lowenstein (who is a member of the CTSI Board of Directors) and a Steering Committee that is chaired by Dr. Lowenstein and includes representatives of the Schools of Medicine, Pharmacy, Dentistry and Nursing. SOS plays a significant leadership role in managing RAP, in that Dr. Lowenstein is Vice-Chair of RAP and works very closely with Dr. Roland Henry, the Chair of RAP. RAP manages pre-award administration for 16 intramural funding agencies at UCSF including a common application process with two funding cycles per year. The review process, which uses specialized review committees, draws from a large pool of faculty. This allows matching reviewer expertise with each proposal to provide a transparent, peer-reviewed process that increases the likelihood of resources being targeted to the most promising applicants and research ideas.

2. Progress:
   SOS continues to solicit, review, and award grants to UCSF faculty in the following areas:
   • Pilot Research Awards for Junior Investigators in Basic & Clinical/Translational Sciences
   • Multidisciplinary Planning Awards
   • Under-represented Faculty in Clinical & Translational Research Awards
   • Digital Health Research (formerly Mobile Health Research)
   • Post Childbearing Professional Development Leave

   New grants offered in Year 08
   • Team Science Grant

   Discontinued or no longer funded by SOS for the coming award period:
   • Pilot award Program in T2 (bedside-to-community) Translational Science
   • Pilot Research Awards in Research Policy
   • Novel Clinical Methods/Translational Technology Development
   • Shared Instrument
   • Pilot for Established Investigators

A list of all projects funded by SOS during the Spring 2013 and Fall 2013 cycles is appended to this report. IRB and IACUC approval numbers for all projects funded by CTSA resources that involve human subjects and animals are also appended to this report. Listed below is a summary of the grants awarded by grant mechanism since the last APR.
Table 1: Summary of Grants Since The Last APR

<table>
<thead>
<tr>
<th>Grant Mechanism</th>
<th>Spring 2013 $</th>
<th>Spring 2013 #</th>
<th>Fall 2013 $ **</th>
<th>Fall 2013 # **</th>
<th>Total 2013 $</th>
<th>Total 2013 #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital Health Research</td>
<td>$29,882</td>
<td>1</td>
<td>$60,000</td>
<td>2</td>
<td>$89,882</td>
<td>3</td>
</tr>
<tr>
<td>Novel Clinical Methods/Translational Technology Development Awards</td>
<td>$29,956</td>
<td>1</td>
<td>$50,000</td>
<td>2</td>
<td>$79,956</td>
<td>3</td>
</tr>
<tr>
<td>Open Proposal*</td>
<td>$57,000</td>
<td>4</td>
<td></td>
<td></td>
<td>$57,000</td>
<td>4</td>
</tr>
<tr>
<td>Pilot for Established Investigators</td>
<td>$0</td>
<td>0</td>
<td>$119,831</td>
<td>4</td>
<td>$119,831</td>
<td>4</td>
</tr>
<tr>
<td>Pilot Research Awards for Junior Investigators</td>
<td>$150,000</td>
<td>5</td>
<td>$89,996</td>
<td>3</td>
<td>$239,996</td>
<td>8</td>
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<tr>
<td>Translational Technology Development Award</td>
<td>$30,000</td>
<td>1</td>
<td>$0</td>
<td>0</td>
<td>$30,000</td>
<td>1</td>
</tr>
<tr>
<td>Under-Represented Faculty in Clinical and Translational Research Awards</td>
<td>$59,991</td>
<td>2</td>
<td>$30,000</td>
<td>1</td>
<td>$89,991</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>$356,829</td>
<td>14</td>
<td>$349,827</td>
<td>12</td>
<td>$706,656</td>
<td>26</td>
</tr>
</tbody>
</table>

** Paid from UCSF Institutional Support.
* SOS managed project.

Recipients of grants from prior cycles were tracked to assess their progress and success in applying for and securing additional funding as well as resulting publications or presentations. The table below shows the significant productivity of pilot projects.


<table>
<thead>
<tr>
<th>Award Category</th>
<th>Number of Awards in Each Category</th>
<th>Publications*</th>
<th>Presentations &amp; Abstracts†</th>
<th>Funded Proposals **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Exploratory Award</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CRS Award</td>
<td>15</td>
<td>2</td>
<td>17</td>
<td>8</td>
</tr>
<tr>
<td>Digital Health Research</td>
<td>3</td>
<td>1</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Professional Leave Awards</td>
<td>5</td>
<td>40</td>
<td>48</td>
<td>3</td>
</tr>
<tr>
<td>Multidisciplinary Planning Grants</td>
<td>27</td>
<td>21</td>
<td>38</td>
<td>33</td>
</tr>
<tr>
<td>New Direction Awards</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Novel Clinical/Translational Methods Awards</td>
<td>17</td>
<td>6</td>
<td>24</td>
<td>13</td>
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<tr>
<td>Open Proposal</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pilot Research Awards for Junior Investigators</td>
<td>60</td>
<td>38</td>
<td>103</td>
<td>54</td>
</tr>
<tr>
<td>Pilot in T2 (Bedside-To-Community) Translational Science</td>
<td>7</td>
<td>4</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Pilot Research Awards in Research Policy</td>
<td>7</td>
<td>0</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Post Childbearing Professional Development Leave</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Technology Mini-Symposium Awards</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Translational Technology Development Awards</td>
<td>20</td>
<td>80</td>
<td>60</td>
<td>23</td>
</tr>
<tr>
<td>Under-represented Faculty</td>
<td>26</td>
<td>29</td>
<td>48</td>
<td>20</td>
</tr>
<tr>
<td>Grand Total</td>
<td>201</td>
<td>224</td>
<td>379</td>
<td>169</td>
</tr>
</tbody>
</table>

* Includes Manuscripts in press.

** A total of $115,133,497 in recruited funding has been reported.
† Includes planned presentations
D. Major Accomplishments

1. During the past 2 cycles SOS funded awards for a total amount of $649,656. The dip in number of grants funded during 2013 was a result of being unable to carry forward pilot projects on NIH funding.

<table>
<thead>
<tr>
<th>Cycle Year</th>
<th>Applications Received</th>
<th>RAP Awards</th>
<th>SOS Awards +</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spring 2013</td>
<td>148</td>
<td>72</td>
<td>10</td>
</tr>
<tr>
<td>Fall 2013</td>
<td>176</td>
<td>63</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 3: One-Time Awards Adjustment

* + Please note Table 1 includes SOS managed projects.

We chose to honor our obligations for Fund Year 7 awardees and use new (FY8) funds for the balance of their projects. This meant that we could fund fewer 2013 proposals. Additionally, because of the inability to carry forward pilot funds, all of the Fall 2013 pilot awards were issued from Institutional Support Funds, rather than NIH funding.

2. SOS has continued to improve the usage of CTSI’s Applicant Review and Tracking (ART) system to monitor our awardees. We completed a quality control project in which we verified data that was previously imported into the system. We were able to clean the data (only very minor corrections were needed) to ensure consistent reporting can be generated through ART.

3. During the spring 2014 cycle, SOS launched a new mechanism called the Team Science Grant. The new mechanism is intended to fund new trans-disciplinary projects and offers larger award sizes to funded teams. With less than one month to assemble new teams during this first cycle, we received 11 proposals and look forward to reviewing their scoring outcomes this summer.

4. Since Spring 2013, the following grant mechanisms were added by other UCSF units to RAP:
   - CAPS-HIV Innovative Grants
   - Informing Tobacco Product Regulation

5. In our Fund Year 7 APR, SOS set forth to increase the reach of our program. We have successfully done this by fine tuning our funding opportunities and increasing our portfolio of new opportunities. We merged several RFAs as well as discontinued lower priority opportunities, to now offer funding in six award mechanisms.

6. SOS looked for alternate forms of funding and ultimately determined that outside funding was not a realistic goal given the many competing fund-raising goals of the campus.

E. Plans for Coming Year

1. Increase the reach of SOS by accommodating any new funding opportunities as well as fine tuning existing opportunities.

2. Maintain administrative efficiency and continue to look for further administrative cost saving measures through already available UCSF resources.

3. Increase awareness of the research community about SOS funding opportunities through additional publicity (through CTSI, RAP and EVC Office).
Virtual Home (VH) Program

A. Personnel
1. Director, Virtual Home: Leslie Yuan, MPH
2. Director, Communications: John Daigre

B. Strategic goals of program
1. Enhance opportunities for collaborative clinical and translational investigation at UCSF through strategic communication, information services and technology-enhanced collaboration tools.
2. Provide a cohesive and engaging face of CTSI to Institute leaders and administrators, the UCSF community, the national health science research community and the public.

C. Program characteristics
1. Structure/function: In Year 8, the Virtual Home team was fully staffed with a team total of nine. We have seen continued growth across UCSF in our products’ reach and use, have spent considerable time sharing our work across the CTSA consortium via open source software channels, and have experienced ongoing success with uptake of our products and services at other institutions. Our continued partnership with Harvard Catalyst has expanded further, with UCSF owning the Profiles 2.0 software code release and now leading the Profiles monthly technical meeting (the sister meeting to the Harvard-led original Profiles User Group monthly call). In addition, while continuing to focus on engagement, we have also expanded our sights to begin leveraging Profiles data for use in research management, analytics and precision/targeted emails.

2. Progress: Aims for the year remained constant: increase discoverability of research expertise and resources; improve mechanisms for idea generation and collaboration; and increase program, research and research administration efficiencies through use of technology and communications. We strategically design and plan for efficient sharing of our software and data as one of the main end-goals. We have once again doubled the web traffic to UCSF Profiles, which now receives more than 85,000 visits per month, nearly 20% of the web traffic on the main ucsf.edu web site. Our project to work across California and connect researchers across institutions now has traction, with University of Southern California (USC) and University of California, San Diego (UCSD) as our initial partners. The Open Proposals platform was used by campus-wide stakeholders for 22 opportunities involving pilot funding to strategic planning to institutional investment in core research equipment. In addition, Open Proposals was adopted this year at 2 external institutions, University of California, Merced and Harvard. The team’s success was recognized with the 2013 University of California Golden Sautter award for technology innovation for UCSF Profiles, various members of the team were invited to speak at national/international conferences this year, and we authored 2 papers that were accepted for publication in peer-reviewed journals.

D. Major accomplishments

1. Expertise discovery & research networking within UCSF and across institutions
With the upgrade to Profiles 1.02 code behind us, our team focused on contributing improvements to the Profiles main code base. UCSF owned the Profiles 2.0 software code release that now enables Profiles as a software platform with the ability to extend functionality via the OpenSocial industry standard. Any institution upgrading to Profiles 2.0 will be able to immediately use UCSF’s extensions to Profiles functionality, such as adding embedded videos or news stories, in addition to contributing extensions of their own. This is all enabled via Open Research Networking Gadgets, or ORNG, UCSF’s open source app library. Profiles 2.0 also includes improvements such as search engine optimizations & personalized URLs; two features that we believe will lead to significant traffic and satisfaction for all Profiles installations. Several institutions are already upgrading to 2.0, which in turn revealed the desire and need for a Profiles Technical Meeting, now being led by UCSF.

2. CA Connect, recently renamed R2R (Researcher to Researcher)
In an effort to promote opportunities where a cross-institutional or regional network would be beneficial and efficient for accelerating research and where resources at different campuses could supplement expertise if
more easily identified, UCSF has embarked upon a project initially called California Connect (recently renamed to R2R, or Researcher to Researcher, as we can already see the expansion beyond CA), with University of Southern California (USC), University of California, San Diego (UCSD), and Lawrence Berkeley National Labs (LBNL). To facilitate progress, UCSF has already partnered with these 3 institutions to host Profiles RNS for them, and there is commitment from the stakeholders at these institutions to convene regularly scheduled meetings to discuss, shape, and define the collaboration and innovation that will enable and accelerate research networking, the connection of experts, resources, and research across the institutions. We look forward to cross-linking researchers at different institutions across their own RNS’s and contributing to the national and CTSA-focused endeavor to utilize Linked Open Data and create a true cross-institutional researcher network.

Additional UCSF Profiles-related accomplishments
The team was awarded one of the 2013 University of California Golden Sautter Awards for technology innovation for UCSF Profiles. We published our first peer-reviewed paper in the Journal of Medical Internet Research, entitled "The Use and Significance of a Research Networking System", and we established working relationships with colleagues at the Food and Drug Administration (FDA) and Executive Office of the President (EOP).

Adoption and expansion of UCSF Open Proposals
Over the last several years, CTSI has used the “Open Proposals" platform and process to support activities from gathering ideas for our grant renewal to strategic planning and promoting CTSI annual pilot funding (see graphic, “Active Opportunities”). This past year, the platform gained traction across UCSF and was the method of choice for 22 opportunities across the enterprise.

The novel approach offers researchers the opportunity to find potential collaborators and improve an original proposal based on public comments and feedback. The platform enables use of social networking tools such as “voting,” and is integrated with UCSF Profiles so that contributor information is readily available. The Open Proposals approach allows individuals to submit the best proposals by enabling team development, peer commenting, and the opportunity to use “crowd” feedback to refine the original ideas.

Interest in Open Proposals systems has expanded beyond UCSF to new ways for patients to engage with researchers and new workflows for research opportunities. Also, we are working on a business model to facilitate use of the platform to institutions across the CTSA consortium.

Program Efficiencies: Continuation of support for CTSI programs, Application, Review & Tracking (ART) System, Clinical Research Systems
The VH team continues to support CTSI’s programs by managing the Accelerate website, the CTSI organizational website, and the ART system. Continued improvements have been made to all, such as the addition of the PCORI Proposal library on Accelerate, and numerous additional forms for CTSI’s Consultation Services. The ART system, deployed in 2010 and managed by VH, continues to gain new users & provide efficiencies for CTSI & UCSF’s School of Medicine (SOM). We also partnered with CTSI’s Clinical Research Systems (CRS) team to help streamline current infrastructure technology systems in place, and select a system to improve the budgeting process. It is the intent of both teams to install SPARC from Medical University of South Carolina next year.

Expanded Strategic Communications
The CTSI Communications team expanded communications efforts to reinforce CTSI’s position as willing partner and resource for other groups on campus, affiliates, and the CTSA network. This year, the team collaborated with the CTSI PET group to launch our first public dashboard at ctsi.ucsf.edu. Other highlights include: 1) further development of CTSI web properties; 2) continued implementation of a social media strategy to showcase content across multiple channels; 3) news/media generation and distribution,
including 50+ news stories and multimedia content developed in conjunction with UCSF University Relations and featured on UCSF.edu and CTSA/NCATS media channels, among others; 4) increased number of communications consultations for other campus groups; 5) e-marketing and other campaigns to increase awareness and promote utilization of CTSI services; 6) implementation of an internal communications strategy, including monthly CTSI e-newsletters, an annual communications survey, monthly meetings of CTSI communications working group, etc.; 7) partnership development to create new media channels and highlight CTSI “thought leadership”; 8) piloting of a “social media bootcamp” for scientists/researchers; and 9) continued implementation of a metrics-based communications strategy encompassing aims and initiatives aligned with CTSI’s overall goals.

**Precision Email Platform, CRM, Data Shoebox Project, Research Analytics**

In conjunction with the CTSI Communications team, we have successfully leveraged Profiles data and our newly launched Customer Relationship Management (CRM) system to initiate precision/targeted email campaigns. Automated personalized emails now welcome new UCSF researchers to UCSF Profiles, encouraging engagement, and email analytics confirm that these efforts are useful, powerful, and effective. Our first “annual report” (see graphic) email informed researchers on the overall number of times their UCSF Profiles page has been viewed and by whom, including other universities, top pharmaceutical companies, and NIH. All 200+ survey respondents considered this information “useful.” Our ability to mine publication data and create graphic representations of collaborations within and across departments has garnered the attention of many across UCSF interested in the use of CTSI services and resources, publications, collaborations and networks.

**E. CTSA Consortium, Activities and Contributions**

**Research Networking** – The team presented multiple posters, panels, and demo sessions in meetings this year, including at the CTSA IKFC Annual meeting, VIVO annual meeting, AMIA Joint Summits on Translational Science, OpenSocial Foundation State of the Union, University of Melbourne Research Profiles Conference, VIVO Implementation-fest. Until the demise of the CTSA KFCs, UCSF continued to participate as an active member of the Research Networking Affinity Group (RNAG) & the IKFC. Director Yuan led the RNAG sub group on Utilization, producing the first Guidelines for Usage Tracking for Research Networking Systems.

**CTSI Connect** – VH member & Director of Information Architecture Chatterjee participated as a group member.

**Communications leadership** – Communications Director Daigre was an active member of the CTSA Communications KFC, and attended the annual face-to-face meeting.

**F. Plans for Coming Year**

- Expand use of Profiles data for research analytics, including tighter alignment with enterprise systems
- Facilitate ORNG and VIVO software, enabling functionality extensions in VIVO in addition to Profiles
- Expand Open Proposals for use at other institutions with new models of interaction including patient-researcher connectivity
- Implement R2R cross-institutional linking, building upon collaborations with UC BRAID and UC Rex
- Further expand the Precision Email Platform & Dashboard efforts
- Implement technology solutions for CTSI’s Clinical Research Services (CRS) program to drive administrative efficiency and recharge strategy. (See CRS section for further detail)
- Continue to build upon and strategically expand communications efforts within and beyond UCSF, and leverage communications strengths to further promote CTSI resources and across campus
- Focus on partnership and grant opportunities that will generate revenue for the Program
### Jennifer Adibi
**eRA Commons Name**: JADIBI  
**Status**: Trainee

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>The effects of phthalate exposure on placental development in early pregnancy: a unified approach combining in vitro and in vivo analyses</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>I am proposing to work simultaneously in vitro and in vivo to identify the effects of phthalate exposure in early pregnancy on placental development and function. Phthalates have been measured in &gt;99% of pregnant women in the U.S. and have been associated with birth and fetal outcomes including the timing of labor, increased risk of delivery by Cesarean section, decreased anogenital distance in boy babies, and adverse effects on behavior and IQ in school age children. The relationship between exposures and outcome are generally measured at term; however the placenta and the fetus are more vulnerable in the first and second trimesters when developmental pathways are most active. In my post-doctoral training in the Fisher Laboratory, I have used primary cells isolated from second trimester placental tissue to measure the dose response relationship between phthalate exposure and the expression of molecules involved in trophoblast (Tb) differentiation such as human chorionic gonadotropin (hCG). These findings confirmed associations that I reported in the context of a pregnancy cohort. I am proposing as the next step to measure the in vivo associations of phthalate exposure and cellular and molecular endpoints in late first and early second trimester placentas. This has not been done previously and will provide necessary insight into the etiologically relevant window; as well as minimize the potential for confounding when sampling full-term placentas that have expired physiologically. In the proposed project, I will collect urine, blood and placental tissue from approximately 30 subjects undergoing first and second trimester pregnancy terminations and analyze, using multivariate methods, the associations of maternal urinary phthalate concentrations and endpoints in the placentas. Thus, at the conclusion of these studies I will have resolved using both experimental and observational methods, the effects of phthalate exposure on placental development and function.</td>
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### Sarah Arron
**eRA Commons Name**: ARRONS  
**Status**: Faculty

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<tr>
<th>Project Title</th>
<th>Start Date</th>
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<th>Description</th>
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<tr>
<td>Voriconazole-associated Squamous Cell Carcinoma in Lung Transplant Recipients</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>Aims 1 and 2: chart review was completed on all 455 patients who have had lung transplant at UCSF. 167 transplant recipients were enrolled in the prospective arm for Cyp2C19 genotyping. We have linked genotypes and outcomes data to the demographic data available through the Scientific Registry of Transplant Recipients. This dataset is currently undergoing analysis, we anticipate publication within the next year. Our team was awarded a Nina Ireland Lung Disease Program grant of $200,000 to continue work on this project. We submitted an R01 which was not funded. The feedback from the NIH was that they would prefer to see an RCT based on the observational data we are collecting here. We anticipate moving on to this after completion of the current study.</td>
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Aim 3: we published an in vitro study demonstrating that voriconazole does
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<tr>
<th>Investigator Name</th>
<th>eRA Commons Name</th>
<th>Status</th>
<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description Include publications, if any, and PMCs</th>
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<tbody>
<tr>
<td>Andrew Boyle</td>
<td>Boylea</td>
<td>Faculty</td>
<td>A New Model of Diastolic Heart Failure</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>This award was to define the hemodynamic profile of pressure overload cardiomyopathy in aging mice as a new model for diastolic heart failure. The grant was awarded to purchase the equipment to perform the hemodynamic evaluations and to purchase the aging mice from the NIH aged rodent colony (which is expensive). To date, we have purchased, configured and calibrated the equipment; we have purchased the mice and performed the experiments on 20 mice. Our experiments are ongoing.</td>
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<td>Mustafa Bseikri</td>
<td>NA</td>
<td>Trainee</td>
<td>Supplemental Nutrition in Asthma Control (SNAC)</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>A family-based intervention to study effects on asthma control in obese adolescents consuming a nutrient-dense supplement bar that improves insulin sensitivity, anti-oxidant defense, dyslipidemia, and vitamin/mineral intake</td>
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<td>Albert Chang</td>
<td>NA</td>
<td>Faculty</td>
<td>Choline-Based Radiopharmaceuticals for Imaging of Prostate Cancer</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>This project will be involved in the development of 18F- and 11C-Choline with quality control and assurance performed. This will be the initial step necessary for introduction for clinical use in the future.</td>
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<tr>
<td>Jolie Chang</td>
<td>joliec</td>
<td>Faculty</td>
<td>Binaural Integration in Asymmetric Sensorineural Hearing Loss</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>The focus of this study over the past 12 months (7/1/2012-6/30/2013) has been on an iPhone study application development, subject recruitment, retention, and follow-up. The testing of the iPhone study application was completed in October 2012. Subject recruitment began in February 2013. As of July 17, 2013, 30 subjects were screened over the telephone, and of those 15 subjects came in for a screening/baseline visit and successfully completed the run-in. In total, 13 met all inclusion criteria and were randomized into either the intervention group or control group. In addition, 2 subjects are currently in the run-in period. Two subjects successfully completed the study.</td>
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<tr>
<td>JiWon Choi</td>
<td>JIWONCHOI</td>
<td>Faculty</td>
<td>The MoTHER (Mobile Technologies to Help Enhancing Regular Physical Activity) Trial: A Pilot Study for Overweight and Obese Pregnant Women</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>With funding from CTSI-SOS, we have completed Aim 1 of the proposed studies, and Aim 2 is ongoing. Aim 1 is to determine roles of in vivo-expressed lipoproteins in disease pathogenesis using mouse bacteremia model. We compared virulence of USA300 wild-type strain and 6 isogenic lipoprotein gene-deletion mutants. One of these mutants, containing deletion in gene encoding a manganese transporter MntC, was avirulent in the mouse model, strongly indicating its importance in pathogenesis. A series of follow-up studies were performed to dissect</td>
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<tr>
<td>Binh Diep</td>
<td>BINHDIEP</td>
<td>Faculty</td>
<td>Roles of In Vivo-Expressed Lipoproteins in Pathogenesis of, and Vaccine-Induced Protection Against, Invasive MRSA Infection</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>not potentiating photodamage from UVB (Angeles et al., in press, J Clin Exp Derm). We are currently analyzing microarray data from voriconazole and UV-treated cell lines.</td>
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<td>Steven DuBois</td>
<td>Evaluation of Biomarkers of Radiation Exposure in Patients Treated with 131I-MIBG</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>We have obtained preliminary data on a panel of putative biomarkers of radiation exposure in children and young adults with neuroblastoma who were treated with 131-I-MIBG. From our panel of initial markers, we have identified serum amylase, plasma flt3 ligand, and expression of radiation-response genes as markers that are significantly modulated after 131-I-MIBG. We have characterized the time course and range of modulation of each marker. Specifically, we observe significant modulation of each marker within 72-96 hours after 131-I-MIBG infusion. Moreover, we observed that patients treated with 131-I-MIBG together with a systemic radiation sensitizer had greater degree of modulation of plasma flt3 ligand. We will be incorporating these markers into a national phase 2 clinical trial of three different 131-I-MIBG treatment regimens. This trial and the embedded correlative radiation biology studies have been funded by an R01 grant.</td>
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<td>Elena Flowers</td>
<td>MicroRNA in Insulin Resistance and Prediction of Response to Pharmacologic Interventions</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>This study will provide novel evidence as to whether blood-based microRNA functions as a proximal indicator of response to proven pharmacologic interventions for type-2 diabetes well before changes in established clinical markers (e.g., blood glucose) are observed.</td>
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<td>Judith Ford</td>
<td>Pilot studies for Conte Center proposal to study efference copy dysfunction in schizophrenia</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>Behavioral data from schizophrenia patients and healthy controls using reaching tasks are being analyzed using algorithms developed by Philip Sabes for nonhuman primates. They will form the basis for an R01 or R21. We have analyzed human speech data from schizophrenia patients and healthy controls using algorithms developed by Michael Brainard for songbirds to study single trial variability. We found auditory cortex is exquisitely sensitive to deviations in vocal output during talking, but not during listening to the same sounds played back. This is true in spite of no instructions to maintain consistent vocal output. This may underpin our ability to unconsciously monitor and adjust our speech to match others in our social group. Data from the schizophrenia patients suggest their auditory cortex is not as sensitive, but these data are still being analyzed. Data from controls have been submitted for publication and were presented in my successful R01 submission.</td>
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<td>Heather Fullerton</td>
<td>Prospective Study of Radiation</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>SOS funding allowed us to expand enrollment in the Radiation Arteriopathy</td>
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<td>Investigator Name</td>
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<td>Project Title</td>
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<td>Description</td>
<td>Include publications, if any, and PMCIDs</td>
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<tr>
<td>eRA: fullertonh</td>
<td>(Faculty)</td>
<td>Arteriopathy in Childhood Cancer Survivors (Rad Art PRO)</td>
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<td>(RadArt) Study of cerebrovascular outcomes in childhood cancer survivors from a single-center (UCSF) to 5 centers: Childrenâ€™s Hospital Central California (CHCC), Childrenâ€™s Hospital Oakland (CHO), Washington University (WashU), and Childrenâ€™s Hospital Los Angeles (CHLA). CHCC opened the study in 11/2011, followed by CHO in 1/2013. Our current enrollment total is 174: 90 study participants at UCSF, 46 at CHCC, and 38 at CHO. WashU recently joined and will begin enrollment in July. Childrenâ€™s Hospital Los Angeles is currently undergoing IRB review. We have collected baseline clinical data and imaging studies on all patients, and blood samples from 86. We are starting an interim analysis that will focus on microbleeds and large vessel vasculopathy outcomes. We will use these preliminary data to submit an R01 proposal to fund this prospective, multicenter study.</td>
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<tr>
<td>Stuart Gansky</td>
<td>eRA: sgansky</td>
<td>Tools and Infrastructure to Facilitate Compliance with ClinicalTrials.Gov Results Reporting</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>This funding will allow developing a cadre of staff with expertise in ClinicalTrials.Gov results reporting, allow expanding computer programs to summarize the required elements of trial results, and allow developing other tools to meet the needs of UCSF investigators to comply with federal law. By developing and refining training materials and consultation, staff will provide technical assistance to UCSF investigators to help them use these free tools to meet compliance requirements. This service would remain sustainable with a recharge mechanism through existing CTSI Consulting Service infrastructure and could serve other UC health science campuses and CTSAs which are also struggling to comply with results reporting.</td>
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<td>Roland Gosling</td>
<td>eRA: Unlisted</td>
<td>Modeling malaria transmission interruption to inform intervention study design</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>Modeling work and meetings supported by the CTSI RAP grant lead to a presentation at the American Society of Tropical Medicine and Hygiene annual meeting in 2012 supporting the use of the malaria vaccine RTS,S/AS01 for use in adult populations. The study team is now looking at other options for funding.</td>
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<td>Vanessa Grubbs</td>
<td>eRA: GRUBBSV</td>
<td>The Association of Periodontal Disease with Kidney Function Decline: the MrOS Dental Study</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>Funding was used to measure creatinine and cystatin C on stored sera. Data was provided from outside laboratory in June 2013. Analysis is pending at this time.</td>
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<tr>
<td>Stefan Habelitz</td>
<td>eRA: habelitz</td>
<td>Directing cells to facilitate synthesis and regeneration of dental tissues</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>A main objective of tissue engineering and one of its biggest challenges is to design structures that will direct biology to do its own regenerative cascade. In order to engineer functional tissues, cells must be provided with appropriate spatial and temporal signals to enable growth, differentiation and synthesis of an extracellular matrix of sufficient volume and functional integrity. In this application, I propose to join the Biomaterials &amp; Tissue Engineering Lab of Dr. Kevin Healy at UC Berkeley and acquire a set of new skills and techniques, as listed in the application, that will enable me to expand on my current research on the in-vitro synthesis of dental tissue, in particular on a recently award project on dental pulp engineering. Furthermore this “Professional development leave” will allow me to focus on a new direction in</td>
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<td>Grady, Deborah</td>
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<td>my research and move toward translational approaches for applying engineered constructs in animal models and clinical settings. The Healy-Lab is highly interdisciplinary and collaborative across many institutions in the Bay Area which will provide me with the prospect to initiate joined projects with scientists in Chemistry, Biology, Materials Science and Bioengineering as well as with Clinicians in Medicine and Dentistry.</td>
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<tr>
<td>Korey Hood</td>
<td>Audio Health Engagement Analysis in Diabetes: The AHEAD Study</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>The AHEAD Study focuses on improving provider-patient/family communication during clinic visits for type 1 diabetes management. Through the use of an innovative program, CareCoach, patients and families are empowered to organize and manage type 1 diabetes.</td>
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<td>Liusheng Huang</td>
<td>Profiling of isoniazid metabolites in plasma from isoniazid treated patients and analytical method development</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Analytical methods will be developed for major isoniazid metabolites, and new isoniazid metabolites will be explored.</td>
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<tr>
<td>Vanessa Jacoby</td>
<td>Decreasing Approval Time for CHR Full Committee Review</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>The UCSF time for study approval by the Committee on Human Research (CHR) is unacceptably long at 84 days; the national target is ≤42 days for the duration of the approval process. The aim of this project is to significantly decrease CHR study approval time. We will identify the most frequent causes for approval delay and then design, implement, and evaluate effective strategies to minimize time to approval.</td>
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<tr>
<td>Rajkumar Kalapatapu</td>
<td>&quot;Cognitive Training for Alcohol Use Disorders: A Pilot Study&quot;</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>This will be the 1st study to integrate adjunctive computerized cognitive training with a comprehensive outpatient alcohol addiction treatment program for veterans.</td>
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<td>Michelle Khan</td>
<td>Focal treatment of high-grade cervical intraepithelial neoplasia</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Rationale: Standard excisional treatment of high-grade cervical intraepithelial neoplasia (HGCIN), the precursor to invasive cervical cancer, is associated with 2 to 3-fold increased risk of adverse obstetric outcomes including preterm delivery and neonatal death. Minimizing procedural complication and subsequent obstetrical risks after treatment of HGCIN would represent a substantial improvement in care. Objectives: To conduct a pilot study of the safety, acceptability, and feasibility of focal treatment of HGCIN, and to estimate 6-month recurrence rate of HGCIN following focal treatment. Design: Pilot study of focal treatment for HGCIN, with treatment targeted to the colposcopically-visualized lesion as compared with standard treatment of the entire transformation zone. Reproductive-age women with histologically-confirmed HGCIN will be eligible. Inclusion criteria will be satisfactory colposcopy with lesion occupying ≤2 cervical quadrants. Women consenting to the study will undergo focal treatment. Complications will be assessed via patient-reported adverse events at 2 weeks and 6 months. Acceptability will be measured by a survey administered before and after focal treatment, and feasibility via provider survey after each procedure. At 6-month follow-up, participants found to have recurrent HGCIN will be offered standard...</td>
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Incidence of Sudden Neurologic Death
6/1/2012  6/30/2013
Acute neurologic conditions have the potential to cause sudden death through a variety of poorly understood mechanisms that can mimic sudden cardiac death. For example, aneurysmal subarachnoid hemorrhage, intracerebral hemorrhage, and ischemic stroke can secondarily cause congestive heart failure and arrhythmic death. Furthermore, for patients with epilepsy, SUDEP (sudden unexplained death in epilepsy) is the most common direct cause of death. The widely used World Health Organization (WHO) criteria defines sudden cardiac death as a sudden unexpected death within one hour of symptom onset when the event is witnessed, or within 24 hours of having been observed alive and symptom-free when the event is un witnessed. Current estimates for the incidence of sudden neurologic death are based on countries with ethnically homogeneous populations or on retrospective record review in populations where autopsy are applied selectively and autopsy rates are low which may lead to incomplete ascertainment of the cause of death. Therefore there is considerable potential for systematic misclassification and the distinct possibility that primary neurologic causes may underlie a substantial proportion of cases of sudden death that may otherwise attributed to cardiac etiologies. Here, we propose to demonstrate the feasibility of a unique collaboration between cardiology, stroke neurology, and forensic pathology to systematically evaluate the incidence of acute neurologic causes of death in a consecutive and comprehensive series of cases of WHO criteria sudden cardiac death cases within a well-defined multi-ethnic geographic study base. Our proposal takes advantage of a substantial research investment that has already been made by NHLBI, Dr. Tseng, and Dr. Moffatt to actively capture all sudden death cases within the City and County of San Francisco and to perform autopsies and comprehensive prior record.
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<tr>
<th>Investigator Name</th>
<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>Charlie Kim, eRA: CharlieK (Faculty)</td>
<td>Origins of Excess Macrophage Colony Stimulating Factor in Perforin-Deficient Mice</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>The immune system must not only respond to infectious threats, but also maintain homeostasis in the absence of infection to prevent pathology due to excessive inflammation and autoimmunity. Perforin-dependent cytotoxicity has been implicated in immune homeostasis, and deficiencies in perforin in both humans and mice result in development of hemophagocytic lymphohistiocytosis (HLH), a life-threatening disease characterized by fever, inflammation, and ingestion of erythrocytes by activated macrophages. We will investigate the molecular and cellular mechanisms of the immunoregulatory process that has gone awry in this disease.</td>
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<tr>
<td>Scott Kogan, eRA: skogan (Faculty)</td>
<td>Kinetic Parameters of Acute Leukemia to Pilot Mathematical Modeling of Optimum Therapy</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Using a pre-clinical mouse model of acute myeloid leukemia with FLT3 mutation, this project will gather preliminary data to support a funding application aimed at developing and testing mathematical models of optimum treatment schedules for utilizing tyrosine kinase inhibitors in an alternating, sequential manner.</td>
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<tr>
<td>Jasleen Kukreja, eRA: JASLEENK (Faculty)</td>
<td>Pre-clinical ex-vivo rehabilitation of donor lungs (PERL) project</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>Both the availability of donor lungs and subsequent primary graft dysfunction of transplanted lungs remains a challenging problem. The mortality of those waiting on the list for available organs remains at 15-20% and the mortality from severe primary graft dysfunction exceeds 50%. With the help of CTSI funds, we have now successfully established an ex-vivo lung perfusion model that will allow us to study/improve these factors more effectively. We can now: a) accept marginal donor lungs that we can rehabilitate on this ex-vivo device; b) study the effect of perfusing and ventilating organs on primary graft dysfunction. This ex-vivo lung perfusion model will allow us to study in the future the impact of various treatment modalities not only for lung transplantation but also other end stage lung diseases.</td>
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<tr>
<td>Rachel Kuperman, eRA: Rachel A Kuperman (Other)</td>
<td>Pilot Cross Sectional Trial to Determine the Utility of Oculometrics as a Surrogate Seizure Detector (TOSS)</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>Physicians use seizure burden to guide medical and surgical treatment of patients with epilepsy. The literature shows that estimating seizure burden from clinical history and electroencephalogram (EEG), which is the current standard of care, significantly underestimates the true seizure burden. This pilot cross-sectional trial focuses on a novel approach to determining seizure burden in the ictal and interictal state through changes in eye movements such as pupillary size, blink frequency, eye position etc, (please see appendix for full list) collectively referred to as oculometrics. Analysis of the oculometric data will lead to identification of variables that are specific and sensitive for the ictal state. The goal is to identify oculometric variables that will be used in a definitive trial to develop a real time seizure alarm. A real time seizure alarm will mitigate the uncertainty and loss of control which negatively impacts the quality of life of people with epilepsy.</td>
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<td>Peder Larson</td>
<td>Magnetic Resonance Imaging of Myelin Membranes</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Myelin plays a critical role in facilitating rapid neuronal signaling across relatively long distances, and loss of or abnormal myelination leads to neurodegenerative disorders, such as multiple sclerosis, leukodystrophies, and Acute disseminated encephalomyelitis in children, and has also been implicated in cognitive decline in Alzheimers' disease. Using imaging biomarkers of myelin has the potential to allow for non-invasive assessment of myelination, and could be applied for diagnosis, localization, surgical planning, and monitoring response to treatment in many neurodegenerative disorders, or to study brain development. This project aims to develop of a new, robust Magnetic Resonance Imaging (MRI) method to quantitate myelin membrane integrity. The conventional techniques that are currently being used for myelin imaging include MR spectroscopy, diffusion, magnetization transfer, and T2 relaxation. There is an additional myelin biomarker associated with methylene protons in myelin membranes, found in ex vivo studies, which cannot be observed with conventional imaging methods. In this project, a new MRI method for quantitation of the myelin membrane signal will be developed and validated. Previous MRI approaches have been unsuccessful due to low sensitivity and obfuscation of this signal by free and myelin water components. This project will develop a novel multi-spin-echo ultrashort echo-time (UTE) approach in order separate the multiple types of tissue proton components robustly in the presence of field variations. This will be used in conjunction with specialized image reconstruction approaches of linear combination T2 filtering and parametric compressed sensing. The MRI will be performed on a high-field system (7 Tesla) available at QB3 in UCSF-Mission Bay in the Surbeck Laboratory Imaging Core. This system will provide a theoretical signal increase of ~4.5x over 1.5 Tesla clinical systems.</td>
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<tr>
<td>Ann Lazar</td>
<td>Statistics in Dentistry: Review of the Reporting of Baseline Data in Clinical Trials from Top-Tier Non-Speciality Specific Dental Journals</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>When appropriately designed, conducted and reported, randomized clinical trials (RCTs) represent the gold standard in evaluating oral health interventions. However, RCTs can yield biased results if they lack methodological rigor, which can be assessed through transparent reporting. Inadequate reporting of RCTs fuelled the development of the Consolidated Standards of Reporting Trials (CONSORT) statement. The objective of this study was to evaluate the conduct and reporting of oral health reports in top-tier dental journals. We hand-searched articles published in 2011 obtained from twelve top-tier journals: six dental specialty and six non-specialty journals. Articles were included if they were original RCT reports. Each article was independently assessed by two reviewers. We identified 307 RCTs and 191 were eligible for review. Of the 15 CONSORT criteria evaluated, the average number of criteria present or score was 8.7 (SD = 3.4). Examination of individual CONSORT criteria revealed that most trials did not present information about the randomization method (62%) or identify the primary endpoint (59%).</td>
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<tr>
<td>Heather Leutwyler</td>
<td>OASIS: MOVE</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>The specific aims of this study in a sample of 49 older (55+) adults with schizophrenia are to examine the feasibility and acceptability of a physical activity program using the Xbox 360+ Kinect video game system, examine the short term adherence to the physical activity program during a 6-week study period, and describe changes in the amount of physical activity and level of physical function from baseline to intervention completion (week 6). Thirty-four patients completed the study. A preliminary report based on the study findings was published in the Games for Health Journal. Preliminary acceptability results from the physical activity program reveal that older adults with schizophrenia rate the Xbox Kinect, especially bowling from Kinect Sports, as an enjoyable and fun way to be active.</td>
</tr>
<tr>
<td>Heather Leutwyler</td>
<td>Video Games to Promote Physical Activity in Younger Adults with Schizophrenia</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>People with severe mental illness, such as schizophrenia and bipolar disorder, die 25 years earlier than the general population, most frequently from cardiovascular disease. This 25-year mortality gap is evidence of the damaging consequences of health care disparities impacting this population and requires immediate attention. The causes of this increased morbidity and mortality are multifactorial, although poor access to primary care has been identified as a contributing factor. In addition, many commonly prescribed antipsychotic medications have high rates of metabolic complications (e.g., diabetes, dyslipidemia), which in turn increase cardiovascular disease risk. Despite national metabolic screening guidelines, people taking antipsychotic medications are unlikely to receive metabolic screening. Improving health care access through integration has the potential to increase early detection of cardiovascular disease risk and reduce premature mortality among this vulnerable population. The California Mental Health Care Management Program (CalMEND) was established in 2005 as a quality improvement project to promote wellness and recovery for individuals with mental illness. In early 2010, programs within six counties in California received CalMEND Pilot Collaborative on Integration (CPCI) grants to improve the primary care for people with severe mental illness served at specific county clinics. Each county utilized different integration of care models. Given the wealth of data available in administrative databases collected by the State of California across all counties, there is a tremendous opportunity to determine how effective the different integration of care models are in improving metabolic screening and overall quality of care using a quasi-experimental design. Our</td>
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<tr>
<td>Anne Marsh</td>
<td>Microparticles as biomarkers for osteonecrosis of the femoral head in sickle cell disease</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>The primary objective of this pilot study was to determine whether microparticle (MP) levels in patients with sickle cell disease (SCD) who have osteonecrosis of the femoral head (ONFH) differ from SCD patients without ONFH, as well as healthy African American (AA) controls. The institutional review board at Children’s Hospital and Research Center Oakland approved the study protocol and written informed consent was obtained from all participants. A total of 30 subjects were recruited for the study. Blood samples were collected from each subject and MP levels were analyzed. The results indicate that MP levels in individuals with SCD who have ONFH are elevated compared to controls. Additional studies are needed to better understand the mechanistic effects of MPs on the development of ONFH and to determine whether MP levels may be useful as a predictive biomarker for early disease detection.</td>
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<tr>
<td>Daniel Mathalon</td>
<td>Neural Predictors of Schizophrenia/Bipolar Disorder Risk Syndrome</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>The goal of this study was to assess the cross-site reliability of functional magnetic resonance imaging (FMRI) task-related brain activation protocols implemented on 3T MRI scanners at UCSF and UC Davis in order to support a future grant submission involving a collaboration between the two sites. Healthy subjects (n=10) between ages of 16 and 25 (5 males and 5 females, age 21.2 ±2.6 yrs) underwent FMRI scans at both UCSF’s Neuroscience Imaging Center and UC Davis’s Imaging Research Center. The scans included a T1 structural scan and FMRI scans. During FMRI acquisitions, subjects performed a working memory task and an executive control/context processing task. These FMRI paradigms will be proposed for use in a two-site collaborative study investigating brain dysfunction in schizophrenia and other related mental illnesses. Cross-site reliability for FMRI is a critical methodological consideration for a two-site study. Analyses are underway to determine if reliability is sufficiently high.</td>
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<tr>
<td>Kelly McDermott</td>
<td>Improving Physical Activity Adherence with Mobile and Social Media</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>This study will collect feasibility and preliminary efficacy data on the integration of mobile and social media components to support physical activity maintenance. The study will take place over two phases, a development phase (n=10) and a pilot testing phase (n=30) and will use existing technologies including the FitBit accelerometer, RunKeeper mobile app and RunKeeper online social network.</td>
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<tr>
<td>Monica McLemore</td>
<td>Discovering the continuum between conscientious objection and designated staff in the care of women needing abortions</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Nurses have a strong tradition of advocating for and participating in sexual and reproductive health care. This tradition began with Margaret Sanger, founder of Planned Parenthood Foundation who was trained as a nurse and opened the first birth control clinic in the US in 1916. The involvement of nurses in care of women needing and seeking abortions has been</td>
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<td>Oanh Meyer</td>
<td>Examining the Attitudes and Experiences of Vietnamese Caregivers of Individuals with Dementia or Mild Cognitive Impairment</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>The current project uses a qualitative approach to assess the experiences of Vietnamese caregivers whose parent has dementia or mild cognitive impairment (MCI). Vietnamese caregivers may be at greater risk for poor health and mental health outcomes given their traumatic immigration history and attitudes about aging. Despite this, little is known about Vietnamese caregiver beliefs about dementia, MCI, or caregiving experiences. We will determine how cultural influences affect caregivers’ attitudes and beliefs about ADRD and MCI, caregivers’ experiences of caring for their parent, and the types of caregiver interventions that would be culturally appropriate.</td>
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<tr>
<td>Judith Moskowitz</td>
<td>A smartphone-based intervention for real-life positive emotion skills practice to ameliorate or prevent clinical depression</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>We propose a pilot project bringing together two approaches that have promise to reach large numbers of depression sufferers: a skills-based intervention for increasing positive affect delivered in an inexpensive self-paced format. We will also make use of smartphone technology to improve conventional outcome measurement via in-the-moment sampling and mobile assessment of heart-rate variability.</td>
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<tr>
<td>Bat-Erdene Myagmar</td>
<td>Alpha-1A-Adrenergic Receptors in Neuroprotection</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>Results: Ex vivo, treatment with the a1A agonist A61603 preserved brain slice ATP levels 1.5 fold compare with vehicle treated (N=4). In vivo, in the TBI model, BBB disruption was 2 fold increased in a1A-KO mice versus WT and BKO (N=4). The agonist treatment reduced amount of active Caspase 9 (apoptosis), nitrosylated tyrosine (oxidative stress) levels and preserved NeuN levels (live neurons) after 72hrs of TBI (N=3). Treatment for 4 weeks after TBI with a low dose of A61603 (10ng/kg/d) reduced the volume of lesion and ventricle by 50% and increased hippocampal volume by 65% (N=2). Conclusion: a1-ARs are required for brain protection in vivo during ischemia or trauma, and an agonist for the a1A protects neurons ex vivo and</td>
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documented in the scientific literature since 1968. Advanced practice nurses are currently targeted as a potential solution to the abortion provider shortage and yet, despite this rich history, staff nurses are considered one of many current barriers to abortion care provision. The aims of this study are grounded in the need to discover and identify the continuum between conscientious objectors and designated staff nurses in care of women needing and seeking abortions. A grounded theory qualitative research design will be used for this study to recruit a sample of nurses who have worked in the emergency department, labor and delivery, the operating rooms and post anesthesia care units. Semi-structured interviews will be conducted to examine and explore the cognitive, emotional, and behavioral processes associated with how nurses make decisions to care for women needing and seeking abortions. Data from this study will be used to: 1) design and develop evidenced-based curricula for practicing clinical nurses that integrates ethical responsibilities in clinically challenging situations and 2) develop a theoretical approach to how institutions can support nurses and other staff across the continuum of objection. |
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<tr>
<th>Investigator Name</th>
<th>eRA Commons Name</th>
<th>Status (Trainee, Scholar, Faculty)</th>
<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description Include publications, if any, and PMCID(s)</th>
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<tr>
<td>Diana Naranjo</td>
<td>eRA: DIANA_NARANJO</td>
<td>(Faculty)</td>
<td>Diverse patients with diabetes: Transitions from pediatric to adult care with Latino and African American patients.</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>The aim of the proposed research is to investigate barriers and facilitators of diabetes care for ethnically diverse children with type 1 diabetes as they transition from pediatric to adult health care. There is a growing body of literature suggesting transition-aged youth are particularly vulnerable to negative health outcomes given unique individual, family, and system challenges (1, 2). For instance, changes in insurance eligibility criteria, expectations of self-care, and resource support have all been identified as barriers to care (3). Preparing youth and their families for this process is paramount. This encompasses providing health care support during the transition period, ensuring continuity of care, and fostering the development of skills necessary for successfully navigating the complex health care system (4). This need is even more pronounced among disadvantaged ethnically diverse patients who have high rates of diabetes related distress (5), may lack health insurance (3), may have negative perceptions of health care professionals (6), and are at high risk of developing diabetes related complications and comorbidities (7). However, to date, research has lacked a cultural and contextual framework when examining and identifying the salient psychosocial and health needs of ethnically diverse transition-aged youth. A better understanding of the processes at play, how family and culture influence health care behaviors, and how to best facilitate a successful transition period for these underserved youth are essential and will provide critical data to design preventive interventions during this transition period to optimize diabetes management and outcomes. Further, using a mixed-methods approach will provide the richness in this area of research that is currently lacking.</td>
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<tr>
<td>Donna Odierna</td>
<td>eRA: odierna</td>
<td>(Faculty)</td>
<td>Representation of Minorities, Women, and Older Adults in T2 Studies of Herbal Medicine</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>Preliminary findings suggest that while most but not all of the studies we reviewed report the age and sex of participants; very few performed any subgroup analyses. Older adults were underrepresented in herbal medicine research; representation of women varied among studies of different herbs and medical conditions. Reporting of race/ethnicity was extremely rare; appearing n less than 1% of the papers we analyzed. Many of the studies that are included in our sampling frame (Cochrane reviews of herbal medicines) were conducted in other countries; some of these are unavailable in English. Study location also varies by the intervention being tested and the outcome of interest. Information on funding and conflicts of interest was also rarely reported, making it impossible to determine if reporting of age, gender, and race/ethnicity is better in publicly-funded studies than in studies supported by industry.</td>
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<tr>
<td>Aoife O'Donovan</td>
<td>eRA: AOIFEO</td>
<td>(Faculty)</td>
<td>Resolving Psychological Stress (REPS): A mobile health application for modifying attention bias to threat</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>To date, this project has yielded a fully functioning smartphone-based mobile health application for use as an adjunct treatment for post-traumatic stress disorder (PTSD). During 2012-2013, we collaborated with the UCSF mLabs</td>
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### Investigator Name
**Grady, Deborah**

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<td><strong>Investigator Status</strong></td>
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<td><strong>End Date</strong></td>
<td><strong>Description</strong></td>
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<tr>
<td>Anna Ordonez</td>
<td>in post-traumatic stress disorder</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>Team and the private company AptMobility to successfully develop the REPS application, which includes a cognitive task for training attention, daily and weekly assessment questions on mood and stress-related symptoms, and a sleep diary for use with actigraphy activity monitoring. In recent months, we added a cloud-based server feature to the application, which allows data to be loaded to a HIPAA-compliant server in real time. Our next step is to test the application in a pilot study and we prepared all of the UCSF and SFVAMC approval applications, study protocols and materials for this study during the award period. This project has also led to several new collaborations and novel grant applications.</td>
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<tr>
<td>Gabriel Ortiz</td>
<td>Layering of the myeloid compartment of the human immune system and impact on neonatal vaccine responses.</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>While the initial intention was to recruit 500 students, parents and students expressed such a large interest in the study that we requested bioethical approval to increase our sample size and recruited 633 adolescents, ages 12-18, into the study. At present, we have completed data collection on all students this includes all screening questionnaires on all 633 students and clinical interviews on 20% of the sample (N =126). In order to have validated and accurate diagnoses, we are now working with a collaborative team of child psychiatrists at UCSF, to review the clinical interviews and provide a best estimate of the clinical diagnosis for each participant. At the same time, we have begun the process of cleaning the data-set. Once this process is completed we will run our final data analyses, write the manuscript and submit it for peer review.</td>
</tr>
<tr>
<td>Emily Perito</td>
<td>Causes and consequences of post-transplant metabolic syndrome in pediatric liver transplant recipients</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>The hypothesis motivating this research is that post-transplant metabolic syndrome (PTMS) mediates the relationship between obesity and late mortality after pediatric liver transplant. In a cross-sectional study, we will evaluate the contributions of central adiposity and insulin resistance to PTMS and investigate the impact of PTMS on non-alcoholic fatty liver disease and premature atherosclerosis in these children.</td>
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| Kathryn Phillips | CROSS-DISCIPLINARY EXPANSION OF T2 RESEARCH ON ADOPTION OF NEW TECHNOLOGIES | 2/1/2012 | 6/30/2013 | The objective of this award was to build cross-disciplinary, translational (T2) breadth for research on adoption of new technologies, focusing on personalized medicine and mentoring junior faculty. We achieved this objective in several ways:  
1. We worked closely with several mentees. In addition to the three mentees named in the proposal (Kim; Shin; Long-Boyle), we also worked with several others (Hoef; Arron; Nguyen; Khanna; Kelley; Braithwaite; Kurian).  
2. We hosted numerous mentoring activities including a monthly works-in-
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<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description Include publications, if any, and PMCs</th>
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<tr>
<td>Reno Reyes</td>
<td>rcreyes</td>
<td>Scholar</td>
<td>Modulation of Glutamatergic Signaling by Inositol Hexakisphosphate Kinases</td>
<td>7/1/2013</td>
<td>6/30/2014</td>
<td>Dysfunction of glutamatergic neurotransmission is implicated in many neuropsychiatric disorders, including schizophrenia. I am studying a class of enzymes, inositol hexakisphosphate kinases (IP6Ks) which differentially modulate glutamatergic vesicle recycling. Our goal is to uncover basic mechanisms that regulate glutamate signaling and are amenable for drug therapy in patients.</td>
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<td>Soraya Rofagha</td>
<td>Unlisted</td>
<td>Faculty</td>
<td>Reliability, Validity and Cost-Effectiveness of an iPhone-based Camera (iPhone Cellscope) for the Screening of Diabetic Retinopathy at San Francisco General Hospital</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>We will compare diagnosis of diabetic retinopathy using 2 cameras: a novel iPhone-based retinal camera and a standard fundus camera. We will assess the sensitivity and specificity of the iPhone-based camera assuming the traditional fundus camera as a reference standard.</td>
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<td>Shuvo Roy</td>
<td>shuroroy</td>
<td>Faculty</td>
<td>Universal Bluetooth 4.0 Module and Data Transfer Protocol Framework for Clinical Device Studies</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>The use of sensors and actuators embedded in medical devices for clinical research studies is becoming increasingly common at UCSF. However, there has been little standardization of the hardware/software architecture design, particularly in how acquired data is stored and handled. Development of a common customized Universal Bluetooth 4.0 Module (cUBM) with Unified Medical Information Protocol (UMIP) firmware will speed up the development of these custom monitoring devices while embracing the mobile health platform as a means to store and analyze large amounts of data. The cUBM will modularize the control hardware in devices, enabling the integration of multiple sensors / actuators with “plug-and-play” ease and providing a common wireless platform for data transmission. The UMIP will allow handling of different types of data streams from different transducers through the same cUBM hardware architecture and will deposit data streams into the emPATH framework developed by the UCSF mHealth Group.</td>
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<tr>
<td>Danielle Schlosser</td>
<td>Schlosser2</td>
<td>Faculty</td>
<td>Project Title: PRIME to Action: Enhancing Motivation in Schizophrenia Using a Personalized Real-Time Mobile Health Intervention</td>
<td>6/1/2012</td>
<td>6/30/2013</td>
<td>The purpose of this project was to initiate the design and development process for PRIME, a mobile app focused on enhancing motivation in schizophrenia patients to engage in more health promoting behaviors. We completed a series of focus groups and 1:1 meetings with the target population. This resulted in two user-centered design workshops to sketch out the features and flow of the app. We also successfully completed a prototype of the app. The pilot data and screen shots of the prototype were used in an NIH/NIMH R34 application, which we recently learned will be funded.</td>
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<tr>
<td>John Stein</td>
<td>Jcstein</td>
<td>Faculty</td>
<td>Enhancing Patient Recruitment in Clinical Trials Using Automated Screening Tool</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Clinicians in emergency departments often find it challenging to screen and enroll patients for research studies while maintaining their clinical priorities. Further, it is a laborious and time-consuming for study investigators to train and keep up the knowledge of the faculty and clinical staff on the clinical trial</td>
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| Investigator Name | eRA Commons Name | Status | Project Title | Start Date | End Date | Description
|------------------|------------------|--------|---------------|------------|----------|-----------------------------------------------|
| Rosa Maria Sternberg | eRA: STERNROS | (Faculty) | Psychometrics of the Demand of Immigration (SI) Scale in Mexican Immigrant Women (MIW) | 2/1/2012 | 6/30/2013 | We developed a new Stress of Immigration Scale (SOI-S). One hundred and thirty three low income Mexican immigrant women living in the San Francisco Bay Area completed the 22-item scale. Participants were asked to rate the amount of stress from 1 (no stress) to 5 (severe stress) they had experienced in the past three months related to: speaking English; documentation; work and employment; family and culture; and living in the United States. The total mean stress score of the SOI-S was 3.87 (moderate to a lot of stress). The SOI-S and its sub-scales demonstrated good internal consistency reliability (a = .81) The concurrent validity with the Perceived Stress Scale (PSS) demonstrated moderate correlations between the two scales (a = .34). Test re-test reliability of the SOI-S was calculated at a = .97 making this a stable, valid and reliable instrument to measure stress of immigration in low income Mexican immigrant women.
| Lisa Talbot | eRA: ltalbot | (Trainee) | The interrelationships among aerobic fitness, sleep, and psychiatric symptoms in PTSD | 2/1/2013 | 6/30/2014 | The goal of this research is to assess whether objective improvements in aerobic fitness and sleep from an Integrative Exercise intervention explain potential psychiatric symptom improvement in PTSD.
| Saul Villeda | eRA: VILLEDA.SAUL | (Faculty) | Role of Beta 2 Microglobulin in Regulating Regenerative and Cognitive Impairments in the Aging Brain | 7/1/2013 | 6/30/2014 | The discovery of neural stem/progenitor cells (NPCs) in the adult brain incited possibilities for restoring cognitive dysfunction in the elderly by enhancing neurogenesis in the aging brain. However, advancements remain necessary in our understanding of how normal environmental changes during aging alter adult neurogenesis. Our previous work implicated B2M in age-related changes in NPC function, and associations between increased systemic levels of B2M and conditions with cognitive impairments have been observed. Therefore, the goal of this proposal is to understand the involvement of B2M in age-related impairments in regenerative and cognitive function.
| Zhen Wang | eRA: ZHENWA | (Faculty) | Hyperpolarized 13C MR Markers of Diabetic Nephropathy | 7/1/2013 | 6/30/2014 | The goal of this project is to develop hyperpolarized 13C magnetic resonance (MR) methods, using a mouse model of diabetic nephropathy, to study criteria. In the absence of better strategies, most academic emergency departments still use the traditional approach of screening for eligibility using research assistants. Some of the known problems with this approach is the cost and/or availability of research assistant coverage 24/7, variability among physicians in their knowledge about ongoing studies, and lack of enrollment due to missed or delays in notification. We believe that some of these drawbacks of the traditional approach could be overcome by use of an automated electronic screening tool. The automated tool will use the UCSF APeX system to send page alerts based on predetermined triage screening criteria as well as clinical data, to research assistants. Eligibility will be confirmed by the research assistants. Our objective is to assess the comparative effectiveness of this method to the traditional system of screening in the setting of an ongoing NIH funded clinical trial in the emergency department. We believe that if effectiveness is demonstrated using this study, this could be rolled out to inpatient and clinic settings.
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<th>Investigator Name</th>
<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>Paul Wolters</td>
<td>Development of a Northern CA Scleroderma Research Consortium</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>The funds from this award have been used to establish the Northern California Scleroderma Research Consortium. During the initial planning period we developed the mission statement and bylaws of the organization. Next, we developed a web-based database that can be used by multiple centers to gather clinical information on patients with scleroderma. Patients are now being enrolled at UCSF and Stanford into this database. Finally, there were off site bi-monthly meetings between investigators at UCSF and Stanford at which the collaboration and individual research projects were discussed.</td>
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<tr>
<td>Joshua Woolley</td>
<td>Oxytocin and unhealthy interactions in family of patients with recent-onset schizophrenia: A novel biomarker and pharmacological intervention to reduce negative expressed emotion</td>
<td>2/1/2012</td>
<td>6/30/2013</td>
<td>Our preliminary data is based on parents and their children with schizophrenia. The preliminary data suggest that administering oxytocin to the parent increases how close the parent feels towards the child and how much tension the child feels in the interaction. Furthermore, oxytocin appears to increase the number of critical comments during the conflictual conversation and constructive comments during the positive conversation in both in the child and in the parent. During the neutral conversation, oxytocin administration appears to increase both conflictual and constructive comments. Finally, intranasal oxytocin administered to the parent increases the total number of words spoken by the child.</td>
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| Joshua Woolley   | Improving Social Cognition in Patients with Severe Mental Illness: Neuroplasticity-Based Cognitive Training on a Mobile Device | 2/1/2013 | 6/30/2014 | Deficits in social cognition, such as impairments in eye-gaze and facial emotion detection, play a prominent role in the disability associated with several common mental illnesses, including schizophrenia, autism, substance use disorders, and certain neurodegenerative diseases. Despite their clinical importance, effective therapies for these deficits are lacking. Our laboratory, in collaboration with the Brain Plasticity Institute, has developed a computerized social cognitive training program derived from recent developments in the basic science of implicit learning and cortical plasticity. Our preliminary data demonstrate that this training program improves social cognitive deficits and enhances quality of life in patients with severe mental illnesses such as schizophrenia. To date, all computerized training in mentally ill patients has occurred on desktop computers, often in the clinic setting. However, with the ubiquity and growing sophistications of mobile smartphones” (approaching 100% penetration in the US), delivering cognitive training on a mobile phone is now feasible and provides significant advantages. For example, any patient with a mobile phone can train anywhere, anytime, without the need for a computer or Internet connection, and patients’ training adherence and progress can be remotely monitored in real-time, allowing for training supervision from professionals. Furthermore, in an ongoing study, we have established the feasibility of using mobile phones in patients with severe mental illness for research purposes. In the current proof-of-concept study, we will adapt two existing social cognitive}
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<th>Investigator Name</th>
<th>Project Title</th>
<th>Start Date</th>
<th>End Date</th>
<th>Description</th>
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<tr>
<td>Grady, Deborah</td>
<td>Training exercises for use on a mobile phone and test the feasibility of using this application in ten patients with schizophrenia in a 2-week field study. Our ultimate goal is to develop a highly scalable treatment tool that targets basic deficits in the processing of socially relevant information and can be delivered to a wide variety of patients. If successful, this approach would improve the delivery of healthcare services to underserved clinical populations and have significant public health relevance.</td>
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<td>Lydia Zablotska</td>
<td>Meeting of international collaborators to extend studies of radiation-related hematological malignancies among cleanup workers of the Chornobyl nuclear accident.</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>Health effects of low doses of ionizing radiation are important to understand because of the growing concern that rapidly increasing utilization of diagnostic radiation procedures such as computed tomographic (CT) scans, as well nuclear accidents such as the 2011 Fukushima accident may adversely impact the health of a large proportion of the general population. While direct studies clearly offer the best evidence, pooling data will likely provide more accurate risk estimates. This could lead to better risk models, which in turn can be useful in developing and implementing effective radiation safety standards. We propose to organize a meeting of UCSF, domestic and foreign radiation epidemiology experts and collaborators from other disciplines in order to prepare an R03 application to pool data from two published studies of leukemia in Chornobyl cleanup workers. The R03 will also allow us to analyze outcomes and occupational and environmental health risks of exposures to non-Chornobyl radiation and hazardous chemicals, which were not presented in either publication. This conference will also allow us to develop plans to apply for a multidisciplinary R01 grant to extend the follow-up of the cohort of Ukrainian cleanup workers for hematological malignancies to 30 years (1986-2016). In comparison with previous studies, we will expand our R01 proposal to include the following: multiple myeloma and non-Hodgkin lymphoma; genetic studies of both heritable and somatic mutations and gene-radiation interactions; new statistical methods for dose-response analyses to provide more accurate radiation risk estimates. Going forward, this new line of research will allow for risk projection analyses of low-dose ionizing radiation exposures such as CT scans. This study will address many knowledge gaps on radiation-related risks of hematological malignancies, with clear translational implications for practice. We believe that this conference will enhance the competitiveness of our research team in terms of obtaining future funding for this research. ** No international CHR or foreign data collection took place. **</td>
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<tr>
<td>Alberuni Zamah</td>
<td>Use of Immuno-PCR Assay as an Ultrasensitive, Quantitative Protein Detection Method</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
<td>We propose utilizing a non-invasive method of reliably quantifying oocyte secreted proteins as a method of assessing the translational program within the oocyte. This requires an extremely sensitive and quantifiable approach that is capable of being used on small fluid volumes. Our proposed solution</td>
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<td>Investigator Name</td>
<td>eRA Commons Name</td>
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<td>Ami Zota</td>
<td>eRA: AMIZOTA</td>
<td>Social determinants of telomere length among low-income women during and after pregnancy</td>
<td>2/1/2013</td>
<td>6/30/2014</td>
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<td>Malcom John, MD, PhD</td>
<td>(Scholar)</td>
<td>Pre-experience Perceptions about Telehealth: A Cross-Sectional Descriptive Study of Chinese and Filipino Populations in San Francisco, CA</td>
<td>1/23/2013</td>
<td>1/23/2014</td>
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<td>Pooja Mittal, DO (Assistant Professor, Family &amp; Community Medicine. Site Director of Maternal and Child Health)</td>
<td></td>
<td>Partnering to Increase Breastfeeding Exclusivity in Latina Mothers: Leveraging Research to Strengthen Promotora Education</td>
<td>1/23/2013</td>
<td>1/23/2014</td>
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<td>Suzan Goodman, MD, MPH (Associate Clinical Professor, Director, TEAH Program)</td>
<td></td>
<td>Continuing Reproductive Education for Advanced Training Efficacy (CREATE)</td>
<td>1/23/2013</td>
<td>1/23/2014</td>
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<td>Laura Schmidt, PhD, MSW, MPH eRA: LASCHMIDT (Professor of Medicine, Co-Director of CE&amp;HP) Maria X. Martinez, MPA (Senior Staff to the Director of Public Health)</td>
<td></td>
<td>Home Telephone Pilot Study</td>
<td>1/23/2013</td>
<td>1/23/2014</td>
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Training Individual Progress Report
Grant Number: TL1 RR024129

Start Date: June 2013

Scholar Name: Sina Akhavan

Degree Sought (if applicable): N/A

Primary Mentor: Kevin Bozic

Sponsor’s report on progress and performance during the past year (the sponsor report should not exceed 250 words):
Sina has been a superior researcher in the department of orthopaedics. He has been conducting his primary project on patient activation in total joint patients, as well as several other projects where he has been a prominent contributor. He has been following over 100 patients across two campuses with multiple survey forms while enrolling patients for 2 other studies (a smoking cessation project and a physical therapy project). I have been impressed with his commitment, diligence, work ethic and creativity. He was an excellent student at the start of the year, and after this year I am extremely confident he will have the skills and qualities to make a stellar academic physician.

Project Title:
Patient Activation and Functional Recover in Total Joint Arthroplasty

Description of multidisciplinary integration (the project report should not exceed 250 words):
This project involved working with residents at UCSF and at UCLA, with members of the research team in arthroplasty and nurse practitioners and physicians assistants at Mission Bay Orthopaedic Institute.

Description of the research project:
In this prospective study, we enrolled patients undergoing primary hip or knee arthroplasty. Patient activation was assessed pre-op as one of four stages using the Patient Activation Measure (PAM) and correlated to determine if there is a relationship with recovery after surgery. The PAM is a patient-completed 13-item questionnaire that addresses key psychological factors and personal competencies. Individuals were stratified into one of four stages as assessed with the PAM: Stage I (individuals who tend to be unprepared to play an active role in their own health), Stage II (individuals who lack confidence for self-management), Stage III (individuals who are beginning to take action), and Stage IV (individuals who have adopted many of the behaviors to support their health). Patients have evaluations at six weeks and twelve months after surgery. Pain and disability along with physical and mental health will be evaluated with use of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Short Form-36 (SF-36), and patient satisfaction with use of the Hip and Knee Satisfaction Scale.

We expect overall, pain and disability to decrease after surgery. We expect Stage-IV participants to experience a greater degree of decrease in pain than Stage-I participants. We also expect overall, physical and mental health to improve after surgery with significant improvements in patients in Stage IV compared to Stage I.
Sponsor’s report on progress and performance during the past year:
It has been my pleasure to mentor Dana Dominguez as a CTR fellow for his work in developing a new project to use mass spectrometry to differentiate malignant from benign pancreatic cystic tumors. Dana joined our new collaborative project with Pharmaceutical Biochemistry at the ideal time in that the concept was clearly conceived but all the data acquisition, troubleshooting, design reformulations, and writing had yet to be done.

Dana jumped into the deep end, quickly mastered complex new assays, including mass spectrometry, and fluorescent imaging techniques. On the project he has led the way, doing all the heavy lifting required to generate high quality reproducible data. His efforts resulted in an early abstract that was accepted to the American Association for Cancer Research National Meeting. He also spearheaded and drafted a new grant proposal for the lab that was submitted to the AACR Pancreatic Cancer Network.

This project is a collaboration among multiple PIs and many more postdocs. The mass spectrometry assays and subsequent steps to identify specific proteases that are uniquely present in cyst fluid from malignant pancreatic tumors are both labor and time intensive. His data suggest that protease profiling of pancreatic cyst fluid may facilitate risk stratification among pancreatic cystic lesions and thereby guide clinical decision-making.

Project Title:
Differentiating benign from invasive pancreatic cystic lesions using protease profiling.

Description of multidisciplinary integration (the project report should not exceed 250 words):
This project involves a group consisting of multiple clinicians and researchers both within UCSF as well as at the University of Pittsburgh. It is a collaboration between the Department of Surgery and the Department of Pharmaceutical Chemistry. It involves everyone from the clinical team consisting of nurses and physicians participating in specimen collection, as well as the biochemical side consisting of the researchers performing experiments on the cyst fluid.

Description of the research project:
Decision-making for patients with pancreatic cystic lesions represents the greatest area of clinical uncertainty in the management of pancreatic disease today. Short of pancreas removal, there is no definitive technology that differentiates benign, pre-malignant, and malignant pancreatic cystic neoplasms. As a result, some patients die from undiagnosed cancers, while others undergo unnecessary pancreatic resections with considerable morbidity. Protein levels of proteases and their inhibitors differ between benign and malignant cystic neoplasms, however, effects on enzymatic activity and specificity profiles are unknown. My research aims to identify and characterize proteolytic signatures specific to different stages of pancreatic carcinogenesis. We used a new protease substrate profiling technology recently developed in our lab, Multiplex Substrate-Profiling by Mass Spectrometry (MSP-MS), that can detect and classify the specificity of endo- and exopeptidases in a complex sample. This assay consists of a physiochemically diverse library of 228 tetradecapeptides designed by incorporating all combinations of neighbor and near-neighbor amino acid pairs to provide maximum specificity information. MSP-MS has the unique ability to monitor every peptide bond that is cleaved from this library of peptides, thereby simultaneously detecting aminopeptidase, carboxypeptidase and endopeptidase activity.

Start Date: July 1, 2014

Scholar Name: Evan Walker

Degree Sought (if applicable): n/a
Primary Mentor: Andrew Ko, MD

Sponsor's report on progress and performance during the past year (the sponsor report should not exceed 250 words):
The initial months of Evan's research fellowship were devoted to learning the statistical theory and programming techniques necessary to carry out his proposed analyses. He then investigated the hypothesis that metformin use is associated with decreased risk for pancreatic cancer. He performed detailed analyses of the interaction between type 2 diabetes, duration of metformin use, and cancer risk, using advanced statistical techniques such as propensity score analyses and various methods to account for confounding by indication. A manuscript reporting his findings is currently under peer review. He then explored the associations between statin use and pancreatic cancer risk, and the resultant manuscript is also currently under review. Evan is now initiating a collaboration with epidemiologists at MD Anderson Cancer Center in order to pool case-control data, thereby enhancing statistical power and generalizability of his findings. He is currently developing the necessary statistical acumen to conduct survival analyses, specifically to investigate the associations between metformin or statin use and survival after pancreatic cancer diagnosis.

Project Title:
Investigation of the association of metformin and statins with risk for pancreatic cancer in a case-control study of patients seen at UCSF and from the San Francisco Bay Area.

Description of multidisciplinary integration (the project report should not exceed 250 words):
Evan is working with a multidisciplinary group including clinicians, clinical researchers, epidemiologists, and biostatisticians. These researchers and specialists include faculty from UCSF and MD Anderson Cancer Center in Texas.

Description of the research project:
Pancreatic cancer (PC) has a poor prognosis, with overall five-year survival of 6%. This is partially attributable to delayed diagnosis due to a lack of effective screening. Improved screening, and thus earlier detection, requires better understanding of the effect of clinical exposures on PC risk. To this end, Evan is investigating the association between use of metformin or statins and pancreatic cancer risk. He is utilizing data collected in a large case-control study (536 cases, 869 controls) of patients with pancreatic ductal adenocarcinoma conducted at UCSF, in which cases and controls were interviewed using standardized questionnaires designed to assess for risk factors. He is testing the relationship between the above medications and PC risk using the SAS statistical software package. Results will be stratified by sex, specific type of medication, mechanism of action, age at first and last use, frequency, and duration of use. The large sample size of this study enables powerful detection of the associations between use of these medications and PC risk. Evan will also investigate associations between these medications and duration of survival after PC diagnosis. He will maximize his statistical power for survival analyses by collaborating with researchers at MD Anderson Cancer Center.
Priyanka has successfully designed and executed a clinical trial in her year of research. She worked independently with great initiative on this project. At this point, she almost has full patient accrual (19/20 patients), and we anticipate that she will finish her project ahead of time. We are actually expecting that we may be able to over-enroll our trial in order to obtain more robust data. We aim to have a manuscript written and published before September 2014. In addition, while doing an excellent job moving this study forward, she has designed two retrospective databases looking at our superficial skin cancer experience as well as testing prognostic factors for thymic tumors, and she is completing data analysis on both of these projects with the plan of generating two additional manuscripts. She has gained tremendous experience this past year in retrospective and prospective clinical research as well as valuable experience working with a statistician in designing hypotheses and analyzing data. She has also learned how to explain a clinical trial to patients and facilitate their enrollment into studies. These skills will be important in her maturation as a medical researcher.
Start Date: 6/15/2013

Scholar Name: Brandon S. Imber

Degree Sought (if applicable): n/a

Primary Mentor: Manish K. Aghi, MD, PhD

Sponsor's report on progress and performance during the past year (the sponsor report should not exceed 250 words):
Brandon Imber has been active in many projects during his TL1 fellowship. While the unifying theme has been the treatment of malignant brain tumors, he has participated in several basic science and clinical research projects. In lab, he is working to understand the role of autophagy in the development of glioblastoma (GBM) drug resistance. Brandon has successfully designed and conducted in vitro and in vivo cancer experiments. In terms of clinical research, he is currently collecting and analyzing patient data for several retrospective chart reviews. These projects include queries into a) the role of surgery in patients with multiple synchronous brain metastases, b) the role of radiosurgery for recurrent GBM, c) the outcomes of ventriculoperitoneal shunting for GBM patients who develop hydrocephalus and d) predictors of malignant degeneration in patients diagnosed with low grade oligodendroglioma. Brandon will be included on numerous peer-reviewed publications.

Project Title: Characterizing the role of tumor autophagy in the development of GBM therapeutic resistance

Description of multidisciplinary integration (the project report should not exceed 250 words):
In the lab, Brandon works with a multidisciplinary group which includes laboratory technicians, graduate students and other physicians. He also routinely interacts with pre-medical students, and is actively mentoring an undergraduate. Mouse experiments and protocols were reviewed and approved by the UCSF Institutional Animal Care and Use Committee. For clinical research, he interacts with attending physicians in neurosurgery, radiation oncology and neurology, as well as medical residents, biostatisticians and database managers.

Description of the research project:
GBM is the most common adult brain tumor and is characterized by aggressive growth and uniformly poor prognosis. Recent FDA approval of the anti-angiogenic agent bevacizumab ushered optimism, but hope has been tempered since half of initial responders develop therapeutic resistance. GBM tumors resistant to anti-angiogenic therapy demonstrate increased capacity for migration. The mechanisms driving resistance remain elusive but we recently demonstrated that hypoxia induced by these agents triggers GBM cells to adaptively undergo autophagy. Pharmacologic or genetic autophagy disruption blocked acquired resistance. These observations support our key hypothesis that autophagy not only allows tumors to survive external stressors, but also endows surviving tumor cells with greater migratory capacity. We will generate GBM cells expressing shRNAs against key autophagy genes to explore whether these knockdowns show decreased cellular adhesion, motility, and invasive capacity. Since autophagy inhibition has emerged as a potential cancer therapeutic strategy, we will study how small molecule autophagy antagonists impact migration. Completion of the proposed aims should address important emerging questions in tumor biology with relevance to multiple cancers, such as how tumors develop therapeutic resistance. This work also has the potential to offer insights for novel approaches to treat GBM.
**Sponsor's report on progress and performance during the past year (the sponsor report should not exceed 250 words):**

Stephanie is currently a fourth-year medical student at UCSF who is spending a year working full time in my laboratory through the Pathways to Careers in Clinical and Translational Research program at UCSF. Stephanie designed a project to analyze images acquired using a novel, high-resolution imaging technique, adaptive optics scanning laser ophthalmoscopy (AOSLO), to study individual cone photoreceptors in the eyes of living patients with inherited retinal degenerations, including retinitis pigmentosa and Usher syndrome. This project has been challenging because a systematic method to monitor cone photoreceptors longitudinally over time in the eyes of living patients had not been developed previously. Stephanie analyzed images from eyes treated with ciliary neurotrophic factor (CNTF), and contralateral eyes that received sham surgery, as part of a Phase 2 clinical trial. Stephanie has shown initiative, dedication, persistence, resilience and a high degree of professionalism during her research experience. She has overcome several setbacks with grace and maturity. Her resilience and creativity have been instrumental in addressing challenges that have arisen during the project, and her growth as a scientist this year has been tremendous. Stephanie has presented her research on three occasions, and her presentations are well-organized, thorough, and thoughtful. She is currently writing a manuscript describing her findings and will present her findings at a national meeting in May, 2014.

**Project Title:**

Cone Photoreceptor Structure in Patients with Inherited Retinal Degeneration at 12 months in a Randomized Trial of Sustained-Release Ciliary Neurotrophic Factor

**Description of multidisciplinary integration (the project report should not exceed 250 words):**

This Phase 2 clinical trial involves collaboration between the scholar and a multidisciplinary team of ophthalmologists, research assistants, vision scientists, ophthalmology technicians, and biostatisticians at both UCSF and UC Berkeley.

**Description of the research project:**

The current study uses adaptive optics scanning laser ophthalmoscopy (AOSLO), a high-resolution imaging system, to assess cone survival in subjects with RP participating in a randomized trial of ciliary neurotrophic factor (CNTF). Eight subjects (16 eyes) with RP were randomized to receive a CNTF implant in one eye and sham surgery in the fellow eye. Visual acuity (VA), visual fields, and full-field electrophotography (ERG) were tested at each visit. In addition, retinal layers were imaged with two non-invasive technologies: spectral-domain optical coherence tomography (SD-OCT) and AOSLO. AOSLO was used to capture longitudinal images of photoreceptors at pre-specified regions of interest (ROIs) in the retina. Subsequently, cone photoreceptors were identified at each ROI and were analyzed using a computer-aided algorithm. A masked, interim analysis will be performed at 12 months to assess changes in cone spacing and retinal layer structure among the 16 study eyes.
Start Date: June 15, 2013

Scholar Name: Kunal Raygor

Degree Sought (if applicable): N/A

Primary Mentor: Edward Chang, M.D.

Sponsor's report on progress and performance during the past year (the sponsor report should not exceed 250 words):
Over the past year, Kunal has worked hard to learn many new skills that will undoubtedly help him in his future career as an academic neurosurgeon. Kunal came to this project with a background in molecular biology but has adapted and transformed his skills to include many informatics-based techniques, including programming (in its most basic sense), advanced statistics, and machine learning. His primary project has made progress in showing how voice onset time (VOT) category can be decoded from a population of neurons (and that such decoding is not sparse), and he is now focusing on understanding the exact mechanism of VOT encoding. One issue Kunal has had during his year is remembering to think big picture in his scientific approach. He has tried to remedy this by meeting with senior lab members and asking for their thoughts and advice.

Project Title:
Encoding of voice onset time in the human superior temporal gyrus

Description of multidisciplinary integration (the project report should not exceed 250 words):
Kunal's project looking at the encoding of temporal cues (specifically, VOT) in the human cortex has required that he work closely with a variety of health professionals and students in different professional schools. In particular, he has interacted closely with nurses and other health care professionals while performing his tasks with patients in the hospital. He has also spent significant time working with UCSF graduate students and post-doctoral fellows in the neuroscience and biomedical engineering departments.

Description of the research project:
Speech is one of the most complex aspects of daily human functioning; yet, the neural basis for this ability remains poorly understood. While specific phonemes vary continuously across acoustic parameters such as voice onset time, they are perceived categorically, suggesting that the brain is able to transform the linear temporal cue into a categorical, phonetic code. Subjects will listen to stimulus tokens that linearly vary in only the temporal cue, VOT, and high-density intracranial electrodes will record the neural representation of that variable. Data will be analyzed both as average evoked potentials and in the high gamma frequency range (>80 Hz) after using the Hilbert transform to extract time-frequency information. We will use custom-designed pattern classification algorithms utilizing L1-norm regularized multivariate logistic regression to determine if the neural recordings are categorically organized and to elucidate which features are critical to that organization. Overall, the results of this project will provide a more thorough understanding of speech perception and will act as a foundation for the development of novel treatments for speech disorders in the future. In particular, it may prove useful in finding treatments for individuals suffering from dyslexia, which is characterized in part by changes in perception of temporal acoustic cues.
Start Date: 7/1/2013

Scholar Name: Nichole Young-Lin

Degree Sought (if applicable): n/a

Primary Mentor: John K. Chan & Lee-May Chen

Sponsor's report on progress and performance during the past year (the sponsor report should not exceed 250 words):
From the Cancer Registry, our team obtained a list of 358 patients who were diagnosed with primary ovarian cancer between the years 1999-2009. After extensive chart review and cross-referencing with pathology reports, 152 patients met our inclusion criteria. We were able to obtain pathology slides for 112 patients and tissue blocks for 110 patients. Tissue microarrays are currently being made for the specimens of interest. We are in the process of obtaining slides and blocks for the ones that are missing in order to obtain as complete of a set as possible. In late April, we should be able to perform immunohistochemistry stains and to start analyzing data.

Project Title:
Utility of molecular markers in surgery and chemotherapy for advanced ovarian cancer

Description of multidisciplinary integration (the project report should not exceed 250 words):
This project was a combined effort between the Division of Gynecologic Oncology in the Department of Obstetrics, Gynecology and Reproductive Science and the Gynecologic Division of the Department of Pathology. Surgical ovarian cancer specimens were obtained from surgeries performed by obstetrician gynecologists. The project then depended on our pathologist collaborator to review the pathology slides, make tissue microarrays and perform the immunohistochemistry staining and evaluation.

Description of the research project:
Background: Previous sequencing studies have demonstrated that gene expression of P-cadherin is upregulated in tumors undergoing optimal cytoreduction rather than suboptimal cytoreduction. Vimentin genetic expression has also been shown to be upregulated in tumors that are more invasive and chemoresistant.

Objective: This project aims to validate the protein expression of P-cadherin and vimentin on advanced stage ovarian tumors and to establish predictive markers to direct ovarian cancer treatment.

Method: The University of California, San Francisco's ovarian tumor bank comprise of over 400 specimen correlated with clinical annotation. With these specimens, we will create tissue microarrays and utilize immunohistochemistry to measure the protein expression of P-cadherin and vimentin. For our initial set of specimens, the protein expression levels will be correlated with known clinical outcomes of the patients. Next, we will create a nomogram that combines clinical-pathologic features with our protein expression data to predict clinical outcomes. Using the second set of specimens, we will then validate the predictive accuracy of our nomogram.

Relevance: The utility of molecular markers to select for patients who are more likely to respond to surgical or chemotherapy outcomes can significantly impact our ability to individualize care towards decreasing morbidity and improving outcomes.
Scholar Name: Sarah Arron

Mentors: Meg Chren

Sponsor's report on progress and performances during the past year (the sponsor report should not exceed 250 words):
During the past year, her final year of KL2 support, Dr Arron continued as an active participant in the K scholar senior works-in-progress seminars. Dr Arron heads her own lab and during 2013, published 7 papers, 6 of which were as last author, including a computational analysis pipeline for metagenomic analysis of high throughput sequence data (Dimon et al, 2013). She and her team have completed exome and whole genome sequencing to demonstrate that human papillomavirus does not integrate into the genome to cause insertional mutagenesis (Dimon et al, 2014). She also identified somatic mutation in Notch as a mechanism by which SCC forms; she and her team are currently exploring the interaction of HPV protein E6 with Maml-1 as a viral inhibition mechanism for Notch signaling.

Dr. Arron submitted several research grants in the past year, of which four were funded, three foundation grants and one intramural grant.

Project Title:
Human Papillomavirus as an Etiologic Agent of Cutaneous Squamous Cell Carcinoma

Description of multidisciplinary integration:
This project is collaboration between colleagues in dermatologic surgery, virology, and bioinformatics.

Description of the research project (the project report should not exceed 250 words):
The goal of this project is to examine the role of HPV in cutaneous SCC. We plan to screen human tumor samples for novel virus infection using the broad Virochip microarray screening strategy. In addition we are developing a specific HPV microarray for genotyping HPV in tumor tissue. Finally, we are assessing tumor gene expression to look for virus-specific responses.
**Scholar Name:** Chloe E. Atreya

**Mentors:** Alan Venook, MD, Kevan Shokat, PhD, Robert Warren, MD

**Mentor report on progress and performances during the past year (not to exceed 250 words):**
Dr Atreya completed three quarters of the two-year Master’s Degree in Clinical Research degree program during the reporting period, including a course on Responsible Conduct of Research, and coursework in epidemiologic and biostatistical methods for research, other methodologies, and subject-matter specific coursework. Despite the demands of the first year of the Master’s degree program, she also wrote a protocol for establishing a colorectal cancer specimen banking at UCSF that received IRB approval and began collecting specimens. Dr Atreya received a K23 grant from the NCI during the reporting period.

**Project Title:**
Molecular Predictors of Outcome and Therapeutic Response in Colorectal Cancer

**Description of multidisciplinary integration:**
My mentorship team includes Dr. Alan Venook, Madden Family Distinguished Professor of Medical Oncology and Translational Research; Dr. Kevan Shokat, Professor, Department of Cellular and Molecular Pharmacology and Howard Hughes Medical Investigator; and Dr. Robert Warren, Professor of Surgical Oncology. My project utilizes specimens collected as part of an Alliance for Clinical Trials in Oncology clinical trial, in collaboration with a molecular diagnostics company. Training in biostatistics is an important part of my career development plan.

**Description of the research project (the project report should not exceed 250 words):**
My project aims are to determine whether specific molecular markers in the epidermal growth factor receptor pathway are of predictive or prognostic value in patients with metastatic colorectal cancer treated with chemotherapy plus either cetuximab or bevacizumab on CALGB/SWOG 80405 and to establish a state-of-the-art colorectal cancer specimen bank at UCSF.
Scholar Name: Alexis Beatty

Mentors: Mary A. Whooley, Yoshimi Fukuoka, Judith T. Moskowitz

Mentor report on progress and performances during the past year (not to exceed 250 words):
Dr. Beatty has made significant progress towards her training and research goals in the first year as a KL2 scholar. For training, she has completed a UCSF Department of Epidemiology and Biostatistics Course (EPI 240) on Qualitative Research Methods and completed a Coursera course on Human Computer Interaction. For research, Dr. Beatty made significant progress towards Aims 1 and 2 of her proposed research – she has worked with mobile application developers to build a working mobile application for cardiac rehabilitation, and has begun conducting usability tests of this mobile application in participants. Dr. Beatty published a first-author paper in the Journal of the American Heart Association entitled “Using Mobile Technology for Cardiac Rehabilitation: A Review and Framework for Development and Evaluation.” A first-author paper, entitled “Trends in Referral to Cardiac Rehabilitation after Myocardial Infarction: Data from the NCDR 2007-2012” was reviewed favorably and has been resubmitted to the Journal of the American College of Cardiology. Dr. Beatty also submitted an abstract describing the initial development of the mobile application to the American Association of Cardiovascular and Pulmonary Rehabilitation 2014 Annual Meeting. In March 2014, Dr. Beatty resubmitted a K23 application to the NHLBI. We are pleased with the progress that Dr. Beatty has made to date and expect her to continue to make progress towards her training and research goals in the coming year.

Project Title:
Increasing participation in cardiac rehabilitation using mobile technology

Description of multidisciplinary integration:
The development and study of a behavior change intervention using mobile technology requires integration across disciplines. The scholar is gaining training and experience in health psychology (mentor: JTM), mobile technology (mentor: YF), and clinical research methods (both qualitative and quantitative) (mentor: MAW).

Description of the research project (the project report should not exceed 250 words):
Cardiac rehabilitation is an effective, but underused, intervention for patients with ischemic heart disease. Mobile technology offers a potential solution for increasing participation in home cardiac rehabilitation. The goal of this research is to develop and test a behavior change theory-based mobile application for cardiac rehabilitation. To accomplish this goal, this research has three specific aims: 1) Identify barriers and facilitators to participation in cardiac rehabilitation, 2) Develop a highly usable mobile application for cardiac rehabilitation, and 3) Conduct a pilot randomized clinical trial comparing use of the mobile application to usual care in patients with ischemic heart disease. To date, progress has been made on Aims 1 and 2 of this research. The investigators have begun interviewing participants with ischemic heart disease to learn more about barriers and facilitators to participation in cardiac rehabilitation. In addition, the investigators contracted with a mobile application developer to design and program a mobile application for cardiac rehabilitation (Figure). In the coming year, work will focus on usability and field-testing of the mobile application to improve its usability (Aim 2). Investigators will also begin to plan for a pilot randomized clinical trial of use of the mobile application compared to usual care (Aim 3).
**Scholar Name:** Sonia Bonifacio MD

**Mentors:** Donna Ferriero, Anthony James Barkovich, Maria Roberta Cilio, Chuck McCulloch

**Mentor report on progress and performances during the past year (not to exceed 250 words):**
During the period of support, Sonia was able to secure funding from NINDS in the form of a K23 award (awarded in September of 2013). This was one of her major goals to accomplish while being supported by the KL2 award. She has also spent a large portion of her time completing coursework required for her Master’s Degree. With regards to her research program she has been involved in collaborative multidisciplinary work, which resulted in 4 publications of original research, 2 of which she was second author, and she also co-authored an editorial. She is currently enrolling patients for her primary project and beginning to analyze data.

**Project Title:**
Early Biomarkers of Neonatal Brain Injury

**Description of multidisciplinary integration:**
This is a multi-disciplinary project that requires involvement of pediatric neuroradiologists, MRI scientists, neonatal neurologists, neonatal epileptologists, and biostatisticians. The aims of the project are to study the ability of multi-modal monitoring and early-specialized magnetic resonance imaging to predict outcomes of neonates treated with hypothermia.

**Description of the research project (the project report should not exceed 250 words):**
Hypoxic-Ischemic Encephalopathy (HIE) in neonates occurs in 1-6/1000 live births and results in significant morbidity and mortality. Therapeutic hypothermia is the first treatment to have demonstrated success in reducing the risk of death or severe disability, although it is not completely efficacious with death or adverse outcome in 40-55% of neonates in randomized trials. Following a hypoxic-ischemic insult, there are different phases of cerebral injury during which timely administration of phase-specific therapeutic agents in addition to hypothermia can provide additional neuroprotection and promote repair in experimental models. Unfortunately, early markers that identify the phase of injury and repair are not yet well understood. Potential biomarkers in humans include real-time measures of brain function (EEG), metabolism (1H-MRS - lactate, creative, N-acetyl aspartate) and evidence of parenchymal brain injury (MRI). We propose that these biomarkers can assist in interpreting the timing and severity of injury, provide information on the mechanisms of injury, and can delineate those neonates who could benefit from additional neuroprotection. This study will evaluate the ability of early and continuous monitoring of brain function and advanced imaging to identify neonates that may benefit from additional neuroprotective agents and strategies. Early MR imaging may be able to rationally guide adjunctive therapies that are now being considered for clinical trials. Use of continuous bedside EEG and serial MRI will allow us to visualize the phases of injury, the cerebral response to therapy and to understand the appropriate windows for intervention.
Scholar Name: Rebecca Brown, MD, MPH

Mentors: Michael Steinman, MD; Margot Kushel, MD

Mentor report on progress and performances during the past year (not to exceed 250 words): During the progress report period, Dr. Brown made several major steps towards her goal of becoming a leader in aging research. She demonstrated accelerating productivity by publishing 4 peer-reviewed first-author publications in well-respected journals including JAMA Internal Medicine and the American Journal of Public Health; gained national recognition for her research by receiving several awards at the 2013 American Geriatrics Society meeting including a New Investigator Award; received a perfect score on her K23 submission; and was appointed Assistant Professor of Medicine in the UCSF Division of Geriatrics in July 2013. Her research activities during the past year continue her focus on building a research program to improve health outcomes among socioeconomically disadvantaged older adults. These include her KL2 project identifying the epidemiology and outcomes of early-onset geriatric conditions with a focus on the role of low socioeconomic status; a study examining functional disability in a large cohort of socioeconomically disadvantaged older adults admitted to a safety-net hospital; and a project examining the risk factors for late-life homelessness.

Project Title: Epidemiology and Outcomes of Premature Geriatric Syndromes

Description of multidisciplinary integration: This research is multidisciplinary because it spans the fields of general internal medicine and geriatrics by identifying the epidemiology and outcomes of geriatric syndromes – a key concept in aging research – among adults in late middle age. My K program mentorship team includes experts in both of these fields. In addition, the K program has allowed me to pursue other multidisciplinary collaborations, including a project to examine the risk factors for late life homelessness that includes an epidemiologist with expertise in life course analysis and clinician-investigators trained in general internal medicine and geriatrics. I am also conducting a multidisciplinary project with a team including PhDs in social work and leaders of a community-based organization to determine if a permanent supportive housing program for older homeless adults is associated with decreased use of acute health care services.

Description of the research project (the project report should not exceed 250 words): The main research project uses data from the nationally representative Health and Retirement Study to describe the epidemiology and risk factors for early-onset geriatric conditions (Aim 1) and to identify the relationship between early-onset geriatric conditions and adverse outcomes, including hospitalization, institutionalization, and mortality (Aim 2). I will then conduct a qualitative study to better understand patient and clinician perspectives on the clinical needs of patients who develop these conditions, and to identify models of care that may help to address those needs (Aim 3). I have conducted preliminary work to carry out Aims 1 and 2, including obtaining IRB approval for the project, preparing the analytic plan, and drafting the methods section for the first manuscript related to the project. I also work on several other projects, including a study to validate functional status measures in national Veterans Affairs databases, a project to identify the risk factors for homelessness in late life (after age 50) versus early life, and a study examining risk factors for functional decline among older homeless adults.
Scholar Name: Winston Chiong

Mentors: Howie Rosen

Mentor report on progress and performances during the past year (not to exceed 250 words):
Dr. Chiong has made substantial progress in his research and career development goals. In his career development, he has taken two quarters of coursework in biostatistics and three quarters of coursework in epidemiologic methods, in addition to regular Grand Rounds and laboratory meetings at UCSF and UC Berkeley. Over the summer, he also co-directed the CTSI’s course on Responsible Conduct of Research, advancing his career aims in ethics education while also fulfilling his RCR requirements as a K awardee; he continues to teach medical ethics to medical students, neurology residents, and behavioral neurology fellows. Research from his K project will be presented at two platform sessions and a highlights session at the upcoming American Academy of Neurology Annual Meeting; and a first-authored manuscript has been accepted as a Research Letter in JAMA with other publications to follow. He has received pilot funding with his collaborator Ming Hsu through the UC Berkeley Center for the Economics and Demography of Aging, and has grant applications pending for an R21 from the National Institute on Aging and for an internal UCSF Resource Allocation Program pilot award.

Project Title:
Neuroeconomics of Framing Effects and Risk Attitudes in Early Dementia

Description of multidisciplinary integration:
My principal area of research is human decision-making, including financial, medical and moral decision-making, the effects of aging and neurological disease on brain systems responsible for decisions, and ethical implications of these findings. This research requires expertise from many domains, and in my work I draw upon my multidisciplinary training in clinical medicine, philosophy and cognitive neuroscience, alongside the new opportunities made available through my involvement in the UCSF KL2 program, I am establishing collaborations with investigators in many disciplines including neurochemistry (Blennow & Zetterberg, Univ. of Gothenberg), neuroeconomics (Hsu, UC Berkeley), cognitive aging (Chapman, UT Dallas), law (Farahany, Duke) and philosophy (Jaworska, UC Riverside).

Description of the research project (the project report should not exceed 250 words):
Under Aim 1 of my research project (“Assess framing effects and risk sensitivity in aging, mild AD & mild bvFTD”) my research has uncovered significant differences in reward-related decision-making in mild bvFTD as compared to both healthy older control subjects and patients with Alzheimer’s disease. This work will be presented in a platform session at the upcoming American Academy of Neurology Annual Meeting. Work on Aim 2 of my research project (“Evaluate the influence of large-scale neural network perturbations on framing effects and risk sensitivity in aging, mild AD & mild bvFTD”) is currently underway with neuroimaging analyses of previously-collected functional MRI data. Under Aim 3 (“Characterize and compare financial errors in aging, mild AD & mild bvFTD”) I have developed a new, computer-based testing instrument to gather caregiver reports of financial errors in aging and early dementia; work on validating this instrument is anticipated to begin in fall 2014.
**Scholar Name:** Christine Fox

**Mentors:** Drs. Richard Grant, Heather Fullerton, Rochelle Dicker, Charles McCulloch, Stephen Sidney

**Mentor report on progress and performances during the past year (not to exceed 250 words):**
Dr. Fox has made excellent progress in establishing her research program examining risk factors and outcomes for stroke in the young. During the reporting period, Dr. Fox has presented her original, first-author work at two national meetings. In October 2013 she presented a multi-center, prospective study of acute and remote seizures after pediatric stroke at the Child Neurology Society annual meeting. In February 2014, she presented a population based study of stroke after trauma at the American Heart Association International Stroke Conference. The manuscripts for both these studies are in preparation. She has collaborated successfully with radiology colleagues to publish unique brain imaging of stroke and cerebral arteriopathy due to ACTA2 mutation in a child (BMJ Case Reports, Nov. 2013). She has begun to mentor child neurologists in training, and is senior author for a review of risk factors for arterial ischemic stroke in children (Current Neurology and Neuroscience Reports, January 2014). With her increasing national recognition as an expert in pediatric stroke, she serves on the Data Safety Monitoring Board for “Pumps for Kids, Infants and Neonates” (NIH/NHLBI, Division of Cardiovascular Sciences), which aims to study circulatory support devices for children with congenital or acquired heart disease (a risk for stroke). Her training program includes active participation in the K Scholar program, and she plans to enroll in formal classes in the upcoming cycle.

**Project Title:**
“Improving Stroke Risk Stratification after Head and Neck Trauma”.

**Description of multidisciplinary integration:**
I am an active participant in the multi-disciplinary seminars to discuss works-in-progress through the UCSF K scholars program. My mentors and collaborators include experts in neuro-interventional radiology, trauma surgery, emergency medicine, biostatistics and epidemiology.

**Description of the research project (the project report should not exceed 250 words):**
As a pediatric neurovascular specialist, my goal is to build an independent program of patient-oriented research of stroke in the young. My KL2 project focuses on evaluating vascular imaging and stroke risk in children and young adults with trauma. The aims of the research are to measure short term (4-week) stroke incidence among patients with head and neck trauma while enrolled in Kaiser Permanente Northern California over a 15 year study period, identify clinical injury patterns that place patients at higher risk for stroke and evaluate the role of vascular screening tests in this population. Thus far, from an initial population of 34 million patients, we have electronically identified a cohort of patients with 1.3 million trauma encounters, including 120,494 with head or neck injury. Within the trauma cohort, we confirmed 145 ischemic strokes, giving an estimated 4-week stroke incidence of 0.011 (95% CI 0.009, 0.013). Our preliminary data suggests that patients with injury to the head or neck were more likely to have a stroke compared to those with other types of injuries. The 4-week stroke incidence rate after head or neck injury was 0.02% (95% CI 0.1, 0.3) overall; 0.02% (95% CI 0.01, 0.03) among adults and 0.005% (95% CI 0.001, 0.01) among children (P<0.0001). Of the 145 stroke cases, 10% (95% CI 6, 16) had a diagnostic code for cranio-cervical dissection. Our next step is a case-control study with more detailed data from medical chart abstraction to identify predictors of higher stroke risk.
**Scholar Name:** Jeffrey M. Gelfand, MD, MAS

**Mentors:** Ari J. Green, MD, MAS; Stephen Hauser, MD; Roland Henry, MD (UCSF CTSI K Scholars program advisor: Dr. Kirsten Bibbins-Domingo)

**Mentor report on progress and performances during the past year (not to exceed 250 words):**
Dr. Gelfand has continued to build his neurosarcoidosis cohort, regularly attends K scholars WIPs and seminars, has presented at works in progress sessions, attends scheduled teaching conferences in the MS Division and Neurology department and has had regular mentoring sessions and tutorials with is advisors. As the lead PI on a competitive >$500K institutional clinical fellowship training grant (National MS Society), Dr. Gelfand has also demonstrated his ability to compete successfully for funding and support trainees. He has given a number of grand rounds and invited presentations on his neurosarcoidosis work (Cleveland Clinic Lou Ruvo Center, UCSF MAC, CPMC Neurology). He also has a number of manuscripts in preparation related to neurosarcoiosis, neurological symptoms in pulmonary sarcoidosis and encephalitis and first-authored chapters on neurosarcoidosis (ACP Medicine, in press) and fatigue (Harrison’s Textbook of Internal Medicine, in press). Under our guidance and in consultation with CTSI K scholar faculty and his KL2 adviser, Dr. Gelfand has also been actively exploring new directions in his research, specifically harnessing the EMR to build a clinical dataset from the UCSF MS Clinic that will be linked to actual post-processed MRI data from clinical scans. These efforts will position Dr. Gelfand to be a leader in building clinical datasets by harnessing the electronic medical record, which will further his interests in studying rare neuroimmunological conditions.

**Project Title:**
Determining how Sarcoidosis Spreads within the CNS
Building a clinical dataset from the MS Clinic population using the EMR and MRI data

**Description of multidisciplinary integration:**
I have established a number of collaborations across disciplines, including 1) neuroradiology (MS MRI research program, PACS team, clinical radiology), 2) information technology (EMR and PACS), 3) pulmonary (Sarcoidosis Research Program, Dr. Laura Koth PI), 4) neuropathology, 5) neuropsychology, 6) biostatistics and epidemiology (CTSI faculty).

**Description of the research project (the project report should not exceed 250 words):**
My research focuses on understanding how sarcoidosis spreads within the CNS. I have established and continue to expand a cohort of subjects with biopsy confirmed neurosarcoidosis. I am analyzing the natural history of the disease and correlating with MRI. I also work with Dr. Roland Henry and his team in the MS MRI research lab to analyze and optimize imaging for neurosarcoiosis and have a manuscript in preparation analyzing my initial observations about the natural history and MRI features of this understudied disease. Based on career development training and mentorship, I am expanding and redirecting some of my research focus to learn how to harness the EMR to build a clinical dataset from the MS Center clinic population. This includes working and training with experts in information technology and the EMR at UCSF to abstract clinical data as well as the IT team in radiology to abstract data from PACS to search and process clinical MRIs.
Scholar Name: Marlene Grenon, MD

Mentors: Kirsten Bibbins-Domingo, MD and Michael S. Conte, MD

Mentor report on progress and performances during the past year:
In the last year, Dr. Grenon has remained extremely productive with her research activities and clinical projects. She has now completed recruitment of patients in the OMEGA-1 Trial and is working on the overall analysis of the trial and manuscript preparation. Dr. Grenon submitted an application for a K23 Award to the NIH Heart, Lung and Blood Institute and received a score of “24” on the initial review. We are currently awaiting the decision on funding. She has also submitted an application for an intra-mural grant. Her publication record within the last year has been outstanding with 6 published peer-reviewed manuscripts (5 first-authors, 1 senior author) and she has currently two other papers in press. The data from which most of these papers arise was collected prospectively as part of the OMEGA-1 Trial. She has continued to remain actively involved in the K Scholar Program Activities and participated as a member of the the KL2 Selection Committee. Overall, she has done an outstanding job in the pursuit of her KL2 Award and academic activities.

Project Title:
n-3 Polyunsaturated Fatty Acids Supplementation in Peripheral Artery Disease: the OMEGA-PAD Trial

Description of multidisciplinary integration:
The current study funded by a KL2 Award has led to a multidisciplinary with a close collaboration with Dr. Matt Spite from the University of Louisville for the measurements of metabolo-lipidomics. Dr. Spite is a molecular biologist with expertise in the role of fatty acids in the resolution of inflammation. The KL2 program has also led to multidisciplinary collaborations with researchers in the field of medicine and depression (Heart and Soul Study), generating 3 peer-reviewed manuscripts. These studies have aimed to gain a better understanding of the relationship between depression and peripheral artery disease.

Description of the research project:
Dietary supplementation of n-3 polyunsaturated fatty acids (n-3 PUFAs) has been shown to improve endothelial function and reduce inflammation in different cohorts, as well as to decrease cardiovascular events in secondary prevention trials in patients with coronary artery disease. Their effects in the PAD population are however less well understood. The OMEGA-PAD study (NCT01310270) is a Phase II trial that examined the impact of a high-dose, short-duration dietary oral supplementation of n-3 PUFAs on vascular function and inflammation in patients with established PAD. Eighty patients with stable, mild-severe claudication and ABI<0.9 received 4.1gm of fish oil (FISH) vs placebo capsules (CTL) for 1 month. The primary endpoint was EF as measured by brachial artery flow-mediated vasodilation (FMD). Secondary endpoints included biomarkers of inflammation, generation of n-3 fatty acid-derived lipid metabolites, lipid profile and walking impairment questionnaires. We completed the study in November 2013 and are now processing blood samples. Our preliminary analysis have suggested that fish oil supplementation increases the production of downstream n-3 fatty acid metabolites in patients with PAD as well as triglycerides profile. Our goal is to complete the analysis and submit the finalized manuscript in the summer of 2014.
Scholar Name: Scott Ryan Greysen

Mentors: Kenneth Covinsky (Primary), Andrew Auerbach (Co-Mentor), Daniel Dohan (Co-Mentor)

Mentor report on progress and performances during the past year (not to exceed 250 words):
Dr. Greysen has made great progress towards both his scientific (specific aims) and career goals in the first year of his work as a K scholar. He has already completed the first sub-aim of his K on functional vulnerability. Notably, he is presenting results from at the American Geriatrics Society (AGS) this spring as a finalist for the Presidential Poster session and is being awarded the AGS New Investigator Award in association with this work. In addition to this progress with his K specific aims, he is also making great progress towards becoming a leader in hospital care for geriatric patients. He is currently completing an interdisciplinary faculty development course on the care of aging patients and is a regular participant and presenter at geriatric research meetings. Indeed, he even led a Geriatrics Grand Rounds discussion about optimizing care for older, hospitalized adults/caregivers in November. Beyond his research and career development activities described in his K, he is also applying his findings and experiences to impact clinical care for older, functionally-vulnerable adults in the hospital. In collaboration with my colleagues in hospital medicine and geriatrics, he is developing new protocols to use wearable sensors in hospitalized older adults for early identification and treatment of functional decline to prevent readmission. This work, along with the steady completion of his K aims, will put him in great position to submit an R01 by the end of his K award training.

Project Title: Functional, Cognitive, and Social Vulnerabilities and Hospital Readmission

Description of multidisciplinary integration:
My work at the intersection of hospital medicine and geriatrics exemplifies the multi-disciplinary research strengths of the UCSF-CTSI. This work focuses on an often overlooked population of vulnerable, hospitalized adults who are over age 65 and at risk for poor outcomes (such as hospital readmission) due to functional, cognitive, and social vulnerabilities. Beyond this clinical multi-disciplinary integration, my K aims utilize both quantitative techniques using the robust Health and Retirement Study and advanced qualitative techniques for in-depth patient/family interviews. This mixed-methods approach brings together clinicians and researchers in multiple traditions to produce rigorous results with high potential for policy impact.

Description of the research project (the project report should not exceed 250 words):
I have accomplished several key steps towards completing my specific aims. First, I finalized the cohort of subjects in the Health and Retirement Study (HRS) necessary for analyses (final cohort contains 6,695 individuals with 20,357 hospitalizations from 2000-2008) and formed all variables necessary to execute my first sub-aim. I also completed preliminary analyses of this sub-aim (1a. association between functional vulnerability and hospital readmission) with abstracts submitted to the Society for Hospital Medicine and American Geriatrics Society (AGS) in 2014. For both conferences, I am a finalist for “best research poster” and for AGS I will also receive the New Investigator Award for this work and Outstanding Junior Manuscript Award for publication of my K proposal preliminary data in the J. of AGS in 2013. My preliminary qualitative results were also just accepted by J. of AGS in 2014. Next steps include publishing the above results as a full manuscript (currently in preparation) and executing my next sub-aims (relationship of cognitive (1b.) and social (1c.) vulnerability with readmission) this summer. By next year, I anticipate completion of all sub-aims for Aim 1(a-c) using HRS data and beginning the qualitative studies in Aim 2. With respect to my overall career goals, I am making great progress in acquiring advanced biostatistical skills by executing above analyses and have made significant progress towards acquiring knowledge in principals and practice of geriatrics through coursework, clinical activity, and advocacy/leadership roles for vulnerable older adults at my hospital.
Scholar Name: Raymond Hsu

Mentors: Chi-yuan Hsu, Charles McCulloch, Alan Go

Mentor report on progress and performances during the past year (not to exceed 250 words):
Raymond Hsu was highly productive in his research and training during the reporting period. In addition to two published manuscripts listed below, he has embarked on several new research projects, including observational studies using data from the Chronic Renal Insufficiency Cohort (CRIC) and from Kaiser Permanente Northern California, looking at cardiovascular outcomes after acute kidney injury and the association between renal function decline and mortality after end-stage renal disease. He has also started his own chart review study at UCSF Medical Center looking at physician documentation of acute kidney injury. He additionally prepared an abstract titled “Explaining the temporal trend in dialysis-requiring AKI in the U.S.” that was ultimately selected as an oral presentation at the American Society of Nephrology Kidney Week in November 2013. He completed the “Responsible Conduct of Research” course, and finally he received a K23 award.

Project Titles:
A. Elevated Blood Pressure after AKI
B. Abrupt Decline in Renal Function and Mortality after ESRD
C. Physician Documentation of AKI

Description of multidisciplinary integration:
A. Project involves collaboration with a large integrated healthcare system, Kaiser Permanente Northern California (KPNC), under the mentorship of Alan Go, and the biostatistical team at KPNC.
B. Project involves collaboration with large NIH-sponsored cohort, the Chronic Renal Insufficiency Cohort (CRIC), the CRIC biostatistical team, as well as data from the U.S. Renal Data Systems.

Description of the research project:
A. This is a cohort study involving KPNC adult patients who were hospitalized with and without acute kidney injury, and studying their longterm risk of developing elevated blood pressure, using the comprehensive health data system of KPNC.
B. This is a cohort study involving CRIC subjects who have reached dialysis-requiring end-stage renal disease. The aim is to determine whether an abrupt decline in kidney function immediately prior to dialysis initiation is associated with mortality after end-stage renal disease.
Scholar Name: Megan Huchko

Mentors: Kirsten Bibbins-Domingo, Craig Cohen, Steve Shiboski

Mentor report on progress and performances during the past year (not to exceed 250 words):
During the past year, Megan worked on data analysis, manuscript production, program planning and submission of larger grants. Specifically, she submitted an R01 (PI), a U54 (Project Leader) and an STI CTG concept proposal (PI). She submitted seven manuscripts, five of which were accepted for publication and two of which are currently being revised. She has been invited to give grand rounds for the ob/gyn department at UCSF, and to speak at the public health meeting as part of the International Papillomavirus Conference in August 2014. She was received the Center for AIDS Research Early Career Investigator Award for Clinical Research, for which she'll give the keynote talk at the CFAR Mentoring Workshop in April 2014. Additionally, she taught the online section of the designing clinical research section of a CTSI course in the summer quarter.

Project Title:
Cervical Cancer Screening and Treatment among HIV-infected women in Kisumu, Kenya

Description of multidisciplinary integration:
The study activities in this KL2 award have been developed by researchers in the clinical virology lab at the UCSF CTSI as well as biostatisticians. In addition to the aims specified in the KL2, study data and experiences have promoted additional multidisciplinary collaborations. I am working on a cost-effectiveness analysis with Jim Kahn (Dept of Medicine, Global Economics). I am also pursuing a certificate in implementation science, and the R01 that I applied for was in response to a program announcement from a Implementation and Dissemination Science Study Section. The R01 is a collaboration between social scientists, epidemiologists, biostatisticians, cost-effectiveness experts and ob/gyns. The P54 is a multidisciplinary collaboration between experts in Kaposi's sarcoma, ART adherence and behavioral scientists.

Description of the research project (the project report should not exceed 250 words):
This is the final year of a four year award to evaluate the safety, efficacy and feasibility of cervical cancer screening and treatment techniques among HIV-infected women in Kisumu, Kenya. The specific aims of this KL2 were to validate Visual Inspection with Acetic Acid as a screening test for cervical dysplasia among HIV-infected women, using the gold standard of colposcopy. Enrollment of 1800 women for this cross-sectional study was completed in November 2012, and we are currently in the middle of data cleaning and completeness queries. The second specific aim was to assess the safety of outpatient treatment procedures for cervical dysplasia through a longitudinal study of HIV-1 genital shedding among women undergoing loop electrosurgical excision procedure. All enrollment and specimen collection has been completed. Our findings showed the women who are stable on antiretroviral therapy who have cervical dysplasia do not have increased levels of HIV-1 found in genital secretions compared to women without cervical dysplasia, and women on HAART have a limited and low level of genital HIV-shedding at two weeks post-procedure that is not sustained further out. VIA was shown to have sensitivity in HIV-infected women similar to that for HIV-negative women. The results of this study have been used to design the program protocol for the cervical cancer screening and prevention program at the HIV-care program at FACES, and to inform the Kenya guidelines for cervical cancer prevention within HIV care programs in the country.
Scholar Name: Vivek Jain, M.D., M.A.S.

Mentors: Diane Havlir, M.D.

Mentor report on progress and performances during the past year (not to exceed 250 words):
Vivek Jain continues to perform outstandingly in his role as a UCSF second-year KL2 scholar. He has continued participating in the KL2 works-in-progress seminars, presenting his own ongoing research multiple times, and has continued his involvement with the UCSF CTSI and UCSF Center for AIDS Research (CFAR), giving talks at two large scale forums in the past year. Dr. Jain’s research agenda is continuing to advance the field focused on early HIV antiretroviral therapy (ART) strategies. One half of his research agenda focuses on the implementation science behind ART delivery in resource limited settings. He is doing an excellent job leading one of the only ART trials in Africa examining ART outcomes among high CD4+ T cell count individuals receiving care through a streamlined nurse driven health system (the EARLI Study). He recently presented the Year 1 results from the EARLI Study at the Conference on Retroviruses and Opportunistic Infections (CROI) in March 2014 in Boston and has completed a manuscript detailing this study. In 2013, Dr. Jain also advanced his studies of population-level assessments of HIV viral loads as a marker of how well ART strategies are succeeding in penetrating and diffusing through a population. The other half of Dr. Jain’s research lies in clinical translational studies of immunologic parameters and viral reservoir measurements in early-treated versus later-treated HIV positive individuals.

Dr. Jain published 7 papers in 2013, 3 of which he first-authored, and 4 of which he co-authored.

Project Title:
Early Antiretroviral Therapy in High CD4+ Cell Count Patients

Description of multidisciplinary integration:
My research agenda currently combines several disciplines. In studying early ART strategies, I am combining research approaches from implementation science, as well as clinical cohort based observational research. In running the EARLI Study, I am combining interventional clinical study work with practices and procedures for biobanking of specimens, and fostering collaborations with laboratory based scientists to perform both immunologic and virologic assays on stored patient samples.

Description of the research project (the project report should not exceed 250 words):
1) I am studying the implementation science of ART delivery to early-stage HIV-infected individuals (e.g., high CD4+ count persons) in resource-limited settings, primarily Sub-Saharan Africa. I am leading the EARLI Study (described above) which is now in its second year of operations, and continues to measure ART efficacy and safety in the high CD4+ count population. I have recently presented Year 1 data on this study at an international HIV conference and will this month submit a manuscript on these results.

2) I am also studying immunosenesence, T and B cell dysfunction, and monocyte activation in HIV positive persons who have started ART either early or later in the course of their disease. I am performing this work in two separate cohorts: one is an acute HIV cohort based at UCSF, and the other is a biobank of specimens I am building from the Ugandan patients enrolled in the EARLI Study. These unique patient populations have fostered my ability to ask relatively difficult yet important questions about the impact ART can have in preserving immune strength, both as a result of ART, as well as separate from the effects of ART.
Scholar Name: Joyce Lee

Mentors: Talmadge King

Mentor report on progress and performances during the past year (not to exceed 250 words):
Dr. Lee has been very productive during the past year. From a career development perspective, she is undergoing a promotion from Adjunct to Clinical X series. She has also taken on a leadership role in interstitial lung disease (ILD) outreach through working with the hospital marketing department and organization of our biennial CME. She also was an invited speaker at a national meeting on pulmonary fibrosis last winter. She directs our ILD clinic and has increased access to patients in the last 2 years. She continues to work on other ways to improve our ILD clinic, including participation in a national Registry effort with the Pulmonary Fibrosis Foundation. From a research perspective, she has been first author on 1 manuscript, senior author on 2 manuscripts, and mid-author on 4 manuscripts. She has completed enrollment into one of her investigator-initiated studies on gastroesophageal reflux and aspiration in ILD. She continues to spend much of her time on establishing an RA-ILD cohort here and at Mayo Clinic, Rochester. Last, she is working on a project with Dr. Homer Boushey in the development of a test for microaspiration and they will begin enrolling for this study in April.

Project Title:
Understanding Rheumatoid Arthritis Associated Interstitial Lung Disease (RA-ILD)

Description of multidisciplinary integration:
Through my participation in the K program, I interact with investigators of different backgrounds and expertise, including statisticians. In particular, this forum allowed me to form a collaboration with one of the rheumatologists to do a project on the outcomes of hospitalized patients with RA-ILD. In addition, my research incorporates several disciplines outside of pulmonology, including rheumatology, radiology and the basic sciences. Every Friday, I meet with a radiologist and pathologist to discuss clinical ILD cases. In addition, I interact on a monthly basis with two rheumatologists who are helping me coordinate the rheumatologic arm of my prospective study. Finally, I participate in weekly lab meetings that engage both clinical and basic scientists to discuss translational approaches to human-based research.

Description of the research project (the project report should not exceed 250 words):
My goal is to become an independent clinical investigator and leader in interstitial lung disease. To continue my progress towards this goal, I am performing a prospective cohort study addressing specific hypotheses surrounding the significance of RA-ILD subtypes. Specifically, I am interested in addressing 3 primary issues: (1) the natural history of RA-ILD subtypes, (2) the autoantibody profile of RA-ILD subtypes, and (3) the role of telomere length in RA-ILD subtypes. The knowledge and experience gained from this research will allow me to develop additional studies focused on clinical and biological understanding of RA-ILD. In addition, successful execution of this research proposal will transform our understanding and treatment of RA-ILD by demonstrating the importance of subtype. This may significantly impact the health of these patients because not only could the underlying pathobiology of RA-ILD subtype be contributing to the shortened survival experienced by these patients, the conventional treatments being used could also be hastening their death.
**Scholar Name:** Heather Leutwyler

**Mentors:** Sophia Vinogradov, Bruce Miller, Dilip Jeste

**Mentor report on progress and performances during the past year (not to exceed 250 words):**

**Funding:** Heather submitted an intramural grant in February 2013 that was successfully funded by the CTSI Resource Allocation program and K23 application that was funded by the NIA in December 2013. **Studies:** Heather continued work on 3 pilot studies: Pilot study # 1: The purpose of this cross sectional pilot study is to examine the relationships between neurocognitive function, schizophrenia symptoms, serum BDNF, and physical function in older adults with schizophrenia. Forty-six participants completed the study. Pilot study # 2: The specific aims of this study are: to describe older adults with schizophrenia perceptions about barriers and facilitators to engage in activities that promote physical function; and to describe the perceptions of clinicians and staff members about barriers and facilitators to engage in activities that promote physical function among older adults with schizophrenia. Twenty-three staff and 16 patients completed the study. Pilot study #3: The specific aims of this study in a sample of 34 older (55+ years) adults with schizophrenia were to examine the feasibility and acceptability a physical activity program using the Xbox 360+ Kinect video game system, examine the short term adherence to the physical activity program during a 6-week study period, and describe changes in the amount of physical activity and mobility from baseline to intervention completion (week 6). **Publications** Heather published 8 papers (3 first-author) and has 1 first authored manuscript currently under review.

**Project Title:**
Factors associated with poor physical function in older adults with schizophrenia

**Description of multidisciplinary integration:**
The project incorporates the expertise of nursing, geriatric psychiatry, neurology, and basic science.

**Description of the research project (the project report should not exceed 250 words):**
Older adults with schizophrenia are a growing segment of the population yet a limited amount of evidence suggests their level of physical function is extremely poor. In order to design targeted interventions to improve the physical function of this vulnerable population, the factors that contribute to poor physical function must be understood. Limited data suggest that more severe schizophrenia symptoms and poorer neurocognition have a negative impact on physical function. In addition, Brain Derived Neurotrophic Factor (BDNF) may be an important link between schizophrenia and physical function that warrants exploration. To better understand these relationships and how they may change over time, Dr. Leutwyler will conduct a longitudinal study of 75 older (55+) adults with schizophrenia to: **Aim 1:** evaluate the relationship between neurocognitive function and physical function and how this relationship changes over time; **Aim 2:** evaluate the relationship between the number of schizophrenia symptoms and physical function and how this relationship changes over time; **Aim 3:** evaluate the relationship between severity of schizophrenia symptoms and physical function and how this relationship changes over time; and **Aim 4:** evaluate the relationship between serum levels of BDNF and physical function and how this relationship changes over time. These data will lay the foundation for future NIH R01 grant applications that will include intervention studies to improve physical function in older adults with schizophrenia.
Scholar Name: Eleni Linos

Mentors: Mary Margaret Chren (Dermatology), Louise Walter (Geriatrics)

Mentor report on progress and performances during the past year (not to exceed 250 words):

Since January 1st 2013, Eleni has published 14 papers, 6 as first or last author. Eleni has also presented her work at 2 conferences (AAD 2014 and BEES 2013). Eleni has submitted a large PCORI grant in April 2013 that got a nearly fundable score and has been resubmitted in December 2013. She is currently preparing a collaborative grant proposal through the CDC Prevention research center.

Project Title: Non melanoma skin cancer care in patients with limited life expectancy

Description of multidisciplinary integration:
My collaborators include those from multiple specialties including Geriatrics, Dermatology and Internal Medicine.

Description of the research project (the project report) The central hypothesis motivating this research project is that significant overtreatment of NMSC occurs in patients with limited life expectancy across the US, because of the lack of practice guidelines for this group. The overall goal of this study is to inform clinical decision-making for NMSC in patients with limited life expectancy. To accomplish this goal, we will use the following methodology. First, we will characterize care for NMSC at the end of life by determining treatment patterns for NMSC in these patients. Second, to understand how current treatment choices are made, we will survey clinicians to learn their goals for care, considerations they use to make treatment choices, and challenges they anticipate to the development of treatment guidelines for these tumors. Finally, we will use the results of this research to develop an intervention for decision making for NMSC in patients with limited life expectancy. The rationale for the proposed research is that understanding current treatment patterns of NMSC and the factors that influence current clinical decisions is critical for improving care.

Specific aims of this research project are outlined below: **Aim 1.** To describe the treatment of NMSC in patients with limited life expectancy, using representative national databases **Aim 2.** To understand current treatment decisions for NMSC in patients with limited life expectancy by conducting surveys of a nationally representative sample of dermatologists. **Aim 3.** To develop a decision-support intervention for improving clinical decision making for NMSC care in patients with poor life expectancy.
Mentor report on progress and performances during the past year (not to exceed 250 words):
During the review period Dr. Boyle’s major accomplishments include (1) receiving a UCSF CTSI Resource Allocation Program Award, (2) the publication of 3 peer-reviewed manuscripts (1- third author, 2- last author), and (3) the presentation of her work at the American Society of Bone and Marrow Transplantation Annual Meeting oral session. Additionally, Dr. Boyle continues to make significant progress on her KL2 research project with the successful development of a population pharmacokinetic model for both plasma and intracellular fludarabine drug concentrations in children undergoing hematopoietic cell transplantation (HCT) (Aim 1). This work demonstrates the impact of patient-specific factors that influence drug levels including age, weight, and renal function and will form the basis for generating improved dosing strategies in children (AIM 3). Finally, Dr. Boyle continues to enhance her skills in pharmacokinetic modeling with advanced coursework in pharmacometrics available through the Metrum Institute.

Project Title:
Population Pharmacokinetics of Fludarabine in Pediatric Patients Undergoing Hematopoietic Cell Transplantation

Description of multidisciplinary integration:
I have become actively involved in several collaborative research initiatives in the pediatric population.

California Institute of Regenerative Medicine (CIRM) Disease Team Therapy Developmental Award- The major goals of this project are to investigate clinical efficacy and define the pharmacokinetics of anti-CD117 mAb for the treatment of the pediatric genetic disorder severe combined immune deficiency. As co-investigator Janel’s role is to extrapolate first-in-human adult PK data to the application of use in a pediatric population.

Primary Immune Deficiency Treatment Consortium (PIDTC)- The goal of this NIH sponsored consortium is to develop novel interventions for the treatment of the severe combined immune deficiency. A grant submission aimed to design a prospective dose-escalation study of targeted exposure busulfan in infants less than 3 months of age is underway. Janel’s role as co-investigator on this submission is to develop a pharmacokinetic model for busulfan, which can be applied to accurately achieve targeted drug exposure in infants.

Description of the research project (the project report should not exceed 250 words):
The long-term goal of my research is to improve outcomes in pediatric HCT through the application of personalized dosing strategies. My KL2 research is focused on identifying and quantifying sources of variability that influence fludarabine exposure (plasma and intracellular) in children undergoing HCT (Aims 1 and 2) and establish the relationships between drug exposure and clinical outcomes (Aim 3). As part of this proposal I will develop and utilize a novel state-of-the-art method for the quantification of intracellular f-ara-ATP in small volume clinical samples to optimize pharmacokinetic-pharmacodynamic studies in children. Pharmacokinetic model development using concentration-time data will be carried out using standard population PK methodologies and NONMEM VII software.
Mentor report on progress and performances during the past year (not to exceed 250 words):
Manuscripts are in preparation for the results of Aim 1 and Aim 2. This work was presented at the American College of Rheumatology Meeting in November of 2013. Additionally, Dr. Margaretten has published or been a co-author for the following publications: (i) Margaretten et al. Missed opportunities for depression screening in patients with arthritis in the United States. J Gen Intern Med. 2013 Dec, (ii) Yazdany et al. Choosing wisely: The American College of Rheumatology's (ACR) top 5 list of things physicians and patients should question. Arthritis Care Res 2013 March, (iii) O'Donovan et al. Elevated risk for autoimmune disorders in Iraq and Afghanistan veterans with posttraumatic stress disorder. In review. Biologic Psychiatry. With regard to grants submitted, Dr. Margaretten is a co-investigator on an intramural grant “Expanding UCSF Action Research Program to SFGH” (7/2014-6/2016) and a co-investigator on an ACR randomized controlled trial of Physical Activity for RA Fatigue (7/2013-6/2015). Finally, Dr. Margaretten received the Eph Engleman Award for Excellence in the Field of Arthritis Research from the UCSF Division of Rheumatology.

Project Title:
Inflammation and Depressive Symptoms in Patients with Rheumatoid Arthritis

Description of multidisciplinary integration: Since this study incorporates systemic inflammation, RA disease activity, disability, and socioeconomic status into a model of depression, I am able to evaluate which aspect contributes the most to depressive symptoms and target interventions accordingly. Additionally, depression is associated with numerous disorders that involve chronic inflammation (cardiovascular disease, obesity, multiple sclerosis), and this study can provide further evidence for the association between depression and inflammation in a less common chronic condition. My work has led to several multidisciplinary relationships including collaborations with: (i) Dr. Patti Katz and evaluating the effect of exercise on RA patients with fatigue with a randomized controlled trial, (ii) Dr. Jinoos Yazdany resulting in a provocative project (The American College of Rheumatology Top 5) which is a list of tests, treatments, and services that are commonly used or performed in rheumatology practice and whose necessity should be questioned due to low value and discussed by physicians and patients, and (iii) Dr. Aoife O'Donovan studying the association between autoimmune disease and PTSD in US Veterans.

Description of the research project (the project report should not exceed 250 words):
My research project is evaluating if systemic inflammation is associated with depressive symptoms in patients with rheumatoid arthritis (RA) independent of synovitis, functional limitation, and disability. Patients with RA and subsequent depressive symptoms have poor health outcomes. While it is well established that RA can lead to depressive symptoms and consequently worse health outcomes, the role of systemic inflammation in the pathogenesis depressive symptoms in patients with RA has not been determined. The aims of the longitudinal study are (Aim 1) to retrospectively assess if acute phase reactants are correlated with depressive symptoms in patients with RA, (Aim 2) to prospectively evaluate if pro-inflammatory cytokines are associated with depression scores independently or in combination, and, (Aim 3) to prospectively evaluate if prednisone, synthetic, and/or biological disease-modifying anti-rheumatic drugs influence the relationship between inflammation and depressive symptoms. By assessing acute phase reactants and the contributory role of pro-inflammatory cytokines, I can see if these potential indicators may be useful for identifying or tracking depressive symptoms, which are often overlooked in the rheumatology clinic.
**Scholar Name:** Sabine Mueller

**Mentors:** Dr. DuBois, Dr. Haas-Kogan, Dr. Prados

**Mentor report on progress and performances during the past year (not to exceed 250 words):**
For her KL2 project Dr. Mueller is leading a multi-center national phase 1 trial of specific Wee1 inhibitor MK-1775 for children with newly diagnosed diffuse intrinsic pontine glioma (DIPG) through the Children’s Oncology Group. The trial is actively enrolling patients and Dr. Mueller was already able to dose escalate to the next level. She is actively collecting samples on this trial to assess pharmacodynamics changes in these patients. Further, Dr. Mueller recently published her preclinical studies of MK-1775, which are the basis for the clinical study in Neuro-Oncology. Dr. Mueller is actively designing new studies for children with brain tumors. She is currently the Co-PI of 2 studies for children with gliomas and she will be the PI of a new study for children with DIPG that will use molecular profiling to determine an individual treatment plan. She is also the site PI for an industry sponsored trial for children with medulloblastoma. She recently submitted a concept to Novartis to investigate their new MEK inhibitor for the treatment of patients with NF1 and associated plexiform neurofibromas. Dr. Mueller is also the PI of a multi-institutional study to assess late-effects in children with cancer. Dr. Mueller’s grant proposal to investigate the use of molecular profiling in clinical treatment decision making for children with newly diagnosed DIPG was chosen to compete in the final round for funding from the V-foundation. Dr. Mueller participates actively in Advanced Training in Clinical Research Course and will complete the Masters of Clinical Research.

**Project Title:** A Phase 1 Study of MK-1775 (IND# 116495) Concurrent with Local Radiation Therapy for the Treatment of Newly Diagnosed Children with Diffuse Intrinsic Pontine Gliomas

**Description of multidisciplinary integration:**
My research field is highly multi-disciplinary. For my next clinical trial for children with DIPG I work closely together with neurosurgery, experts in genomics through the Translational Research Institute in Arizona as well as basic scientist with expertise in animal modeling such as Dr. Hashizume from the Department of Neurosurgery, UCSF. For my late effects research I have been interacting with several other institutions within the United States. Part of my research is imaging based and I successfully established collaborations with Dr. Wintermark, Chief of Neuroradiology, University of Virginia as well as Dr. Krull, neuropsychologist at St Jude’s research hospital.

**Description of the research project (the project report should not exceed 250 words):**
My KL2 project is to conduct a phase 1 clinical trial of specific Wee1 inhibitor for children with newly diagnosed DIPG. To date we have successfully enrolled 8 patients on this study and were able to escalate to the next dose level. We are also collecting PK and PD samples on this trial. I will perform the PD analysis whereas the PK analysis is performed in collaboration with Dr. Reid, Mayo Clinic. Accrual has been as expected. In addition to the ongoing trial I am actively working on a new protocol for children with DIPG using molecular profiling of these tumors for clinical decision-making. The concept has received contingent approval by the Cancer Center and I anticipate that this study will open in June 2014. In addition to design and conduct therapeutic trials for children with brain tumors, I also investigate late effects in this patient population with a focus on vascular effects of radiation therapy such as stroke. Currently I am the PI of a prospective cohort study that is actively enrolling at 4 different sites and we have enrolled up to 150 patients to date. These patients are followed with dedicated vascular imaging as well as neurocognitive outcomes. My abstract on risk of stroke recurrence in pediatric cancer survivors was selected as award winning presentation at the Annual Meeting of the Society of Neuro-Oncology.

**Scholar Name:** Sara Newmann

**Primary Mentor:** Craig Cohen

**Sponsor’s report on progress and performances during the past year (the sponsor report should not exceed 250 words):**
Dr. Sara Newmann took some family leave in the spring of 2013 due to several tragic family deaths, however she has been back at work since mid-June 2013 and has been impressively productive. Since March 2013, she has had nine papers published, four of which she was first author and one last author. She has submitted three additional manuscripts, which are currently under review and is close to submitting three more for publication. She also presented several presentations on her work on family planning and HIV at the International Conference on Family Planning in Ethiopia in November 2013 and several of her colleagues have recently presented Dr. Newmann’s research at national conferences. Dr. Newmann and her team were able to complete data collection and the majority of the analysis for a study for a formative qualitative study for which she is the PI about male involvement in family planning in Kenya. She is currently applying for a large grant from the Society for Family Planning to fund the design and piloting of a gender sensitive community-based intervention to increase male involvement in family planning in Kenya in order to increase contraceptive prevalence. Dr. Newmann also took a class in implementation science this past fall.

Project Title:
1. Identifying socio-cultural barriers to contraception among HIV-infected men and women in Western Kenya.
2. Integration of Family Planning into HIV Care and Treatment in Nyanza Province, Kenya
3. Decreasing unintended pregnancy and vertical transmission of HIV through family planning. Where do men fit in?
4. Empowering Women in Kenya through Male Involvement in Family Planning: Suggested Strategies and Potential Negative Consequences

Description of multidisciplinary integration:
An MD by training, my independently initiated research has veered into the social science realm. I am collaborating with a sociologist and public health expert with respect to her work related to the influence of gendered power on family planning use among HIV+ men and women in Kenya. I also collaborate with an epidemiologist and cost-efficacy specialist regarding integrated family planning and HIV care in Kenya.

Description of the research project (the project report should not exceed 250 words):
My current research focus is on ways in which to increase male acceptance of and comfort with family planning in Kenya. I became interested in this topic through my role as lead investigator of a cluster RCT integrating family planning into HIV care and since then has conducted two qualitative studies trying to understand how gendered power differences between men and women and traditional gender norms/notions of masculinity impacts contraceptive use in western Kenya among men and women who have a high unmet need for contraception and live in a high HIV prevalent area. The next step, for which I am currently applying for funding, is to design and pilot a community-based intervention geared towards increasing male involvement in family planning in a way that is not threatening to men or disempowering to women. This pilot study will lead to a cluster RCT to test the intervention with the primary outcome being contraceptive prevalence.
Scholar Name: Catherine Rongey MD MSHS

Mentors: Steve Asch, Mary Whooley

Sponsor’s report on progress and performances during the past year (the sponsor report should not exceed 250 words):
Dr. Rongey’s work incorporates health services, implementation science and health organizational theorems to elucidate how large integrated healthcare systems can improve access to specialty care. Since last update, her work on a large, geo-coded, cohort of 156,000 veterans with HCV examining the impact of rurality on access to specialty care was accepted to PLOSone. She has another manuscript under review examining the staff and administrative barriers and facilitators to telehealth programs. Dr. Rongey successfully applied for a large, multi-site, QUERI-Service Directed Proposal that will examine how health information technologies can improve the specialist-generalist interface to improve specialty care coordination among hard to reach populations. She has an abstract, capturing specialist-generalist interactions over the video-telemedicine interface, accepted in the upcoming Translational Science meeting.

Project Title:
Improving access to liver specialty care using HIT

Description of multidisciplinary integration: This research combines both a health services research and implementation science perspective to evaluate a HIT program, SCAN-ECHO, effect on access to care and guide its dissemination. The multi-year qualitative analysis, that includes video-recording specialist-generalist interactions as well as staff interviews, to better elucidate how this program can improve specialist-generalist communication and the barriers and facilitators to early sustainability. Consequently, Dr. Rongey’s research team is comprised of biostatisticians, implementation scientists, health service trained qualitative analysts and organizational theorists. In addition, the quantitative analysis capturing national changes in liver outcomes among scan-echo sites compared to control sites is ongoing. Her work has been presented in VHA program meetings.

Description of the research project (the project report should not exceed 250 words): My work seeks to resolve the following: With a limited number of specialists, how can a health system improve access to specialty care when the burden of disease is high and the patient population is difficult to reach? As the informatics revolution spreads through the health care system there will be increasing opportunities to more effectively spread knowledge once confined to specialist visits more widely and with less expense. A natural experiment occurring in the nation’s largest integrated health care system, the VHA, will allow researchers to study how best to guide that transformation. Project SCAN-ECHO is based on a structured remote telemedical specialist generalist interaction model that has been shown to improve hepatitis C (HCV) care outcomes in rural areas within the University of New Mexico (UNM) health care system. I plan to take advantage of that variation to ask two questions crucial to the scientific understanding of this innovation. 

Aim 1. To compare HCV and liver related quality of care among patients enrolled in SCAN-ECHO sites to those in structurally similar control sites.

Aim 2. To understand staff perceptions of the processes that facilitate collaboration between specialists and generalists and the implementation of HCV Project SCAN-ECHO.

Rationale. Early understanding of the organizational barriers to and facilitators of program implementation are critical to guide the ongoing national dissemination.
Scholar: Rada Savic

Mentors: Jeff Cox, Susan Dorman, Denise Kirschner, Tony Hunt, Andrej Sali

Mentor report on progress and performances during the past year (not to exceed 250 words):
During her first year as a K scholar, Rada has published 2 articles as a first author: one in Journal of Pediatric Infectious Diseases and one in Antimicrobial Agents and Chemotherapy. In the past year, Rada has applied for number of grants and she has been awarded 3 grants as a Principal Investigator: 1.4M grant (over 3 years) from the Gates Foundation to develop a mechanistic model of combinational therapy in tuberculosis, 72.5K (over 1 year) grant from the Tuberculosis Modeling and Analysis Consortium to develop a translational preclinical-clinical model for TB therapy and 130K grant (over 1 year) from the Gates Foundation to develop a clinical trial simulation tool to optimize the design of the planned randomized trial on the Effect of Progestin-Only Contraception versus the Copper Intrauterine Device on the Risk of HIV Acquisition in Young Women. As a Co-Investigator, Rada has applied for 4 R01 grants, 2 in collaboration with Rutgers University and 2 in collaboration with Johns Hopkins University. One R01 has already been awarded and 2 R01s have been scored and are likely to get funded. Rada has also presented her work at number of national and international conferences, she has been elected a chair of the infectious Disease section of the American Society for Clinical Pharmacology and Therapeutics and she was part of two NIH working groups: “Towards earlier involvement of Children (and pregnant women) in Trials of New TB drugs” and “Enrolling Pregnant Women in Clinical Trials of Antimicrobials and Vaccines”.

Project Title:
System Pharmacology Translational Framework for Tuberculosis

Description of multidisciplinary integration:
During my first year as a K scholar, I have become part of several diverse teams studying different aspects of TB treatment: in-vitro studies of drug resistance and combinational drug treatment, preclinical studies of pulmonary drug distribution and treatment efficacy in animal models and Phase 1-3 clinical trials of novel TB treatment combinations. My collaborators include scientist from JHU, Gates Foundation, Rutgers University, CDC, TB Alliance, ACTG and IMPAACT network, university of Cape Town, and Stellenbosch University.

Description of the research project (the project report should not exceed 250 words):
Under the direction of my mentors, my lab initially worked on the implementation of a number of system biology models for immune response to Mtb infection. These models provided a basis for deep understanding of the dynamics of immune and cytokine response, the conditions that lead to development of active or latent disease and the factors, which define virulence, and persistence of Mtb. A novel research activity included implementation of the multiple treatment drug response model after administration of standard of care treatment and extension with the emergence of resistance model with an ultimate goal to predict treatment outcome (relapse/cure). This initial host-bug-drug framework was implemented as a population-based simulation for 5,000 patients over 500 days, including within- and between-patient variability in pharmacokinetics. Additional host and Mtb parameters incorporated in the model were based on literature values from numerous earlier TB PK/PD studies. The proposed novel dynamic integrated drug, Mtb and host model provides a basis for further analysis of therapy alternatives. The established system can also support extended multi-drug therapy comparative studies of different bacterial resistance patterns.
**Scholar Name:** Caroline Stephens

**Mentors:** Sei Lee, Christine Ritchie, Janet Shim

**Mentor report on progress and performances during the past year (not to exceed 250 words):**
Dr. Stephens has demonstrated exceptional progress with her interdisciplinary program of research and KL2 program this past year. She was accepted into the Advanced Training in Clinical Research (ATCR) program last spring and is currently finishing the year-long ATCR program. She has published 3 articles (2 first author, 1 senior co-author), including an article in JAMA-IM, and currently has 2 articles under review (1 first author, 1 co-author), and 3 in progress (2 first author, 1 senior author). She has completed 2 invited-book chapters (1 in press, 1 under review) and is serving as co-PI on a national subproject for a HRSA grant. In addition, she has presented her work at 2 scientific conferences (2 primary, 1 co-author) and submitted 2 primary author and 4 co-authored abstracts to future scientific meetings. She is part of an interdisciplinary P30 grant that was submitted in Feb 2014; she has submitted an intramural grant to support the next phase of her KL2 project (role: PI), and will be a co-sponsor with Dr. Ken Covinsky (UCSF Geriatrics) on a NRSA F31 being submitted next week by one of her PhD mentees. As a new Associate Director for the UCSF Hartford Center of Gerontological Nursing Excellence, she has assumed greater leadership in fostering more interdisciplinary educational/research collaborations across UCSF’s health professions schools, particularly with the UCSF School of Medicine Division of Geriatrics. She is also involved in national leadership work with the Hartford Gerontological Nursing Leaders and National Geropsychiatric Nursing Collaborative.

**Project Title:**
TeleED: Reducing potentially preventable ED visits by nursing home residents

**Description of multidisciplinary integration:**
Dr. Stephens’ work has always been firmly grounded in multidisciplinary integration, however this has been strongly supported/boosted by her involvement with the UCSF KL2 Scholars program. Her diverse collaborations to date have included colleagues in sociology, geriatrics/palliative care, geriatric psychiatry, neurology, emergency medicine, mHealth and nursing. Many of these collaborations have included current and/or former UCSF K Scholars. She has also served on a multidisciplinary Master’s thesis committee for her UCSF/UCB Joint Medical Program medical student mentee and will be senior author on the publication resulting from that work (in progress).

**Description of the research project (the project report should not exceed 250 words):**
The goal of Dr. Stephens’ KL2 award is to develop, optimize and pilot test an innovative TeleED intervention that enables timely clinical assessment of acutely ill NH residents; rich communication and care coordination across care settings and providers; and more active engagement of patients and families at the critical juncture of a possible care transition. To date, Dr. Stephens has completed 5 focus groups related to key stakeholder perspectives on the use of technology to reduce emergency room transfers by nursing home residents. These focus groups have been conducted with 25 stakeholders, including nursing home nurses, physicians, nurse practitioners, resident families and administrators, with future groups scheduled with emergency room nurses/physicians. She also plans to conduct additional individual interviews with nursing home residents and their families. Preliminary findings suggest that a technology platform that allows for rich communication including video may help nurses, families and doctors reach a common understanding and plan for how best to care for a NH resident. Results from these focus groups will be presented at 2 scientific conferences this year and published as 1-2 articles in peer-reviewed journals. In addition, study findings are providing the foundation for future intramural grants (submitted) to pilot test the intervention and the future submission of an R01/PCORI grant.
Scholar Name: Lisa M. Thompson, RN, FNP, MS, PhD

Mentors: John Colin Partridge, Abbey Alkon, Kirsten Bibbins-Domingo, Kirk R. Smith (UC Berkeley)

Mentor report on progress and performances during the past year:
Research: Dr. Thompson completed her pilot research project, NACER, in December 2013 (detailed below). Dr. Thompson is currently analyzing data from her NACER pilot project and submitting publications. She was invited to present her study results at the International Society of Environmental Epidemiology in Switzerland (August 2013), at the Consortium of Universities of Global Health (May 2014) and the Global Alliance of Clean Cookstoves (May 2014) in Washington, DC. She received an intramural grant award through UCSF RAP program and is using the award to investigate behavioral change related to exposures to household air pollution from cookstoves in rural Guatemala. In December 2013 she was notified that she received a Grand Challenges Canada Global Stars in Public Health, Phase 1 grant in collaboration with Universidad del Valle de Guatemala to conduct a stove intervention project in Guatemala, which will begin in Summer 2014. She enrolled in the R01 grant writing class with Tom Mitchell and submitted an R21 in February 2014 related to her work in Guatemala. Teaching/Learning: She completed the course: Responsible Conduct of Research (RCR) Online Course (Epi 201) in Summer 2013. In Spring 2014, she will be a teaching assistant for Ralph Gonzales’ course: EPI 245 Translating Evidence Into Practice: Theory and Design. She is enrolled in Advanced Approaches to the Analysis of Observational Data (Biostat 215). Overall: In February 2014, she received notice of tenure and will be promoted to Associate Professor, effective August 2014.

Project Title:
NACER “Neurodevelopment and anthropometric growth of infants exposed to household air pollution in rural Guatemala”

Description of multidisciplinary integration:
I am working with Dr. Naila Khan, a pediatric neurologist from Dhaka, Bangladesh, and I have translated and adapted her Rapid Neurodevelopmental Assessment (RNDA) instrument for use with rural, indigenous Guatemalan infants. I work with environmental health researchers at UC Berkeley (Dr. Kirk Smith and his research group) and collected urine biomarkers of woodsmoke exposure which were analyzed by D. Joel Meyer’s lab at Duke University and Dr. Neal Benowitz’ lab at UCSF. Our team in Guatemala is multidisciplinary comprised of 2 epidemiologists, 1 environmental engineer, 1 traditional birth attendant and 2 health workers.

Description of the research project: I recently concluded an 18-month longitudinal pilot study (referred to as NACER, or to be borne) in rural Guatemala. We examined how maternal and infant exposures to household air pollution impact neonatal outcomes, including preterm birth and infant neurodevelopment. I am also co-investigator on two larger, similar studies in Guatemala. The first is a birth cohort of 200 women and their infants, looking at preterm birth and infant pneumonia. The second is a stove effectiveness study to test out 4 different types of wood and gas stoves. The best stove would be used in a future stove intervention trial. Both of these studies are in partnership with UC Berkeley, CDC, and a local Guatemalan University. I am PI for a Grand Challenges Canada, Stars in Public Health, Phase I grant, partnering with a Guatemalan university. This project will develop women entrepreneurs who will distribute gas stoves, liquid petroleum gas tanks, discuss gas safety and health messages around avoiding cook stove smoke.
Scholar Name: Jess Waldura, MD MAS

Mentors: Kevin Grumbach

Mentor report on progress and performances during the past year (not to exceed 250 words):
In the summer of 2013, Dr. Waldura completed her study of primary care clinicians’ experiences managing HIV, and the manuscript describing this research is currently in press. Dr. Waldura also began work on the next phase of her research, which expands her work on improving primary care practice into the realm of female sexual dysfunction in midlife women. She is nearing completion on a qualitative study of primary care clinicians and midlife women patients’ experiences with barriers and facilitators of communication about sexual problems, and she has begun work on the development of her proposed intervention – a mobile software application tool. She continues to gain experience with both qualitative and quantitative research methods. Her skills as a research team leader are continuing to grow, as she manages two paid research assistants and one to two research volunteers. Dr. Waldura has also continued to expand her network of research collaborations and is participating in two multicenter studies related to her main area of study.

Project Title:
Health Information for Positive Sexuality (HIPS): A mobile software application to improve patient-clinician communication about sexuality for midlife women in primary care.

Description of multidisciplinary integration:
My work involves close collaboration with physicians in the UCSF departments of family and community medicine and internal medicine, and with qualitative research analysts at the Center for AIDS Prevention Studies.

Description of the research project (the project report should not exceed 250 words):
Female sexual dysfunction (FSD) is an extremely prevalent and distressing condition, affecting more than 50% of peri- and post-menopausal women. Primary care clinicians are optimally placed to detect and manage FSD, however sexual health discussions occur infrequently in the clinical setting, and FSD remains undiagnosed and untreated in the vast majority. Although multiple barriers have been identified, including mutual embarrassment, lack of time, and insufficient training for clinicians, there has been little research on ways to break the silence.

Our objective is to create a patient-centered, tablet-based software application (app) designed to help destigmatize sexual health problems for midlife women, and empower both women and their clinicians to broach the topic more easily. We plan to: 1. create and refine the app with the help of a user-centered design team; and 2. conduct a pilot study to ensure seamless integration into the healthcare setting and to prepare for a larger randomized controlled trial to demonstrate clinical efficacy. The data from the pilot study will pave the way for a future randomized controlled trial powered to assess additional clinical outcomes and explore wider dissemination potential. We believe that an app of this type could help increase the rate of conversations about sexual health in the clinical setting, and enable millions of women to receive much-needed assessment and treatment for their concerns.
Scholar Name: Adina Zeki Al Hazzouri

Mentors: Mary Haan, Kristine Yaffe, Eliseo Pérez Stable

Mentor report on progress and performances during the past year (not to exceed 250 words):
Dr. Zeki Al Hazzouri has published 3 articles (2 of which are first-author) during the reporting period. She is co-author on 2 other manuscripts under review and she has at least 3 working papers in progress. Dr. Zeki Al Hazzouri has an AHA beginning grant-in-Aid award proposal currently under review, and learned recently that her K01 award would be funded this spring.

Project Title:
Effects of race and lifecourse cardiovascular risk on neuropsychiatric outcomes

Description of multidisciplinary integration:
I submitted a grant proposal for an AHA Beginning Grant-in-Aid award with Dr. Vittinghoff and Dr. Pletcher as collaborators. The theme of the grant is cardiovascular risk, stroke and cognition. Dr. Vittinghoff will contribute to the statistical aspect and Dr. Pletcher will contribute to the clinical aspect of this work.

I also collaborate with Dr. Deborah Barnes on her intervention study the “Mental Activity and eXercise (MAX)” trial. I will be sending pre- and post-intervention blood samples to a lab (quest diagnostics) for lipid assays. This will allow me to use the intervention design of the trial to examine whether there is any effect on lipids; and whether changes in lipid profile mediates any effect of the intervention on cognitive outcomes. This will be my first time to analyze or work with data from an intervention study.

Description of the research project (the project report should not exceed 250 words):
For my KL2 research project, I am working with four biracial prospective cohorts namely, the Coronary Artery Risk Development in Young Adults (CARDIA), Multi Ethnic Study of Atherosclerosis (MESA), Cardiovascular Health Study (CHS), and Health, Aging and Body Composition Study (Health ABC). The aim is to estimate person-specific trajectories of cardiovascular risk factor development over the adult life course, in blacks and whites, and then to examine their association with the development and progression of depressive symptoms and cognitive function. I will also apply advanced state-of-the-art statistical methods to estimate the effect of potential public health interventions that target cardiovascular risk factors over the adult life course on depressive symptoms and decline in cognitive function. Current stage: I am almost done with the data management aspect of the project which has to do with harmonizing the variables across the 4 cohorts. The next step will include a simulation study in order to validate pooling together the 4 cohorts.
# Technology Transfer Report

<table>
<thead>
<tr>
<th>Invention/Patent (i-EDISON)</th>
<th>Title</th>
<th>How CTSA contributed</th>
</tr>
</thead>
<tbody>
<tr>
<td>0577508-03-0036</td>
<td>Neurosteroids as therapeutics for brain disorders</td>
<td>Consultation with clinical and industry leaders to identify key applications of technology and highlight essential differentiating features of the proposed technology. Funded pre-clinical studies to garner proof of concept data that broadens the application of the technology.</td>
</tr>
<tr>
<td>0577508-12-0058</td>
<td>Pro-Resolving Vascular Devices</td>
<td>Consultation with clinical and industry leaders to identify key applications of technology and highlight essential differentiating features of the proposed technology. Funded pre-clinical studies to garner proof of concept data that broadens the application of the technology.</td>
</tr>
<tr>
<td>0577508-13-0052</td>
<td>Development of a Real-Time Intraoperative Fluorescent Imager for Microscopic Residual Tumor</td>
<td>Consultation with clinical and industry leaders to identify key applications of technology and highlight essential differentiating features of the proposed technology. Funded proof of concept prototype design and fabrication and pre-clinical testing that led to sufficient positive evidence for patent filing.</td>
</tr>
<tr>
<td>0577508-13-00220</td>
<td>Low Z Enteric CT Contrast Materials</td>
<td>Consultation with clinical and industry leaders to identify key applications of technology and highlight essential differentiating features of the proposed technology. Funded proof of concept formulation and pre-clinical testing that led to sufficient positive evidence for patent filing.</td>
</tr>
<tr>
<td>0577508-12-0100</td>
<td>Intravenous Chemotherapy Filter: A Novel Device for High Dose Chemotherapy Delivery During Transarterial Chemoembolization</td>
<td>Consultation with clinical and industry leaders to identify key applications of technology and highlight essential differentiating features of the proposed technology. Funded proof of concept prototype design and fabrication and pre-clinical testing that led to sufficient positive evidence for patent filing.</td>
</tr>
<tr>
<td>The Methods For Detecting, Genotyping, And Purifying Cancer Stem Cells And Circulating Tumor Cells In Blood (No CTSI funding)</td>
<td>Robust detection and genotyping of rare circulating tumor cells in human blood</td>
<td>Consultation with clinical and industry leaders to identify key applications of technology and highlight essential differentiating features of the proposed technology. No CTSI funding.</td>
</tr>
<tr>
<td>A Mobile Application And Web-Framework To Perform Cloud-Based Bayesian Treatment Optimization With Continual Model And Target Optimization (No CTSI funding)</td>
<td>Cloud-Based Dose-Individualization of Busulfan in Children</td>
<td>Consultation to determine clinical utility and develop a robust commercial value proposition. Developed a strategy to expand the application to broader use cases. No CTSI funding.</td>
</tr>
<tr>
<td>Heath Passport - Digital Patient Education Tool (No CTSI funding)</td>
<td>Health Passport: A Passport to Wellness (A Digital Patient/Physician Communications Tool)</td>
<td>Consultation to determine clinical utility and develop a robust commercial value proposition. Provided key insights into use cases, user interface challenges and value proposition to providers and other stakeholders. No CTSI funding.</td>
</tr>
<tr>
<td>IND #</td>
<td>Sponsor</td>
<td>Title</td>
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<tr>
<td>1050</td>
<td>Michael J. Fox Foundation for Parkinson’s Research</td>
<td>An Open-label Safety and Efficacy Study of AAV2-hAADC Administered by MRI-Guided Convective Infusion into the Putamen of Subjects with Parkinson’s Disease with Fluctuating Responses to Levodopa.</td>
</tr>
<tr>
<td>1140</td>
<td>Michael J. Fox Foundation for Parkinson’s Research</td>
<td>An Open-label Safety and Efficacy Study of AAV2-hAADC Administered by MRI-Guided Convective Infusion into the Putamen of Subjects with Parkinson’s Disease with Fluctuating Responses to Levodopa.</td>
</tr>
<tr>
<td>76301</td>
<td>Horizon Pharma Inc</td>
<td>A 6-month, Multicenter, Open-label, Safety Study of VIMOVO (250 mg/20 mg, 375 mg/20 mg, and 500 mg/20 mg Naproxen/Esomeprazole) in Adolescents Aged 12 to 16 Years, Inclusive, with Juvenile Idiopathic</td>
</tr>
<tr>
<td>110,080</td>
<td>Merck and Co, Inc</td>
<td>CC#12855: Randomized Phase II Study of MK-3475 versus Chemotherapy in Patients with Advanced Melanoma</td>
</tr>
<tr>
<td>14008</td>
<td>NovoNordisk</td>
<td>An Open-label, Multi-centre, Uncontrolled Trial to Assess Efficacy and Safety of NNC-0156-0000-0009 during Surgical Procedures in Patients with Haemophilia B</td>
</tr>
<tr>
<td>71832</td>
<td>Vertex Pharmaceuticals</td>
<td>A Two-Part, Open-Label, Single-Arm Phase 1/2 Study of Safety, Pharmacokinetics, And Efficacy of Telaprevir in Combination With Peginterferon alfa-2b and Ribavirin In Pediatric Subjects Aged 3 to 17 In</td>
</tr>
<tr>
<td>71,576</td>
<td>Gilead Sciences</td>
<td>A Randomized, Double-Blind Evaluation of the Antiviral Efficacy, Safety, and Tolerability of Tenofovir Disoproxil Fumarate Versus Placebo in Pediatric Patients with Chronic Hepatitis B Infection</td>
</tr>
<tr>
<td>15380</td>
<td>Agenus Inc</td>
<td>A phase II randomized trial comparing the efficacy of heat shock protein-peptide complex-96 (hsppc-96) (nsc #725085, alliance ind#</td>
</tr>
<tr>
<td>IND #</td>
<td>Sponsor</td>
<td>Title</td>
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<tr>
<td>15380</td>
<td>Monash University</td>
<td>15380) vaccine given with bevacizumab versus bevacizumab alone</td>
</tr>
<tr>
<td>Q130698</td>
<td>NIH National Heart, Lung &amp; Blood Institute</td>
<td>Short-term disulfiram administration to reverse latent HIV infection: a dose escalation study</td>
</tr>
<tr>
<td>107078</td>
<td>Novartis Oncology</td>
<td>Development and Validation of test for Gastro-esophageal Reflux and Aspiration</td>
</tr>
<tr>
<td>109262</td>
<td>Edimer Pharmaceuticals</td>
<td>A Phase 2 open-label, dose-escalation study to evaluate the safety, pharmacokinetics, immunogenicity and pharmacodynamics/efficacy of EDI200, an EDA-A1 replacement protein, administered to male infant</td>
</tr>
<tr>
<td>109661</td>
<td>Del Mar Pharmaceuticals, Inc</td>
<td>CC# 13105 Open-label, Single Arm, Safety and Tolerability Dose-escalation Study of DAG in Patients with Recurrent Malignant Glioma</td>
</tr>
<tr>
<td>116237</td>
<td>OncoMed Pharmaceuticals</td>
<td>CC# 13952: A Phase 1 Dose Escalation Study of OMP-52M51 in Subjects with Solid Tumors</td>
</tr>
<tr>
<td>73,382</td>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>In Vivo Drug Interaction Pharmacokinetic Study of Tenofovir 1% Gel and Three Commonly Used Vaginal Products</td>
</tr>
</tbody>
</table>

251
<table>
<thead>
<tr>
<th>IND #</th>
<th>Sponsor</th>
<th>Title</th>
<th>Description</th>
<th>CTSA contribution</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>107,220</td>
<td>Novartis Oncology</td>
<td>CC# 13082 (CLEEO11X2102): A phase I, multi-center, open-label study of LEE011 in patients with malignant rhabdoid tumors and neuroblastoma</td>
<td>To determine the MTD and/or RDE of LEE011 systemic exposure compared to TFV or vaginal product alone</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td>117,816</td>
<td>Piramal Enterprises Limited</td>
<td>CC# 13953: An Open Label, Multicenter, Phase I Extension Study of an Oral Cdk Inhibitor P1446A-05 Administered with an Oral BRAF Inhibitor Vemurafenib (Zelboraf®) in Patients with Advanced or Inoperab</td>
<td>To determine the safety, maximum tolerated dose (MTD), and dose limiting toxicity (DLT) of the co-administration of P1446A-05 with vemurafenib, in melanoma patients with BRAF mutation</td>
<td>Utilizes nursing, sample processing and bionutrition</td>
<td>Phase I</td>
</tr>
<tr>
<td>119,158</td>
<td>NIH National Heart, Lung &amp; Blood Institute</td>
<td>Cannabinoid-Based Therapy and Approaches to Quantify Pain in Sickle Cell Disease</td>
<td>To determine the effects of inhaling vaporized cannabis on chronic pain in patients with SC feasibility of completing enrollment within 13 months, obtaining 12 month follow-up in at least 90% of enrolled patients, and coordinating centralized interpretation of brain MRI/MRS</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td>102,138</td>
<td>The Thrasher Research Fund</td>
<td>Neonatal Erthropoietin And Therapeutic Hypothermia Outcomes Study</td>
<td>Efficacy measured by SVR12 of Lambda/RBV/TVR compared to alfa-2a/RBV in treatment naive subjects with GT-1 chronic HCV or who relapsed on prior alfa/RBV treatment regimen</td>
<td>Utilizes nursing</td>
<td>Phase I/II</td>
</tr>
<tr>
<td>100,420</td>
<td>Bristol-Myers Squibb Company</td>
<td>A Phase 3 Blinded Randomized Study of Peginterferon Lambda-1a and Ribavirin Compared to Peginterferon Alfa-2a and Ribavirin, Each Administered with Telaprevir in Subjects with Genotype-1 Chronic Hepatitis C</td>
<td>The primary objective of this study is to evaluate whether GS-6624 is effective at reversing cirrhosis in subjects with cirrhosis due to NASH.</td>
<td>Utilizes nursing</td>
<td>Phase III</td>
</tr>
<tr>
<td>112,215</td>
<td>Gilead Sciences, Inc</td>
<td>A Phase 2b, Dose-Ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Safety and Efficacy of GS-6624, a Monoclonal Antibody Against Lysyl Oxidase-Like 2 (LOXL2), in Subjects with Chronic Hepatitis B Infection</td>
<td>To determine the safety and tolerability of intravenous infusions of TPI 287 administered to patients with mild to moderate dementia of the Alzheimer’s type</td>
<td>Utilizes nursing</td>
<td>Phase II</td>
</tr>
<tr>
<td>118,790</td>
<td>Alzheimer’s Association, Inc</td>
<td>A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Sequential Cohort, Dose-Ranging Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of TPI-287 in P</td>
<td>To determine safety and tolerability through 6 weeks of life of raltegravir oral granules for suspension with standard PMTCT</td>
<td>Utilizes bionutrition, sample processing and nursing</td>
<td>Phase I</td>
</tr>
<tr>
<td>77,787</td>
<td>NIH National Institute of Child Health &amp; Human Development</td>
<td>P1110: A Phase I Trial To Evaluate The Safety And Pharmacokinetics Of Raltegravir in HIV-1-Exposed Neonates at High Risk of Acquiring</td>
<td>To evaluate safety and tolerability of raltegravir oral granules for suspension with standard PMTCT</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td>IND #</td>
<td>Sponsor</td>
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<tr>
<td>116495</td>
<td>Children’s Oncology Group</td>
<td>HIV-1 Infection. Version 1.0, dated December 10, 2012</td>
<td>ARV prophylaxis to HIV-1 exposed infants</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ADVL1217: A Phase 1 Study of MK-1775 (IND# 116495) Concurrent with</td>
<td>Estimate maximum tolerated dose or recommended phase 2 dose and of Wee1 inhibitor MK-1775 administered in children with newly diagnosed diffuse intrinsic pontine glioma (DIPG)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Local Radiation Therapy for the Treatment of Newly Diagnosed Children with Diffuse Intrinsic Pontine Gliomas</td>
<td></td>
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<tr>
<td>74,573</td>
<td>Genentech, Inc</td>
<td>A Randomized, Double-Blind, Placebo-Controlled, Phase II Study to Assess the Efficacy and Safety of Oral Vismodegib for the Treatment of Basal Cell Carcinoma Preceding Excision by Mohs Micrographic Surgery</td>
<td>To compare the efficacy of vismodegib versus placebo as adjunctive pre-surgical treatment before MMS, as assessed by the percent change in the post-treatment MMS excision</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase II</td>
</tr>
<tr>
<td>103821</td>
<td>Children’s Oncology Group</td>
<td>ADVL1213: A Phase 1 Study of the TEM-1 Antibody, MORAb-004 (IND# 103821), in Children with Recurrent or Refractory Solid Tumors</td>
<td>Estimate the maximum tolerated dose (MTD) and/or recommended Phase 2 dose of MORAb-004 as an intravenous infusion every week to children with refractory solid tumors</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td>100181</td>
<td>Janssen Biotech, Inc, a K &amp; J co</td>
<td>A Phase 1b Open-Label Study to Assess the Safety and Pharmacokinetics of Subcutaneously Administered Golimumab, a Human anti-TNFα Antibody, in Pediatric Subjects With Moderately to Severely Active Ulc</td>
<td>To evaluate the pharmacokinetics (PK) of golimumab in pediatric subjects aged 2 through 17 years with moderately to severely active UC</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td>100,070</td>
<td>Acorda Therapeutics</td>
<td>A Double-Blind, Placebo-Controlled, Single Ascending Intravenous Infusion Study of rHlgM22 in Patients with Multiple Sclerosis.</td>
<td>To evaluate the pharmacokinetics (PK) and the potential immunogenicity profile of single ascending doses of rHlgM22</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I</td>
</tr>
<tr>
<td>110402</td>
<td>Northwestern University</td>
<td>CC# 13754 Phase III Dose Escalation Trial to Assess Safety of Intrathecal Trastuzumab for the Treatment of Leptomeningeal Metastases in HER2 Positive Breast Cancer</td>
<td>Determine the safety and the maximum tolerated dose (MTD) of IT trastuzumab based on pre-defined dose levels</td>
<td>Utilizes nursing and sample processing</td>
<td>Phase I/II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>An Open-label Safety and Efficacy Study of AAV2-hAADC Administered by MRI-Guided Convective Infusion into the Putamen of Subjects with Parkinson’s Disease with Fluctuating Responses to Levodopa.</td>
<td>Assess the safety and tolerability of two dose levels of AAV2-hAADC delivered to the putamen via convection enhanced delivery in subjects with suboptimal L-DOPA response</td>
<td>Utilizes sample processing and nursing</td>
<td>Phase I</td>
</tr>
<tr>
<td>76,182</td>
<td>Nektar Therapeutics</td>
<td>CC# 13954: A Phase 1 Study to Evaluate the Effect of NKTR-102 for Injection (etirinotecan pegol) on the QT/QTc</td>
<td>To evaluate the effect of NKTR-102 on the QT/QTc interval in patients with advanced or</td>
<td>Utilizes sample processing and nursing</td>
<td>Phase I</td>
</tr>
<tr>
<td>IND #</td>
<td>Sponsor</td>
<td>Title</td>
<td>Description</td>
<td>CTSA contribution</td>
<td>Stage</td>
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<tr>
<td>13,712</td>
<td>Gynecologic Oncology Group</td>
<td>QT/QTc Interval in Patients with Advanced or Metastatic Solid Tumors</td>
<td>metastatic solid tumors</td>
<td>Utilizes bionutrition, sample processing and nursing</td>
<td>Phase II</td>
</tr>
<tr>
<td>13,712</td>
<td></td>
<td>GOG 0265: A Phase II Evaluation of ADXS11-001 (NSC 752718, BB-IND #13,712) in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix</td>
<td>Evaluate the tolerability, safety and nature and degree of toxicity of ADXS11-001 by the numbers of patients with dose limiting toxicities and adverse events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>115561</td>
<td>Gilead Sciences, Inc.</td>
<td>&quot;A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-N</td>
<td>Compare the efficacy of tenofovir alafenamide (TAF) 25 mg QD versus tenofovir disoproxil fumarate (TDF) 300 mg QD for treatment of HBeAg-negative, chronic hepatitis B</td>
<td>Utilizes Body composition/exercise physiology and nursing</td>
<td>Phase III</td>
</tr>
<tr>
<td>117,548</td>
<td>Astellas Pharma, Inc</td>
<td>CC# 13958: A Phase 1/2 Open-Label, Dose Escalation Study Investigating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ASP2215 in Patients with Relapsed or Refractory Acute Myeloid AML</td>
<td>Assess the safety and tolerability, including determination of the maximum tolerated dose (MTD) of oral ASP2215 in subjects with relapsed or treatment-refractory AML</td>
<td>Utilizes sample processing and nursing</td>
<td>Phase I/II</td>
</tr>
<tr>
<td>13178</td>
<td>Cellidx Therapeutics, Inc</td>
<td>CC#13109 A Phase II Study of Rindopepimut/GM-CSF in Patients with Relapsed EGFRvIII-Positive Glioblastoma</td>
<td>Evaluate the antitumor activity of rindopepimut in adult patients with relapsed glioblastoma at PFS 6 and ORR at study entry</td>
<td>Utilizes sample processing and nursing</td>
<td>Phase II</td>
</tr>
<tr>
<td>104,187</td>
<td>Novartis Oncology</td>
<td>A Phase 2, multicenter, open-label study of BGJ398 in patients with recurrent resectable or unresectable Glioblastoma</td>
<td>To assess the anti-tumor activity of BGJ398 for patients with GBM with a translocation or amplification in FGFR1,2,3 or 4, based on PFS6</td>
<td>Utilizes sample processing and nursing</td>
<td>Phase II</td>
</tr>
<tr>
<td>15926</td>
<td>Ma Somsouk</td>
<td>Reconstitution of the gut microbiome to reduce systemic inflammation during treated HIV infection</td>
<td>Fecal transplant for HIV</td>
<td>IND guidance, preparation and review</td>
<td>n/a</td>
</tr>
<tr>
<td>76301</td>
<td>Emily von Scheven</td>
<td>A 6-month, Multicenter, Open-label, Safety Study of VIMOVO (250 mg/20 mg, 375 mg/20 mg, and 500 mg/20 mg Naproxen/esomeprazole) in Adolescents aged 12 to 16 Years, Inclusive, with Juvenile Idiopathic Arthritis (JIA)</td>
<td>This is a Phase IV, US-only, multicenter, open-label, single arm, non-comparator study design to evaluate the safety of VIMOVO (250 mg/20 mg, 375 mg/20 mg, and 500 mg/20 mg naproxen/esomeprazole) in the treatment of JIA in adolescent patients for up to 6 months.</td>
<td>IND guidance, preparation and review</td>
<td>Phase 4</td>
</tr>
<tr>
<td>117959</td>
<td>Nicholas Butowski</td>
<td>Phase I Study of Convection-Enhanced Delivery of Liposomal-Irinotecan Using Real-Time Imaging</td>
<td>This is a single center, prospective, dose escalating, single-arm, open label, phase I</td>
<td>IND guidance, preparation and review</td>
<td>Phase 1</td>
</tr>
<tr>
<td>IND #</td>
<td>Sponsor</td>
<td>Title</td>
<td>Description</td>
<td>CTSA contribution</td>
<td>Stage</td>
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<tr>
<td>120032</td>
<td>Ari Green</td>
<td>With Gadolinium In Patients With Recurrent High Grade Glioma</td>
<td>clinical trial of Convection-Enhanced Delivery (CED) Of Liposomal-Inotocan using real-time imaging with gadolinium in patients with recurrent high grade glioma (HGG):</td>
<td>IND submission</td>
<td>Phase 2</td>
</tr>
<tr>
<td>119930</td>
<td>Uma Mahdevan</td>
<td>A Randomized, Double-Blind, Placebo Controlled Trial to Assess the Efficacy, Safety, and Tolerability of Clemastine as a Remyelinating Agent in Multiple Sclerosis</td>
<td>This is a 5 month randomized single center double blinded crossover study in 50 patients with relapsing remitting multiple sclerosis and identified injury to the anterior visual pathway.</td>
<td>IND guidance</td>
<td>n/a</td>
</tr>
<tr>
<td>120607</td>
<td>Amy Gelfand</td>
<td>PuMPKIN Trial: Pediatric Migraine Prevention in Kids using Injections of the (Occipital) Nerve</td>
<td>A randomized placebo-controlled trial of a greater occipital nerve injection (lidocaine and methylprednisolone mixture) for the treatment of pediatric chronic migraine: (Pediatric Migraine Prevention in Kids using Injections of the (occipital) Nerve)</td>
<td>IND guidance, preparation and review</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Q130698</td>
<td>Homer Boushey</td>
<td>Development and Validation of test for Gastro-esophageal Reflux and Aspiration Development and Validation of test for Gastro-esophageal Reflux and Aspiration</td>
<td>The overall purpose of this project is to develop and validate a simple, non-invasive method to detect aspiration of gastrointestinal fluid into the respiratory tract</td>
<td>IDE guidance, preparation and review</td>
<td>n/a</td>
</tr>
<tr>
<td>118275</td>
<td>Steven Deeks</td>
<td>Short-term disulfiram administration to reverse latent HIV infection: a dose escalation study</td>
<td>This is a limited center phase I/II clinical trial aimed at investigating the safety, PK/PD, and biologic activity of short-term disulfiram dosing in long-term antiretroviral-treated HIV infected adults.</td>
<td>IND guidance, preparation and review</td>
<td>Phase 1-2</td>
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<tr>
<td>111906</td>
<td>Wendy Mendes</td>
<td>Effects of oxytocin on trust and social cognition in intergroup interactions</td>
<td>To examine the effects of oxytocin (OT) administration within an established intergroup paradigm, where participants receive positive or negative feedback from a member of their own racial ingroup or a member of another racial group and then interact with that partner across a number of cooperative tasks.</td>
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<td>Jennifer Clarke</td>
<td>PI3K/mTOR Pathway Activation Selected Phase II Study of Everolimus (RAD001) With and Without Temozolomide in the</td>
<td>Everolimus will be given at 10 mg daily continuously, and TMZ will be dosed initially at 150 mg/m²/day for 5 days out of a 28-</td>
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<td>Treatment of Adult Patients with Supratentorial Low-Grade Glioma</td>
<td>day cycle. If 1p/19q co-deletion is present, patients will be treated in Arm 3 with single-agent everolimus at 10 mg daily continuously.</td>
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<td>Jeffrey Fineman/Monique Radman NCT:01825369</td>
<td>L-carnitine treatment in congenital heart disease with increased pulmonary blood flow: Impact on clinical outcomes</td>
<td>To determine peri-operative changes in carnitine homeostasis, mitochondrial function, reactive oxygen species (ROS) production, and nitric oxide (NO) bioavailability in infants with increased (ventricular septal defect/atrioventricular septal defect, VSD/AVSD) and normal or decreased (Tetralogy of Fallot, TOF) pulmonary blood flow (PBF).</td>
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A New CTSA Partnership to Translate an Oral Cancer Biomarker from Lab to Clinic
Administrative Supplement Progress Report

Award Number: 3UL1TR000004-07S1

A. Overview of the Progress on Each Specific Aim

A biomarker based on tumor genome copy number aberrations has been identified that distinguishes a subtype of oral cancer associated with extremely low to no risk of metastasis. The goal of this project is to begin to prepare for a future clinical validation study by demonstrating the capability to assess the marker status from the easily obtained cells captured by a simple swab/brush biopsy of the tumor (Aims 1 and 2) and by establishing a prototype clinical database (Aim 3) to be used in the future prospective, multi-institutional study. To accomplish our goal, a multidisciplinary collaboration was established that brings together clinical and basic researchers, thereby providing access to critical patient populations, state-of-the-art molecular technology and the diverse and complementary CTSA resources of the participating institutions.

1. **Aim 1.** Develop methods of procedure for sample collection by brush biopsy suitable for pre-surgical assessment of 3q8pq20 status.

In this aim, we proposed to evaluate and optimize collection of patient samples for assessment of copy number of chromosomes 3q, 8p, 8q and 20 by array CGH. Prior to initiation of funding for the project, however, it became clear that low pass single end whole genome sequencing (~0.16x genome coverage) provided a cost effective and very reliable method for determining tumor genome copy number profiles. Therefore, we adopted this technology for assessing copy number at 3q, 8p, 8q and chromosome 20.

Methods for collection and transport of patient specimens (lesional swab biopsies collected with the Isohelix SK-2 swab system or brushings collected with the Rovers® Orcellex® Brush) were evaluated and optimized. A Methods of Procedure document was prepared and Dr. Schmidt instructed clinical colleagues at NYU in the procedure. He also traveled to Portland OR to instruct Dr. Bell and his clinical colleagues in the Isohelix swab biopsy procedure.

2. **Aim 2.** Develop standard operating protocols for measurement of 3q8pq20 status by array CGH.

In this aim, we evaluated DNA isolation methods for measurement of copy number of chromosomes 3q, 8p, 8q and 20. We determined that the Isohelix DSK DNA stabilization solution was suitable for lysis of cells and stabilization of the DNA. The DNAEasy Blood and Tissue kit (Qiagen) was adopted as the preferred method for extraction of DNA. A Methods of Procedure document was prepared.

The switch from array CGH to single end low pass sequencing for copy number measurements, required development of a sequence alignment and copy number calling pipeline. This work has been carried out in collaboration with colleagues, Bauke Ylstra, Ilari Sheinin and Daoud Sie at the VU University Medical Center (Amsterdam).

To evaluate the prototype assay (swab biopsy + copy number measurement by single end low pass sequencing), we investigated (a) the reproducibility of the copy number profiles obtained from two independent swabs and (b) how well the copy number profiles determined from DNA extracted from the swab biopsy compared to copy number profiles obtained using DNA extracted from sections of the surgical pathology tumor block. Swabs were obtained from 29 cancers from 28 patients. Approximately half had copy number profiles with clear copy number alterations (gains, losses and amplifications characteristic of oral cancers), which from experience is an indication that at least ~70% of the sampled cells were tumor cells. Duplicate swabs for three of these cases showed excellent agreement with the first swab (data not shown). In some cases, the copy number profiles showed evidence of copy number alterations, although with greatly attenuated amplitude, suggesting contamination of the sample by normal cells. Nevertheless, comparison of the swab profiles to the archival FFPE surgical specimens.
obtained for 11 cases revealed that copy number alterations were appropriately called in spite of the reduced amplitude (Figure 1).

The swab biopsies also include DNA from the oral microbiome. We have begun to investigate changes in the oral microbiome associated with cancer by comparing the composition of the bacterial communities associated with the cancer to a similar swab biopsy from a clinically normal anatomically matched site from the patient. Microbial taxa are identified by sequencing bacterial 16S rDNA variable region amplicons and/or by paired end sequencing to identify bacterial genes/genomes. In a discovery screen, we found reduced abundance of the phyla *Actinobacteria* and *Firmicutes* in oral cancers. These observations were subsequently confirmed in an independent patient cohort. Consideration of the data from all samples, suggested a reduction in *Streptococcus* and *Actinomyces* genera is a common feature of oral cavity cancers, while an increased abundance of *Fusobacterium nucleatum* may identify a subset of patients.

3. **Aim 3.** Develop a prototype database for storage and exchange of clinical and molecular data for patients enrolled in this preliminary study that will be used to manage the subsequent prospective multicenter validation study of the 3q8pq20 biomarker.

A test database was set-up and, in consultation with users at NYU and UCSF, forms with all the fields related to the process of sample collection (NYU) and downstream work (e.g., DNA extraction, UCSF) were created. Continued work on the database was planned after completion of this project as part of the clinical trial planning process, and in September 2013, Drs. Albertson and Schmidt were awarded a planning grant for the future clinical trial of the 3q8pq20 biomarker (R34 DE023264). Nevertheless, we have not continued work on this database. Mr. Wynden, who was leading the database work, left the University of California and Dr. Albertson moved to New York University College of Dentistry in June 2013. Therefore, locating all data management at NYU was more appropriate.

A. **Accomplishments**

1. **Aim 1.**
   - Tasks a and b (Months 1 – 6). Completed.
     - Development of methods for collection of tumor cells yielding sufficient DNA for copy number analysis by single end low pass sequencing (~300 ng per assay) using either the Isohelix swab or the Rovers brush.
     - Identification of a suitable container for storage and shipping of the Rovers brush. The Isohelix system includes an integral microfuge tube that is leak proof during routine shipping at room temperature. It was necessary, however, to find and evaluate a number of vials for transport of the Rovers brush. A 0.4 ml CryoSure® brand freestanding cryogenic vial with a rim seal cap (Evergreen Scientific) proved to be of sufficient diameter for the Rovers brush and was demonstrated to be leak proof under simulated shipping conditions.
     - A Methods of Procedure document describing the sample collection, storage and shipping procedure was prepared.
   - Task c. (Months 7 -12). Completed.
• Dr. Schmidt instructed colleagues at NYU in the practice of the swab biopsy technique and traveled to Portland OR to teach Dr. Bell and his clinical colleagues the collection procedure.
• Seven swabs from cancer patients were received from Dr. Bell and profiled for copy number aberrations.

2. **Aim 2.**
Tasks a – e. (Months 1-6) and Task f (Months 1-12). Completed.
• A Methods of Procedure document was prepared for DNA isolation.
• Copy number analysis completed for 29 swabs obtained from 28 patients.
• Reproducibility of the swab sampling was confirmed for five cases by comparison of the copy number profiles from two independent swabs.
• Validation of the swab biopsy for copy number analysis was demonstrated for 11 cases by comparison of the copy number profiles from the swab and the tumor block.

3. **Aim 3. Database**
• Creation of user accounts for groups in UCSF and NYU.
• A test project Database “Clinical samples tracker” was created.
• Forms were created with all the fields related to the data for the samples starting from swab collection to downstream studies of the DNA extracted, including the fields for required clinical information.
• UCSF users tested the system and confirmed it to be working properly.

**B. Challenges**
*Hurricane Sandy (October 2012).* As a result of the storm, all out-patient and in-patient facilities were closed at NYUMC until the beginning of 2013. While enrollment of subjects was only modestly delayed, acquisition of pathology blocks for validation of the copy number assays was interrupted by the storm. The closure of the hospitals also disrupted research access to electronic medical records, which delayed progress on the development of the database with NYU.

*Change in clinical sites.* Prior to initiation of the project in August 2012, much of Dr. Bell’s clinical practice moved to Providence Hospital and Cancer Center in Portland OR, which necessitated a change in performance site to Providence Hospital from OHSU for Dr. Bell’s work. There was some delay in obtaining the IRB approvals and setting up the subcontracts at both Providence Hospital and OHSU.

**C. Status of All Milestones on Timeline**
Aims 1 and 2 were completed. Aim 3 was initiated and work is continuing at New York University with support from non-CTSI funding.

**D. Publications Resulted from Administrative Supplement**
• A manuscript describing the analysis pipeline for copy number profiling by low pass sequencing has been submitted.
• A manuscript describing our initial studies of the oral cancer associated microbiome has been submitted.
• We are preparing a manuscript describing the brush biopsy procedure and evaluation of its utility for copy number measurements.
A. Overview of the Progress on Each Specific Aim

The overarching goal of this program is to develop and implement exemplary procedures for biorepository collection and operations at University of California (UC). It is our intent to establish an ethical, efficient, and sustainable system for obtaining, processing, and sharing specimens and data that will advance best practices of human subjects protection and provide a platform for future changes to the Common Rule.

1. **Aim 1**: Engage UC stakeholders (Institutional Officials, investigators, biobankers and patient communities) to identify, develop, and refine community-informed, harmonized strategies for (a) obtaining outpatient informed consent (OIC) and (b) biobanking operations and governance (BOG).

   a. Engage Institutional Officials and research leaders at each campus to review OIC policies and procedures, perceived internal barriers/opportunities to standardized OIC, and best practice recommendations and, based on this review, recommend standard practices and policies for UC.

      To this end, we conducted key informant interviews of institutional stakeholders (including Institutional Officials, IRB Directors, Vice Chancellors of Research, CTSA Directors, CORE Directors, and Legal Counsel) at each of the 5 UC campuses and the UC Office of the President. More than a dozen interviews took place in Summer 2013. Interview questions included: What is the current biobank situation at your campus? What barriers/obstacles do you anticipate for biobank research? Do you have an ideal vision or goal for biobanking at UC? Analysis of these interviews fed into the design of our trial of consent methods (Aim 2).

   b. Employ biorepository leaders at each campus to review current policies and recommended best practices by professional organizations for BOG including consent practices for project-specific and remnant samples, tracking of consent preferences and sample distribution policies and, based on this review, recommend standard practices and policies for UC.

      EngageUC has continued its partnership with the University of California Biomedical Research Acceleration, Integration & Development (UC BRAID) Biobank Working Group in order to aid in the creation of best practices and governance for biospecimens for the 5 UC medical campuses. Over the past year, a group of pathologists and biobank staff from each campus met weekly to discuss these issues. This group has agreed on Standard Operating Procedures for biobanks in the UC system as well as developing a potential governance structure.

   c. Through Deliberative Democracy, educate diverse, multilingual representative communities about biosample research, OIC, and BOG and seek their input on issues relevant to biorepository research.

      Two deliberative community engagement (DCE) events were held in 2013, one in Los Angeles (in June) and one in San Francisco (in September/October). Both events included 26 diverse community participants. The events were held for full days over 2 non-contiguous weekends. The Los Angeles event was bilingual in English and Spanish.

      A professional moderator skilled in Deliberative Community Engagement and knowledgeable about biobank governance and informed consent oversaw both events. On the first day of both events expert speakers provided knowledge and represented various stakeholder views. Deliberants were divided into three small groups to facilitate engagement. By the end of Day 4, final recommendations on the topics of biobank models, informed consent, data sharing, community involvement, and governance were produced and endorsed by the full DCE group.
d. Employ all three groups (institutional stakeholders, biobankers, and community members) to develop a proposed Community Informed Systemwide Consent (CISC) to be tested in Aim 2 and to convene a Community Advisory Board to institutionalize community engagement.

Data gathered from engagement of all three of these stakeholder groups provided us with information to design a study consent form (CISC) to be used in the trial in Aim 2.

2. **Aim 2:** Compare the performance, in practice, of three alternative procedures for obtaining informed consent for outpatient biorepository studies at five participating UC campus: standard consent versus Portable Legal Consent (PLC) versus Community Informed Systemwide Consent (CISC).

Based on information gathered from our three stakeholder groups in aim 1, we have finalized the design for the trial comparing different approaches to biobank consent. Aim 2 will consist of a pragmatic trial comparing current standard forms v. the Community Informed Systemwide Consent (CISC) developed during aim 1 v. CISC + an educational video about biobanking. This design reflects the input of key aim 1 stakeholders. The alternatives we will test in the trial thus reflects output from study aim 1 and will provide valuable input for policy translation activities in aim 3.

The finalized trial design is more statistically efficient than the design proposed in the grant proposal. We anticipate that recruitment on 2-5 UC campuses will provide a sample size with adequate power to address all aim 2 outcomes. This improvement in feasibility is welcomed as it will help address challenges related to identifying appropriate trial sites at all 5 campuses (see Challenges, below).

We have finalized our trial outcome measures, met with potential biobank sites, hired a research associate and are in the process of finalizing site selection. We anticipate beginning data collection Spring 2014, following IRB review of our protocol.

3. **Aim 3:** Based on results from Aims 1-2, develop and implement policies and procedures that will create an exemplary system for obtaining and sharing biospecimens and associated data throughout the University of California in a manner that respects our diverse patient base and uses patient-centered informed consent practices.

Although it was originally planned that translation efforts would begin in month 28 of the project, members of the EngageUC team are already involved in such efforts. In the fall of 2013, Dr. Dohan was funded the UCSF Provost’s office for the creation of a workgroup to look at regulatory and policy issues around the implementation of the UCSF Precision Medicine Initiative.

Additionally, the EngageUC team was funded by the UC Office of the President to hold an all-day workshop that aims to bring together the diverse stakeholders targeted in this project to discuss potential governance structures for biobanks at UC. This meeting will be held in the fall of 2014 and will enable a unique opportunity for institutional officials, biobankers, and select community members to come together to exchange ideas.

**B. Accomplishments**

During the past year, the EngageUC team successfully completed of all of the Aim 1 activities, with the exception of creating a community advisory board, which it was determined should wait until after the Fall 2014 Stakeholder Workshop on biobank governance.

- **Aim 1a:** Interviewed key institutional stakeholders at each of the 5 UC campuses and the University of California Office of the President.
- **Aim 1b:** Biorepository leaders have met regularly to review current biobank policies at the 5 campuses and have developed operations Standard Operating Procedures and a potential governance structure for a 5-campus biobank network.
• Aim 1c: We successfully held 2 Deliberative Community Engagement events in Los Angeles and San Francisco to seek community input on biobank research. The Los Angeles event was bilingual (in English and Spanish), the first event of this kind to be held with simultaneous interpretation.

• Aim 2d: Analysis of data collected in Aim1a, Aim1b, and Aim1c has fed into the creation of a consent form that will be tested in Aim 2, as well as into the overall design of the trial.

Accomplishments related to Aim 2 include: finalizing the Aim 2 trial design, scheduling meetings to begin discussions with the relevant IRBs and potential outpatient clinic sites, and the hiring of a study research assistant.

Dissemination efforts have occurred throughout the project period, including presentations at: 1.) the University of California Davis’ Biorepository Seminar, 2.) the CTSA Biobankers’ Group, 2.) the CTSA Community Engagement annual meeting, 3.) the Clinical Genome Conference, 4.) the annual retreat of the University of California Biomedical Research Acceleration, Integration & Development program (UC BRAID), and 5.) the UCSF mini-medical school course on Precision Medicine. Members of the EngageUC team also participated in educational meetings on proposals to regulate genetic research in California and created a white paper about the project for the University of California Office of the President.

Members of the EngageUC team have leveraged additional funding for related projects:
1. Dr. Dohan received funding from the UCSF Provost’s Office to create and chair a Workgroup investigating regulatory and policy issues related to Precision Medicine.
2. The EngageUC project received funding from the UC Office of the President to hold an all-day Stakeholder Workshop looking at the governance of biorepository research at the University of California.
3. Dr. Koenig received funding to create the UCSF Center for Transdisciplinary ELSI Research in Translational Genomics to develop a novel resource for ethical, legal, social, and policy analysis of emerging issues in translational genomics.

C. Challenges
Our primary challenge pertained to the timing of our Community Engagement events. Our original intent was to hold the San Francisco event in May 2013. Unfortunately, the party we had contracted to do recruitment for the event was unable to recruit enough participants, and we opted to postpone the SF event to September 2013, allowing additional time for recruitment. Because the design and content of the trial (Aim 2) is dependent on results from the community events, this delayed the start of the trial.

A challenge we are currently experiencing relates to identifying appropriate sites for the Aim 2 trial. Our final trial design includes a pragmatic trial approach. This design provides more power than the randomized trial originally proposed but requires larger trial sites. We have identified several potential sites to date and are in the process of finalizing arrangements to field the trial in association with those biobanking studies.

D. Status of All Milestones on Timeline
1. Conduct meetings with Institutional Officials and research leaders at all 5 campuses. Complete.
2. Biobankers recommendations for standard policies and procedures. Complete.
3. Deliberative Democracy community meetings held in LA and SF. Complete.
4. Determination of consent processes to be tested in Aim 2. Complete.
5. Selection of campus clinics for inclusion in trial. In progress.

E. Publications Resulting from Administrative Supplement
We anticipate submitting three articles for publication in 2014: 1.) a concept paper regarding engagement of stakeholders, 2.) an analysis of the results of our community engagement events; and 3.) a paper documenting the process of the biobanking group and the resulting standard operating procedures.
## Detailed Budget for Next Budget Period

**EngageUC**

**Principal Investigator/Program Director (Last, first, middle):** Grady, Deborah G.

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**SUBTOTALS**

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## Consultant Costs

**Equipment (Itemize)**

**Supplies (Itemize by category)**

## Travel

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## Inpatient Care Costs

## Outpatient Care Costs

## Alterations and Renovations (Itemize by category)

## Other Expenses (Itemize by category)

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**Subtotal Direct Costs for Next Budget Period**

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**Total Direct Costs for Next Budget Period**

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BUDGET JUSTIFICATION: Year 9

PERSONNEL EXPENSES

Per UCSF policy, salaries are based on current rates, escalated by published increase schedules depending on title code and the incumbent’s placement on the salary rate scale. Fringe benefits are estimated based on standard rates of 33% for faculty, 41% for staff in year one, with annual escalations in accordance with UCSF’s published guidelines. Per NIH policy released in 2014, salary escalations are not included in this budget.

*Denotes individuals with actual salary exceeding or expecting to exceed the current NIH salary cap at time of project start date; $181,500 is used as institutional base salary.

Deborah Grady, MD, MPH, Principal Investigator (0.12 calendar months in year 9): Dr. Grady will provide overall leadership to the project by interfacing with the CTSA PIs at all 5 University of California campuses that are engaged in this project. Dr. Grady is the PI of the UCSF CTSA awards.

Daniel Dohan, PhD, Co-Program Director (2.4 calendar months in year 9): Dr. Dohan is Associate Professor in Residence at the Institute for Health Policy Studies (IHPS) at UCSF with a faculty appointment in the UCSF Department of Anthropology, History and Social Medicine. He is Associate Director for Training and Development at IHPS and a Member of the UCSF Helen Diller Family Comprehensive Cancer Center and its Program on Developmental Therapeutics. He is member of the Steering Committee of the UCSF CTSI’s Patient Recruitment Core. Dr. Dohan’s PhD is in sociology. His post-doctoral training in health policy was supported by the Robert Wood Johnson Foundation Scholars in Health Policy Research Program and an NIH/NIAAA fellowship. His research uses mixed-methods research to examine recruitment and participation in clinical trials, including among diverse and vulnerable patients. As co-Project Director, Dr. Dohan will share overall responsibility for the scientific and administrative conduct of this project with Drs. Boyd and Dry (at UCLA). He will have primary responsibility for designing, executing, and analyzing the randomized trial for Aim 2, during which time he will co-chair the project.

Elizabeth Boyd, PhD*, Co-Program Director (1.2 calendar months in year 9): Dr. Boyd serves as the institutional officer at UCSF for research ethics and compliance, and has direct oversight over the CHR offices at UCSF. As co-Project Director, Dr. Boyd will share overall responsibility for the scientific and administrative conduct of this project with Drs. Dohan and Dry (at UCLA).

Barbara Koenig, PhD, Program Lead (0.6 calendar months in year 9): Barbara A. Koenig, Ph.D. has extensive experience conducting empirically-focused bioethics research projects. In collaboration with Dr. Arleen Brown of UCLA, she will lead the proposed deliberative community engagement events proposed under AIM 1. She will also participate in other project aims as a co-investigator. She has led two previous deliberative community engagements. In September of 2007 she led a two weekend (four full day) deliberative community engagement focused on designing the Mayo Clinic DNA biorepository linked to electronic health records. Funded by NIH/NHGRI, this project included comparison with similar engagements held in Vancouver, British Columbia and in Western Australia. The results of the deliberation informed the design of the Mayo Clinic Biobank, including procedures used for informed consent of biobank participants and creation of a Community Advisory Board that provides ongoing governance of biobank activities. In 2011, she led an effort to engage the Southeastern Minnesota community about the Rochester Epidemiology Project (REP), a unique research resource for population-based health research that has been funded by NIH for over four decades. She oversees the REP’s efforts in community engagement and consultation, including the creation of an ongoing community oversight mechanism. As an anthropologist, Koenig has particular interest in the perspectives of diverse participants (and enhancing our understanding of their unique needs in public deliberation).
James Wiley, PhD*, Co-Investigator (0.48 in year 9) Dr. Wiley is Professor of Health Policy and Family Medicine with a faculty appointment at the UCSF Institute for Health Policy Studies (IHPS), where he provides statistical expertise for a variety of investigators and projects. In this project, Dr. Wiley will draw on his extensive experience as an internationally recognized research methodologist and continue to develop his research interest in interconnections between social science and public health and ways to improve the translational of research into policy and practice. Dr. Wiley has worked closely with Dr. Dohan on mixed-methods studies of vulnerable populations including welfare recipients and individuals with substance abuse problems. For the last 2 years, he has been a member of the core research team of Dr. Dohan’s NCI R01 study examining patient decision-making and participation in early phase clinical trials. For this study, Dr. Wiley will provide research design and statistical expertise related to the study’s Aim 2 (randomized control trial of consent methods). Dr. Wiley will also be involved in the development of research manuscripts.

Jen Hult, Senior Program Manager (9.6 calendar months in year 9). The Senior Program Manager will manage and coordinate all aspects of the project in all 3 years across all 5 participating campuses. The Senior Program Manager will work closely with the co-PDs at UCSF and UCLA and participate in weekly co-chairs meetings. The Senior Program Manager will coordinate stakeholder engagement activities, manage hiring and supervision of program staff, and coordinate staff training for the randomized trial.

Joseph Guiseppe Cavaleri, Staff Research Assistant (9.6 calendar months in year 9): The Staff Research Assistant (SRA) will work under the supervision of the Senior Program Manager to assist with all aspects of the program at UCSF. During year 9, the SRA will devote half his effort to support the community engagement component to provide assistance with coordination of planned events, recruitment, preparation of background materials for participants, IRB submissions, and analysis of data. The SRA will devote 25% time supporting other stakeholder engagement activities related to Aim 1, and 25% time supporting the co-PDs and Senior Program Manager.

Julie Auger*, Expert Advisor (0.24 in year 9): Julie Auger is the Executive Director of Research Resource Program (RRP) at University of California San Francisco (UCSF). The RRP was developed with the strong support of an advisory committee consisting of campus leaders from several organized research units. Senior campus leaders and directors of on-campus research organizations have recognized that greater access, cost savings, efficiencies and collaborations may be realized through centralized strategic planning and management. These collaborations, which are valued highly among many UCSF researchers, are a key to translating basic research discoveries into broader application.

Sarah Garrett, Graduate Research Student (3.6 calendar months in year 9). The Graduate Research Student (GRA) will work under the supervision of the Senior Program Manager to assist with organization of the community engagement event including assisting with participant recruitment, preparation of materials, creation of the event website, note taking at the event, and analysis of the event data.

NON-PERSONNEL EXPENSES

Travel
We include funds to support travel by project investigators to the other UC campuses to conduct site visits. We are requesting funds for the Steering Committee in year 9, of ($3,700).

Other Expenses
Computing costs include the UCSF-wide capita recharge of $41/month/FTE for data recharge, for a total cost of $1,141 for year 9 and $75/Month/FTE for Computing Device Support for a total cost of $2,088. Funds are included in appropriate project years to compensate research participants in years 9 at $2,273 in year 9 for participation in focus groups and follow up surveys.
Consortium/Contractual Expenses
UCSF is including subcontracts to the 4 other University of California campuses that hold CTSA awards in an effort to optimize the efficacy and reach of this study, as well as take advantage of existing efficiencies already established by the UC BRAID consortium of UC campuses that hold CTSA awards. All campuses will act in advisory capacity in year 7. In year 8, all campuses will participate in a randomized controlled trial. We are requesting $184,154 in direct contractual expenses and $99,738 in indirect contractual expenses for year 9. Because the subcontracts are to other UC campuses, these expenses are exempt from indirects in the prime budget.

Indirect Costs
The indirect cost rate is charged per UCSF’s negotiated rate agreement.
### PERSONNEL (Applicant organization only)

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE ON PROJECT</th>
<th>Cal. Mnths</th>
<th>Acad. Mnths</th>
<th>Sum. Mnths</th>
<th>INST. BASE SALARY</th>
<th>SALARY REQUESTED</th>
<th>FRINGE BENEFITS</th>
<th>TOTALS</th>
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<td>Sarah Dry</td>
<td>Co-Investigator</td>
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**SUBTOTALS**

- DOLLAR AMOUNT REQUESTED: $64,534
- FRINGE BENEFITS: $21,756
- TOTALS: $86,290

### CONSULTANT COSTS

- DOLLAR AMOUNT REQUESTED: $0

### EQUIPMENT (Itemize)

- DOLLAR AMOUNT REQUESTED: $0

### SUPPLIES (Itemize by category)

- DOLLAR AMOUNT REQUESTED: $0

### TRAVEL

- Site Meetings (Quarterly Meetings / Co-Investigators): 1,500
  - DOLLAR AMOUNT REQUESTED: $1,500

### INPATIENT CARE COSTS

- DOLLAR AMOUNT REQUESTED: $0

### OUTPATIENT CARE COSTS

- DOLLAR AMOUNT REQUESTED: $0

### ALTERATIONS AND RENOVATIONS (Itemize by category)

- DOLLAR AMOUNT REQUESTED: $0

### OTHER EXPENSES (Itemize by category)

- Research Participant Payments: 2,890
- Technology Infrastructure Fee: 392

- DOLLAR AMOUNT REQUESTED: $3,282

**SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD**

- DOLLAR AMOUNT REQUESTED: $91,072

### CONSORTIUM/CONTRACTUAL COSTS

- DIRECT COSTS: $0

### CONSORTIUM/CONTRACTUAL COSTS

- FACILITIES AND ADMINISTRATION COSTS: $49,179

**TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD**

- DOLLAR AMOUNT REQUESTED: $140,251
Budget Justification – UC Los Angeles Subcontract

In order to conform with the budget period of the parent award, in Year 9 we are requesting 12 months of support for the period 7/1/2014-6/30/2015.

**Sarah Dry, MD** (1.44 Cal Months Year 9): Dr. Dry will serve as a co-chair of this project, and will also lead the UC BRAID efforts in biobanking harmonization described in Aim #1. As project co-chair, Dr. Dry will work with other co-chairs Drs. Boyd and Dohan, with assistance from the project manager, to ensure all aims in the overall project progress as planned at all five campuses. At UCLA, she will monitor community outreach efforts (Aim #2) along with Dr. Arleen Brown.

**Arleen Brown, MD** (1.20 Cal Months Year 9): Dr. Brown will lead the UCLA based community engagement efforts in year 9. During the clinical trial, she will maintain contact with the community experts during quarterly meetings and thus 5% support is requested during this time. Throughout the study, Dr. Brown will work closely with Dr. Koenig at UCSF and investigators at all the UC campuses to coordinate community engagement, outreach, training, and dissemination efforts.

**Research assistants TBN** (6.0 Cal Months Year 9): We request the following support for a research assistant: In year 9 (3.0 Cal Months for survey support to Dr. Dry, administrative, database and consenting support to the randomized clinical trial and 3.0 Cal Months to Dr. Brown to coordinate community engagement, outreach, training and dissemination efforts).

**TOTAL non-personnel costs for the southern California deliberative community engagement events:** $3,282.

**Travel ($1500 for year 9):** This will cover expenses for Dr. Dry to travel to UCSF for quarterly meetings with the UC campus biobanking leaders and UCSF co-project leaders in year 9 to meet with UC campus leaders.

**Technology Infrastructure Fee (TIF) ($392 for Year 9):** is a consistently-applied direct charge that is assessed to each and every campus activity unit, regardless of funding source, including units identified as individual grant and contract awards. The TIF pays for campus communication services on the basis of a monthly accounting of usage data.

**Research participant payments:** A total of **$2,890** for participant reimbursement is requested to cover surveys (394 participants at $5 per survey), participant interviews (50 participants at $10 per interview) and provider interviews (12 provider interviews at $35 per provider).
**Program Name:** EngageUC _ UC Irvine Subcontract  
Principal Investigator/Program Director (Last, first, middle): Grady, Deborah G.

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD**  
**DIRECT COSTS ONLY**

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE ON PROJECT</th>
<th>Cal. Mnths</th>
<th>Acad. Mnths</th>
<th>Sum. Mnths</th>
<th>INST. BASE SALARY</th>
<th>SALARY REQUESTED</th>
<th>FRINGE BENEFITS</th>
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**SUBTOTALS**  
$22,121 $8,976 $31,097

**CONSULTANT COSTS**  
$0

**EQUIPMENT (Itemize)**  
$0

**SUPPLIES (Itemize by category)**  
$0

**TRAVEL**  
Travel between campuses 982

**INPATIENT CARE COSTS**  
$0

**OUTPATIENT CARE COSTS**  
$0

**ALTERATIONS AND RENOVATIONS (Itemize by category)**  
$0

**OTHER EXPENSES (Itemize by category)**  
Research Participant Payments 1,600

**SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD**  
1,600

$33,679

**CONSORTIUM/CONTRACTUAL COSTS**  
DIRECT COSTS $0

**CONSORTIUM/CONTRACTUAL COSTS**  
FACILITIES AND ADMINISTRATION COSTS $18,187

**TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (Item 8a, Face Page)**  
$51,866
Budget Justification – UC Irvine Subcontract

In order to conform with the budget period of the parent award, in Year 9 we are requesting 12 months of support for the period 7/1/2014-6/30/2015.

Dan Mercola, M.D., Ph.D., F.C.A.P. (.60 calendar months in year 9). D. Mercola will serve as the UCI Project Director. D. Mercola has directed multiple multi-site UO1 projects including the NCI Director’s Challenge consortium, the NCI UCI SPECS Consortium and current the NCI UCI EDRN consortium. These programs had as their main component the development of prostate biorepositories by informed consent and therefore D. Mercola has experience in these efforts, the associated regulatory affairs, and the implications of dealing with up to seven sites per consortium in achieving cooperation and uniformity. A single data base had been developed with up to 12 years of clinical follow-up accumulated from all participating sites with a data dictionary of 250 items. Dr. Mercola is the Director of the UCI Pathology Biorepository. D. Mercola is the Director of the UCI program in Personalized Cancer Medicine which is based on the development of a proactive patient tumor clinical biorepository for all UCI surgical cancer cases analogous to the storage of cord blood for patient care. D. Mercola will cooperate with the P.I., Dan Cooper, in the preparation of all presentations and publications and in the preparation of the annual report.

Anne Sawyers, CCRP, (years 9: 2.64 calendar months). Ms. Sawyers is an experienced tissue technician and has worked as a clinical coordinator with D. Mercola in the development of all consortia biorepositories including obtaining informed consents the development of the data base. Ms Sawyer is the lead technician in the development of ‘CAP best practices’ methods for the collection, storage, documentation and reporting for the UCI Proactive Personalized Cancer Medicine Biorepository. Ms. Sawyers will work with D. Mercola to develop the UCI standardized informed consents, work with the recommendations of this study for the collection, documentation and reporting of experimental consenting procedures and carryout these procedures in applicable clinics. Ms. Sawyers will work with D. Mercola and D. Cooper in the preparation of all publications, presentations, and reports.

Travel ($982 year 9): The project will require frequent travel of the PI to investigator meetings at UCSF and potentially other locations in California. Anticipated expenses include mileage, tolls and parking for UCSF meetings, and possibly airfare for meetings at other UC campuses.

Other Expenses (year 9: $1,600): in year 9, funds are requested for conducting the controlled trial, including preparation and production of surveys, space for focus groups, parking and travel reimbursements for subjects, participation payments for subjects, and other relevant expenses and materials.
**DETAILED BUDGET FOR INITIAL BUDGET PERIOD**

**DIRECT COSTS ONLY**

**FROM** 7/1/2014  **THROUGH** 6/30/2015

### PERSONNEL (Applicant organization only)

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<thead>
<tr>
<th>NAME</th>
<th>ROLE ON PROJECT</th>
<th>Cal. Mnths</th>
<th>Acad. Mnths</th>
<th>Sum. Mnths</th>
<th>INST. BASE SALARY</th>
<th>SALARY REQUESTED</th>
<th>FRINGE BENEFITS</th>
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<td>Yu-Jui Yvonne Wan, PhD</td>
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**SUBTOTALS**

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### CONSULTANT COSTS

- $0

### EQUIPMENT (Itemize)

- $0

### SUPPLIES (Itemize by category)

- $0

### TRAVEL

**Travel between campuses**: 1,000

1,000

### INPATIENT CARE COSTS

- $0

### OUTPATIENT CARE COSTS

- $0

### ALTERATIONS AND RENOVATIONS (Itemize by category)

- $0

### OTHER EXPENSES (Itemize by category)

**Research Participant Payment**: 1,577

1,577

**SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD**

- $30,040

### CONSORTIUM/CONTRACTUAL COSTS

**DIRECT COSTS**

- $0

### CONSORTIUM/CONTRACTUAL COSTS

**FACILITIES AND ADMINISTRATION COSTS**

- $16,222

**TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD**

- $46,262

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Budget Justification - UC Davis Subcontract

In order to conform with the budget period of the parent award, in Year 9 we are requesting 12 months of support for the period 7/1/2014-6/30/2015.

A. Personnel (year 9: $27,463)

1. Yu-Jui Yvonne Wan, PhD (Principal Investigator), Professor, UC Davis Dept. of Medical Pathology and Laboratory Medicine. Coordinating faculty representative for the UC Davis component of the proposal. Participation in project leader meetings, identification of stakeholders at UC Davis for surveys and focus groups, performance of controlled trial for determining best method of obtaining global consent, data interpretation, and preparation of study results for presentation and publication. Salary and fringe benefits are requested (0.6 calendar months in year 9).

2. Staff Research Associate (To Be Hired), UC Davis Dept. of Medical Pathology and Laboratory Medicine. Recruitment of stakeholders and conducting surveys and focus groups addressing the issue of global consent, preparation and maintenance of IRB protocols, and data management. Salary and fringe benefits are requested (year 9 2.5 calendar months).

B. Travel ($1000 for year 9): The project will require frequent travel of the PI to investigator meetings at UCSF and potentially other locations in California. Anticipated expenses include mileage, tolls and parking for UCSF meetings, and possibly airfare for meetings at other UC campuses.

C. Other Expenses ($1,577 year 9): In year 9, funds are requesting for conducting the controlled trial, including preparation and production of surveys, space for focus groups, and travel reimbursements for subjects, participation payments for subjects, and other relevant expenses and materials.
**DETAILS BUDGET FOR INITIAL BUDGET PERIOD**

**DIRECT COSTS ONLY**

**FROM** 7/1/2014  **THROUGH** 6/30/2015

<table>
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<tr>
<th>PERSONNEL (Applicant organization only)</th>
<th>Months Devoted to Project</th>
<th>DOLLAR AMOUNT REQUESTED (omit cents)</th>
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<tr>
<td><strong>NAME</strong></td>
<td><strong>ROLE ON PROJECT</strong></td>
<td><strong>INST. BASE SALARY</strong></td>
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<tr>
<td>Gary Firestein</td>
<td>Co-PI</td>
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<tr>
<td>David Boyle</td>
<td>Site Coordinator</td>
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</tr>
<tr>
<td>Joshua Hillman</td>
<td>SRA</td>
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</table>

**CONSULTANT COSTS**

$0

**EQUIPMENT (Itemize)**

$0

**SUPPLIES (Itemize by category)**

$0

**TRAVEL**

Travel between campuses 1,000

$1,000

**INPATIENT CARE COSTS**

$0

**OUTPATIENT CARE COSTS**

$0

**ALTERATIONS AND RENOVATIONS (Itemize by category)**

$0

**OTHER EXPENSES (Itemize by category)**

Research Participant Payments 1,496

$1,496

**SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD**

$29,363

**CONSORTIUM/CONTRACTUAL COSTS**

**DIRECT COSTS**

$0

**CONSORTIUM/CONTRACTUAL COSTS**

**FACILITIES AND ADMINISTRATION COSTS**

$16,150

**TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (Item 8a, Face Page)**

$45,513
**BUDGET JUSTIFICATION - UC San Diego Subcontract**

In order to conform with the budget period of the parent award, in Year 9 we are requesting 12 months of support for the period 7/1/2014-6/30/2015.

**A. Personnel (year 9: $26,867)**

Gary Firestein, M.D. (Principal Investigator, 0.0 Calendar Months)- Dr. Firestein is the PI for UCSD’s CTSA award and the Director of the Clinical and Translational Research Institute (CTRI). Faculty representative for the UCSD component of the proposal.

David Boyle, BS (Site Coordinator 0.60 calendar months in years 9)
Mr. Boyle will direct the project at UCSD. He will represent UCSD at project leader meetings, work with faculty and supervise staff to assure that the project goals are supported. He is currently the director of CTRI Translational Research Technologies division and oversees the CTRI biomarker lab and biorepository.

Joshua Hillman, BS Staff Research Associate (2.6 Cal Months for years 9)
Mr. Hillman manages the CTRI biorepository. Recruitment of stakeholders and conducting surveys and focus groups. Preparation and maintenance of IRB protocols, and data management. He will also be responsible for sample cataloging, databases, storage and sample distribution.

The UCSD benefits rate is 34.2% for faculty and 44.2% for staff.

**B. Travel ($1,000 for year 9):** The project will require frequent travel of the PI to investigator meetings at UCSF and potentially other locations in California. Anticipated expenses include mileage, tolls and parking for UCSF meetings, and possibly airfare for meetings at other UC campuses.

**C. Other Expenses (year 9: $1,496):** In years 9, funds requested are for conducting the controlled trial, including preparation and production of surveys, space for focus groups, parking and travel reimbursements for subjects, participation payments for subjects, and other relevant expenses and materials.
CHECKLIST

1. PROGRAM INCOME (See instructions.)
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

<table>
<thead>
<tr>
<th>Budget Period</th>
<th>Anticipated Amount</th>
<th>Source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

2. ASSURANCES/CERTIFICATIONS (See instructions.)
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 6).

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS
Indicate the applicant organization’s most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will not be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☐ DHHS Agreement dated: May 23, 2012
☐ No Facilities and Administrative Costs Requested.
☐ No DHHS Agreement, but rate established with ___________________________ Date ___________________________

CALCULATION*

Entire proposed budget period: Amount of base $285,699 x Rate applied 26 % = F&A costs $74,282

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):
☐ Salary and wages base
☒ Modified total direct cost base
☐ Other base (Explain)
☐ Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary): EngageUC Administrative Supplement: UCSF

The F&A Base for this project was calculated as follows:

EngageUC Total Direct Costs = $569,590
Less subcontracts to UC partner campuses = $283,892
Modified F&A Base = $285,698
x rate: 26%
IDC = $74,282
1. PROGRAM INCOME (See instructions.)
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

<table>
<thead>
<tr>
<th>Budget Period</th>
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</table>

2. ASSURANCES/CERTIFICATIONS (See instructions.)
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 6).

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS
Indicate the applicant organization’s most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will not be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

• DHHS Agreement dated: May 23, 2012
• No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with ________________________________ Date ________________________________

CALCULATION*

Entire proposed budget period: Amount of base $91,072 x Rate applied 54% = F&A costs $49,179

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

• Salary and wages base
• Modified total direct cost base
• Other base (Explain)

• Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary): EngageUC Administrative Supplement: UCLA

The F&A Base for this project was calculated as follows:

Total Direct Costs = $91,072
Less exemptions = $0
Modified F&A Base = $91,072
x rate: 54%
IDC = $49,179
1. PROGRAM INCOME (See instructions.)
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

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<th>Budget Period</th>
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</table>

2. ASSURANCES/CERTIFICATIONS (See instructions.)
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS
Indicate the applicant organization’s most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will not be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☐ No DHHS Agreement, but rate established with ___________________________ Date ________________

CALCULATION*

Entire proposed budget period: Amount of base $33,679 x Rate applied 54% = F&A costs $18,187
Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):
☐ Salary and wages base ☑ Modified total direct cost base ☐ Other base (Explain)
☐ Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary):

EngageUC Administrative Supplement: UCI

The F&A Base for this project was calculated as follows:

Total Direct Costs = $33,679
Less exemptions = $0
Modified F&A Base = $33,679
x rate: 54%
IDC = $18,187
CHECKLIST

1. **PROGRAM INCOME (See instructions.)**
   All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

<table>
<thead>
<tr>
<th>Budget Period</th>
<th>Anticipated Amount</th>
<th>Source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

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   In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. **FACILITIES AND ADMINISTRATIVE (F&A) COSTS**
   Indicate the applicant organization’s most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

   F&A costs will **not** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

   - [x] DHHS Agreement dated: May 23, 2012
   - [ ] No Facilities and Administrative Costs Requested.
   - [ ] No DHHS Agreement, but rate established with

   **CALCULATION**

   Entire proposed budget period: $30,040 x Rate applied 54% = F&A costs $16,222

   Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

   *Check appropriate box(es):
   - [ ] Salary and wages base
   - [x] Modified total direct cost base
   - [ ] Other base (Explain)

   Explanation (Attach separate sheet, if necessary.):

   **EngageUC Administrative Supplement: UCD**

   The F&A Base for this project was calculated as follows:

   Total Direct Costs = $30,040
   Less exemptions = $0
   Modified F&A Base = $30,040
   x rate: 54%
   IDC = $16,222
CHECKLIST

1. PROGRAM INCOME (See instructions.)
   All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

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   In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 6).

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS
   Indicate the applicant organization’s most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

   F&A costs will not be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.


   ☐ No DHHS Agreement, but rate established with ________________________________ Date ________________________________

   CALCULATION*

   Entire proposed budget period: Amount of base $29,363 x Rate applied 55 % = F&A costs $16,150

   Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

   *Check appropriate box(es):
   ☑ Salary and wages base ☐ Modified total direct cost base ☑ Other base (Explain)

   ☐ Off-site, other special rate, or more than one rate involved (Explain)

   Explanation (Attach separate sheet, if necessary.):

   EngageUC Administrative Supplement: UCSD

   The F&A Base for this project was calculated as follows:

   Total Direct Costs = $29,363
   Less exemptions = $0
   Modified F&A Base = $29,363
   x rate: 55%
   IDC = $16,150