CTSI at the General

The UCSF CTSI Clinical Research Center

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LETTER FROM THE CRC MEDICAL DIRECTOR

Welcome to this first issue of CTSI at the General. We hope this newsletter will keep you, our current and potential new clinical-translational investigators in the UCSF community, well informed about CTSI clinical research services, accomplishments, important changes, and opportunities that might lead you to new fruitful collaborations at SFGH. If you have any comments, suggestions, or questions, please contact me at mjacobson@php.ucsf.edu.

Best regards,
Mark A. Jacobson, MD
Medical Director
UCSF CTSI Clinical Research Center

ALPHABET SOUP: WHAT ALL THE "C" ACRONYMS MEAN

In 2006, the NIH began to retire its system of funding GCRC's (General Clinical Research Centers) and replace it with a new mechanism called the Clinical Translational Science Award (CTSA) program in order to coalesce, streamline, and better coordinate NIH-funded research infrastructure within major academic medical centers.

UCSF was among the first academic centers to receive a CTSA award and has used it to create and sustain the UCSF Clinical Translational Science Institute (CTSI), an institute within UCSF that incorporates all of the prior UCSF adult and pediatric GCRC units, UCSF's existing K12 and T32 career awards, and a number of new clinical/translational research support sites, services, and training programs.

In 2009, UCSF CTSI hired Dr. Bill Balke to coordinate and direct the CTSI's Clinical Research Services (CRS) as a single program within the UCSF CTSI to integrate its eight clinical research centers (CRC's) across San Francisco and Oakland that provide an array of adult and pediatric services (e.g., inpatient and outpatient clinical research facilities, research nursing, specimen processing, bionutrition, body composition and exercise studies, etc.) and to develop new services such as patient recruitment and research coordinator cores that can serve the entire UCSF research community.

For your future research planning, we offer the following resources and support for you and your research team.

- *For assistance in preparing the CTSI budget component of your new application/s to NIH, Industry or Non-Profits, or NIH competitive renewal applications, or if you have recently received a grant award and plan to use the CTSI Clinical Research Services, please call Cathleen Tierney at TierneyC@gcrc.ucsf.edu or Hector Vizoso at: hvizoso@sfghgcrc.ucsf.eduto discuss your budget and the funding available to support your research study.*
- *To facilitate your future research applications, samples of our standard letter of support are posted on the website at; http://ctsi.ucsf.edu/research/crc/resources. A letter of support will be provided when the CRS budget has been finalized.*
- *For general assistance in accessing CTSI Clinical Research Services, please contact Leslie Mullin (pediatric services) at 514-2292 or Derek Harrison (adult services) at 632-5003. Leslie and Derek can provide you with information about available services, direct you to core directors for more specific information, or connect you with the nursing or medical director at the CRC where the work will be performed.*
- *Information on CTSI Clinical Research Services can be found at: http://ctsi.ucsf.edu/research/crs.*

COST RECOVERY BEGINS ON DECEMBER 1, 2011

In order maintain financial viability of CTSI Clinical Research Services and better accommodate the marked increase in the demand for our services by an ever widening group of UCSF investigators in this era of diminished NIH support, the UCSF CTSI is about to initiate cost recovery for utilization of its clinical research services. While some of our core services and sites have had a policy of cost recovery and many of our investigators have been engaged in this transition over the past several years, we have reached the point where we must fully transition all of our core services and investigators to the new model. Effective December 1, 2011, investigators who submit new, revised and/or competing grant applications that plan on using CRS or CRC resources will be expected to include costs for such utilization in their grant budgets.

Investigators should work with CRS staff during the grant budget development process to allow for timely costing of the study. Investigators will be expected to budget a minimum of 40% of the full CRS/CRC costs in their grant applications to NIH or any other funding agency, as well as in their budget agreement with any industry sponsor of an investigator-initiated protocol. Investigators may be asked to submit funding agency/industry sponsor documentation describing the terms and conditions of funding. As before, industry-initiated protocols will continue to be expected to pay 100% of the full CRS/CRC costs.

We do anticipate that gaps in funding, budgetary challenges, and special circumstances will occur and that additional CTSI support for underfunded studies may be needed. To deal with situations requiring additional CRS support, CTSI is in the process of constituting a committee that will include CRC medical directors, CRS administrative staff, and independent faculty which will review requests for additional support beyond the base 60% of actual CRS/CRC costs the CTSI plans to continue to subsidize. If you are interested in participating in this committee, please contact Cathleen Tierney at TierneyC@gcrc.ucsf.edu or Hector Vizoso at hvizoso@sfghgcrc.ucsf.edu.

If you are planning a competitive renewal of an existing clinical research study or submitting a new clinical research protocol, CTSI CRS staff will help you develop your budget in line with our new cost recovery model. Please note that if you are presently conducting a research project in one of our eight CRCs, every effort will be made to fulfill prior commitments to your on-going, funded research projects.

NEW SFGH CRC HOURS

Given the predicted decline of NIH CTSA support and annual increases in salary and fringe benefits at UCSF, we are rapidly approaching the "tipping point" where we will be unable to sustain our high level of support for investigators using the SFGH CRC unless we change the way we do business.

A cost-efficiency analysis revealed that closing the SFGH CRC on weekends could greatly improve the SFGH CRC utilization rate, saving CTSI funds that can be used to provide continued support to our investigators across the board. However, rather than arbitrarily closing every weekend, we have consulted with those investigators who currently use the SFGH CRC on weekends and have developed a limited weekend schedule (i.e., one full weekend per month plus one additional Saturday day shift for outpatient visits per month) that will allow them to continue their work unfettered.

5B Weekend Hours

Date	*Saturday*	*Sunday*
November		
12,13	Open 8-4pm	Closed
19,20	Open 24hrs	Open 24hrs
December		
3,4	Open 8-4pm	Closed
17,18	Open 24hrs	Open 24hrs
January 2012		
7,8	Open 8-4pm	Closed
21, 22	Open 24hrs	Open 24hrs
February		
4,5	Open 8-4pm	Closed
25,26	Open 24hrs	Open 24hrs
March		
10	Open 8-4pm	Closed
24,25	Open 24hrs	Open 24hrs

5B IS NOW A LOCKED UNIT

5B is a locked unit. Please use the phone outside of the unit that is a direct line to the front desk to get access. Don't forget to mention this when giving directions to your study patients. This also means that when there is no inpatient census, there may be no staff on the unit. We are putting together an emergency closure email list. Contact Hector Vizoso if you would like to be added to the contact list for notification of last minute closures.

NEW STAFF MEMBERS

Antonio Everett

Antonio is our new hospital assistant/phlebotomist who will be working on both 4C and 5B. He comes to us from Lab Corp in Oakland. He is a dog lover with two years of intensive phlebotomy experience.

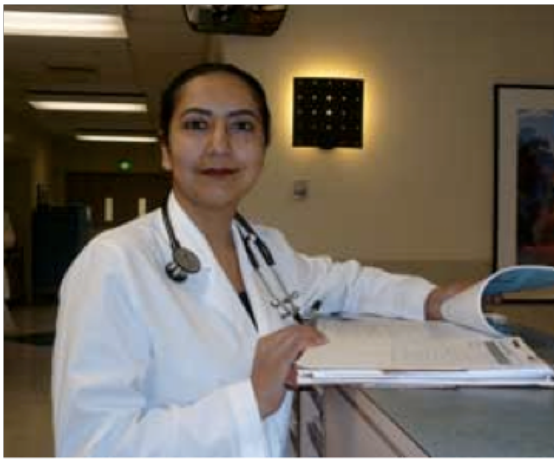
Jimmy Morrow

Jimmy is our second new hospital assistant and phlebotomist who will be working on 4C and 5B. Jimmy has come to work with us at the CTSI after spending the last 20 years as a flight attendant.

Rosemarie Dario

Rosemarie Dario is our new per diem LVN. She will be working on 5B. She also works at CPMC. She is an avid outdoors woman and snowboarder.

Investigator Spotlight



Madana Khalili, MD

Dr. Khalili is an Associate Professor of Medicine at UCSF as well as Chief of Clinical Hepatology at SFGH. Her chief areas of interest and research are identifying the pathogenesis of diabetes in viral hepatitis. Hundreds of patients have been seen under Dr. Khalili's current study "Insulin Resistance in HCV Infection" at the SFGH CRC. She promotes care to underserved populations and looks for ways of addressing the disparity of care for those populations. She has been doing research at the SFGH CRC since 2000. Away from SFGH, she is a soccer mom to 3 active boys who enjoys swimming.

Dr. Khalili enjoys working at the state of the art facilities on 5B. She appreciates the nursing expertise and teamwork, as well as the support and flexibility of the staff.

Sarah Lange, FNP

Sarah was hired as a 5B RN in 2000. She transitioned to the role of NP in 2008. She is the busy mom to two wild little girls. She spends her little bit of spare sailing in San Francisco Bay.

Sarah's favorite aspect of being a team member at the SFGH CTSI is the opportunity to learn from the many experts and brilliant people that come to do their research here with us.

Sarah has privileges at SFGH, the San Francisco VA, and UCSF Medical Center. She is available to admit patients to 5B, sign MD orders, do histories and physicals, write progress notes and do research procedures. She is a great back up for MDs on leave or vacation. If you are interested in using the CTSI NP services please contact Sarah directly at slange@sfghgcrc.ucsf.edu.

DO YOU KNOW ABOUT OUR CORES

Body Composition | Exercise | Metabolism Core

At SFGH we offer a full range of techniques for measuring body composition including, but not limited to, DEXA (dual-energy x-ray absorptiometry), air displacement (Bod-Pod), single and multi-frequency bioimpedance analysis; assistance with a wide variety of exercise tests; and measurement of energy expenditure using indirect calorimetry. Our body composition specialist is Viva Tai, MPH, RD. Following are a few of the new, recently started studies that use our core services at SFGH:

- CRC protocol 6281: Effects of maternal fructose consumption on fat content and distribution in neonates. Investigators: Robert Lustig, MD and Anjali Jain, MD. Core services provided: whole-body DEXA scans for measurement of total body fat in neonates within days after delivery. This requires special software not available on most DEXA instruments and specially-developed procedures. Viva performs these measurements and is also training Dr. Jain in the use of DEXA in this population.
- CRC protocol 6336: Effects of gastric bypass surgery on calcium metabolism and bone density. Investigator: Anne Shafer, MD. Core services provided: DEXA scanning of hip, spine, and forearm. Assistance with exercise testing (e.g. grip strength, gait speed): the core provided training to Dr. Shafer in performance of these tests and use of equipment owned by the Core.
- Two new ACTG studies: CRC protocol 6345: Randomized, double-blind, placebo controlled trial of vitamin D and calcium supplementation for bone health in HIV-infected persons beginning antiretroviral therapy (ACTG 5280); and CRC protocol 6389: Randomized, Double-blind, placebo-controlled exploratory trial of a novel, maraviroc-containing antiretroviral regimen, compared with a tenofovir-containing regimen in treatment-naïve patients (ACTG 5303). Site PI: Anne Luetkemeyer, MD. Core services provided: DEXA scanning of the hip and spine for measurement of bone density, which is the primary outcome of both studies. For further information on core services at SFGH, please contact Kathleen Mulligan, PhD, Core Director, at 206-5882; e-mail: Kathleen.mulligan@ucsf.edu.

Bionutrition Core

Do you have a pressing question about diet and how it affects our health? The CTSI Clinical Research Services (CCRS) Bionutrition Core at San Francisco General Hospital Medical Center (SFGH) can help you design and implement a specialized approach to the nutritional component(s) of your clinical research protocol. The Bionutrition team includes two registered dietitians, a metabolic kitchen supervisor, and three dietary aides with a wide range of expertise in food and nutritional science. We can assist you with:

- nutritional assessment of your study participants
- diet design, preparation and delivery
- nutrition education

Bionutritin TIP

For many of the research studies participants are asked to keep 3-day food records, which are then analyzed with nutrient analysis software. Instructions for keeping food records include information on portion sizes.

For example:
1 cup pasta/veggies =
the size of a man's fist

3oz of meat =
palm of hand

Contact the SFGH CRS Bionutrition Team at
415-206-8886

Some dynamic projects and UCSF investigators our Bionutrition team actively supports:

De Novo Lipogenesis (DNL) in the Pathogenesis of Non-Alcoholic Fatty Liver Disease (PI: Jean-Marc Schwarz, PhD and Kathleen Mulligan, PhD)

Question:

Does diet, specifically sugar, affect the amount of fat that is made and stored in the liver? Bionutrition designs, prepares, and deliver diets for two aims of the study. For the first part of the study, participants follow a weight stable diet that approximates their typical dietary intake of macronutrients and sugar. For the second part, participants are randomly assigned to high or low fructose diets with caloric restriction, for six weeks. Complex metabolic measurements are completed over a four day period at the SFGH CCRS at 5B before and after adherence to the diet plan.

Metabolic Impact of Fructose Restriction in Obese Children (PI: Robert Lustig, MD, JM Schwarz, PhD and Kathleen Mulligan, PhD)

Question:

What is the effect of limiting fructose in obese children who are high sugar consumers? Culturally appealing diets were designed to deliver a low intake of fructose for Hispanic and African American obese children to follow for nine days. Pre and post dietary intervention studies are completed at the Pediatric CCRS at 6M of Moffit Hospital.

Effect of Gastric Bypass Surgery on Bone Metabolism and Calcium Absorption (PI: Anne Schafer, MD)

Question:

Does gastric bypass surgery affect calcium absorption and bone density? A standardized meal test was developed to deliver a prescribed calcium dose so that investigators can measure the rate of mineral absorption in obese women before and six months after gastric bypass surgery. Additionally, changes in bone are followed with site specific bone densitometry measurements at the wrist, hip, and spine.

Recruitment and Planning Services

The Participant Recruitment Service (PRS) is a centralized service to facilitate the enrollment of research participants into UCSF clinical studies. The PRS is available to all researchers at UCSF and at affiliated institutions on a recharge basis.

Recruitment Analysis & Planning

- Experienced recruitment specialists develop a robust recruitment plan that includes suggested strategies, timelines and costs.
- Monthly consultation is provided during recruitment plan implementation by your staff.

Cohort Identification & DirectMail Recruitment

- We help you define the cohort to recruit from the inpatient electronic medical record (Epic and/or THREDS).
- We provide assistance in applying to CHR for approval of this recruitment method.
- We coordinate the data extraction into the secure MyResearch environment.

Direct mail recruitment letters are printed and mailed to the cohort on your behalf.

For more information or to request services contact us at:
recruitment@ucsf.edu or 415-514-8140.

Reminders

New research associates need to do a short (30 minute) orientation with the 5B charge nurse before they can see patients.

Anyone needing to pick up samples from the 5B freezer needs to schedule an appointment with Benny Tong x63327, in order for the lab to maintain an accurate inventory log.

We are happy to draw clinical blood samples for your patients along with their research bloods. Due to changes in the clinical laboratory billing system your patient must register at the clinic where the standard of care bloods were ordered before we can draw those samples.

Remember to cite the CTSI/CRS in your next publication. Each paper really does count! Please notify when your papers are published. We love to see the results of the research that we carry out.

Did your coordinator recently leave for medical school? Did you lose some of your funding? Are you a Junior Investigator with limited funds? Does your current research staff need a little extra help?
The Clinical Research Coordinator Core can help! We are a team of highly experienced, well trained coordinators with current experience and access to most medical systems at MZ, Parnassus, SFGH and the SFVA (pending). We support all UCSF affiliated Physicians in clinical research across all locations, all departments and all specialties. We can see patients anywhere that a UCSF affiliated PI see's patients (even off campus); except home visits.
You can hire a coordinator for a short-term or long-term project, at a %FTE between 10% and 80%. We can: write your consents, do your iMedris & CTSI submissions, help with budgets, recruit and consent patients, schedule and perform study visits, help with sample processing, draw blood (select CRC's only), abstract charts, preform data entry, and MUCH, MUCH MORE!
Please contact Danusia Filipowski, MD at filipowskid@gcrc.ucsf.edu to request a CRC-Core request form, and for any questions about how we can help support your research needs.

Examples of some of our Current and Past Projects:

PI: Schick,Suzaynn PhD
Dept: Occupational and Environmental Med
Study title: Controlled Exposure of Human Subjects to Thirdhand Cigarette Smoke
Study type: Investigator initiated
Time: 50% FTE for 2 weeks
Location: SFGH
Project: Writing consents and Initial IRB submission

PI: Wade Smith, MD
Dept: Adult Neurology
Study title: A Non-Randomized, Non-Significant Risk Study to Demonstrate Proof of Concept of a Non-Invasisve, Passive Vascular Pressure Wave Method of Predicting and Diagnosing Vasospasm.
Study type: Industry Sponsored
Time: Variable from 50-100% for 1+ year
Location: Parnassus
Project: Writing consents & Initial IRB submission, Recruiting & Consenting patients, Conducting study visits, Performing data entry, etc.

PI: Christopher Dvorak, MD
Dept: Pediatric BMT
Study title: Hematopoietic Stem Cell Transplantation for Children with Severe Combined Immunodficiency Disease Utilizing Alemtuzumab and mobilization with Plerixafor & Filgrastim.
Study type: Industry Sponsored
Time: ~11% for 10 months
Location: Parnassus
Project: Creation of a study regulatory binder and study database with a detailed patient data abstraction.

CTSI CRC PUBLICATIONS

All publications resulting from utilization of any CTSI resources are required to credit the grant accordingly:
"This publication [or project] was supported by NIH/NCRR UCSF-CTSI Grant Number UL1 RR024131. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH