Clinical & Translational Science Institute (CTSI) Informational Seminar

Presentation to UCSF Weill Institute for Neurosciences

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November 8, 2019
Quick Background

• The **Clinical & Translational Science Institute** (CTSI) is a cross-school, campus-wide institute that provides infrastructure, services and training to support clinical and translational research at UCSF.

• We’ll go into our program offerings and services later on - hang tight!

• Submit questions “live” during this seminar to **nooshin.latour@ucsf.edu**
UCSF Clinical & Translational Sciences Institute

Facilitates UCSF clinical and translational research with resources and support

**Biospecimen Resources Program**
facilitates the efficient acquisition, QC and management of biospecimens at UCSF

**Catalyst Program**
translational accelerator focused on advancing UCSF discoveries with clinical impact and commercial potential

**Clinical & Translational Science Training**
supports and expands discipline-specific research training programs with an extensive array of research education and training activities

**Clinical Research Services**
infrastructure and research services, including skilled nursing

**Consultation Services**
provides expert advice to investigators with the goal of improving the quality and quantity of science at UCSF and affiliated institutions

**Community Engagement & Health Policy**
supports research and evaluates solutions to pressing public health problems; focuses on bridging academic research, health policy and community practice

**Informatics & Research Innovation**
works to make data more accessible and usable for research

**Participant Recruitment**
implements programs and creates tools that allow research teams to meet recruitment goals with ease and efficiency
Trial Innovation Network (TIN)
Trial Innovation Network (TIN)

• A national collaborative initiative aimed at improving investigator-initiated multi-site trial operations by leveraging resources and the collective expertise of the Clinical and Translational Science Award (CTSA) consortium, which includes UCSF’s CTSI.

• Mission:
  • 1) Accelerate planning & implementation of high-quality multi-center trials & studies
  • 2) Create a national laboratory to study, understand, and improve multi-center clinical trials

• [https://trialinnovationnetwork.org](https://trialinnovationnetwork.org)
Who is eligible?

• Any UCSF investigator across all four schools who are planning multi-site clinical trials or studies are eligible to submit a request for TIN services.

• Investigators who would like to collaborate on multi-site trials initiated by other sites and investigators across other hubs.
Some TIN Services:

• Single IRB support, resources and tools, and web-based platform (IREx)
• EHR-based cohort assessment for informing study design and site selection
• Assistance in identifying study sites across the United States
Number of Sites Recruited for Trials:
Steps to Submit

Using the Trial Innovation Network to Plan Your Trial

Submit Study Proposal
Contact Investigator
Conduct Consultation
Pre-Application Project
Complete Comprehensive Consultation
Funded Project
Approve Resources
Summary Recommendations

Apply to the TIN now for a personalized assessment of what the Network offers.
Assigned TIC/RIC contacts the investigator to assess priorities.
In collaboration with the investigator, the assigned TIC/RIC conducts the initial consultation.
Investigators may wish to have one of the TICs act as the data coordination center / clinical coordinating center and utilize all TIN resources for their study. In this situation, the TIC will be included in the grant application to an individual NIH Institute or Center (IC).

Resource requests will be prioritized based on resource availability and funding status.

Illustrated timeline is approximate and may be subject to change based on the responsiveness and needs of the research team and current number of active proposals.

What makes a good submission?

• Multi-site study design (3 or more institutions)
• Includes all populations affected by the health condition being studied. This should include diverse and special populations including women, racial/ethnic minorities and children.
• Opportunity to study an innovative designs and approach to improve quality, efficiency, or cost of clinical research

  And/or

• Opportunity to provide evidence that can improve future clinical trial designs, conduct, and reportability.
Consultation Example

• Microbiome Initiative
  UC Irvine Researcher, Katrine Whiteson

• Reviewers recommended more samples, but budget in FOA was reduced from $5 million over five years to $3 million over four years

• Consultation provided options for redesign “to do more science with less money”

• Solutions:
  • “randomize the subjects into sub-groups and take different time-points from each, allowing fewer samples overall and fit within the budget”
  • “clarify recruitment plan, get help w/Community Engagement Studio and share the results of the study with the community”

"It was truly helpful to have had the support of this group of people who are extremely skilled and experienced. “ Katrine Whiteson
Recent TIN Collaboration Requests to UCSF Pre-Funding Submission Examples

• Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children (TIC-TOC)
  • Dr. Daniel Nishijima and Dr. Nate Kuppermann UC Davis
  • Double blind, randomized controlled trial of children younger than 18 years with hemorrhagic injuries to the torso or brain.
  • N=2000; 30-40 sites
  • Pre submission for funding

• EE2: 3,4-Diaminopyridine for ALS - The EEDAP-ALS Trial
  • Dr. Richard Barohn, University of Kansas
  • Efficacy Effectiveness -Too trial design (EE2)
  • N=300; ~40 sites
  • Pre submission for funding
Recent TIN Collaboration Requests to UCSF Funded Examples

• A Novel Provider-Focused Training Program to Serve Transition-Age Youth and Adults with Autism Spectrum Disorder
  • Dr. Beth Malow Vanderbilt
  • Develop and pilot test a novel PCP training program with the goal of increasing high-quality community-based healthcare for adults with ASD.
  • N=50; 20 sites
  • Funded by the Department of Defense

• Cardiac arrest awareness and long-term quality of life: a mixed methods study of the experiences and psychological consequences of adult cardiac arrest (Cardiac Arrest Survivorship)
  • Dr. Sam Parnia, NYU Langone Health
  • mixed methods cross-sectional study
  • N=4000; ~20-30 sites
  • Funded
TIN Questions / Comments?
CTSI Programs and Services
Consultation Services

Expert consultations for every stage of research:
- Biostatistics
- Data management
- Study Design
- Recruitment

First hour is free!

Consult.ucsf.edu

Participant Recruitment Program

Resources, services, and infrastructure to support participant recruitment:
- EHR Recruitment
- Tutorials on recruitment budgeting and planning
- Website and flyer templates
- Resources for recruitment of diverse populations

Recruit.ucsf.edu
UCSF Profiles (profiles.ucsf.edu) — like LinkedIn for UCSF researchers

• One of the **top Google hits for your name**! Funders, journals, and colleagues see it
• 1.5 million visits per year to UCSF Profiles
• Log in via MyAccess to keep **overview, photo, and collaboration interests** updated
• These are shared across many campus websites and services
• We now automatically include your Weill affiliation!
• **Questions? Email** [profiles@ucsf.edu](mailto:profiles@ucsf.edu)
UCSF Clinical Trials (clinicaltrials.ucsf.edu) — help patients find your trial

- Patients can browse every trial on campus — 200,000 users/year!
- All the trial details come from clinicaltrials.gov — please keep yours updated!
- When patients inquire about your trial, we email your trial’s clinicaltrials.gov contact
- Hundreds of interested people contact studies each month
- Questions? Email clinicaltrialsfinder@ucsf.edu
UCSF Catalyst Program
Translational accelerator advancing UCSF discoveries with clinical relevance & commercial potential

• Catalyst Awards
  • 200+ industry expert advisors providing volunteer mentorship and guidance
  • Since inception in 2010... 219 projects awarded $7.2M (leading to additional funding for the projects of $210M)

• Internship Program
  • Grad students, med students, interns, residents, clinical and postdoctoral fellows
  • Active participation in Catalyst Award projects
UCSF Catalyst Program
Examples of projects supported (red rectangles identify neurosciences projects)

- Targeting PCSK9 to treat atherosclerosis
- Machine learning for rapid head CT analysis in neurological emergencies
- Catheter-based tissue ablation
- RNA therapeutics delivery
- Ex vivo and in vivo expansion of native and CAR-modified T lymphocytes
- Photodynamic therapy for keratitis
- Development of an inhibitory antibody as a molecular therapy for brain arteriovenous malformation
- Asthma self-management app
- Small molecules targeting Parkinson’s disease
- Proprietary IRE1alpha inhibitors for systemic indications
- Neurosteroid brain therapeutics
- Bioartificial pancreas
- Pulmonary drug delivery
- Nanofilm for ocular drug delivery
- Development of a handheld tool for cortical stimulation
- Therapy response predictor for glioma
- CT contrast agent for the GI tract
- Biomarker for autism
- Diagnostic for Lyme Disease
- Clinical data platform for neural interface technologies
- Stem cell therapy for ARDS
- Immuno-PET tracer for immuno-oncology
- Novel linkers for ADCs
- Replaceable aortic valve
- Oncolytic virus for cancer
- Novel opioid analogs
- Peptidyl-prolyl isomerase inhibitors
- Machine learning CT analysis in neurology
- Cartilage-based alternative to bone grafting
- Biomarker-based personalized spinal cord stimulation for chronic pain
CTSI Pilot Awards (Spring only)

• **Pilot for Junior Investigators, $40,000**
  To support digital health and research of particular relevance to children, the elderly, or socially or medically vulnerable populations. Open to Assistant Professors and Instructors

• **Under-represented Faculty & Senior Fellows in Clinical & Translational Research, $40,000**
  To support researchers from groups historically under-represented in health sciences

• **Pilot Award for Prevention and Treatment of Opioid Use Disorders, $40,000**
  To support research projects focused on prevention and treatment of opioid use disorders

• **Family Support Award, Doris Duke Charitable Foundation, $40,000**
  To support the research of junior faculty with significant family caregiving responsibilities

  Learn more https://ctsi.ucsf.edu/about-us/programs/pilot-awards
Questions / Comments?