UCSF
University of California
San Francisco

Clinical & Translational Science Institute (CTSI) Informational Seminar

Presentation to UCSF Weill Institute for Neurosciences

Payam Nahid, MD, MPH,
Associate Director of Clinical Trial Operations

Molly Belinski, CTSI Program Representative

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 creats 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
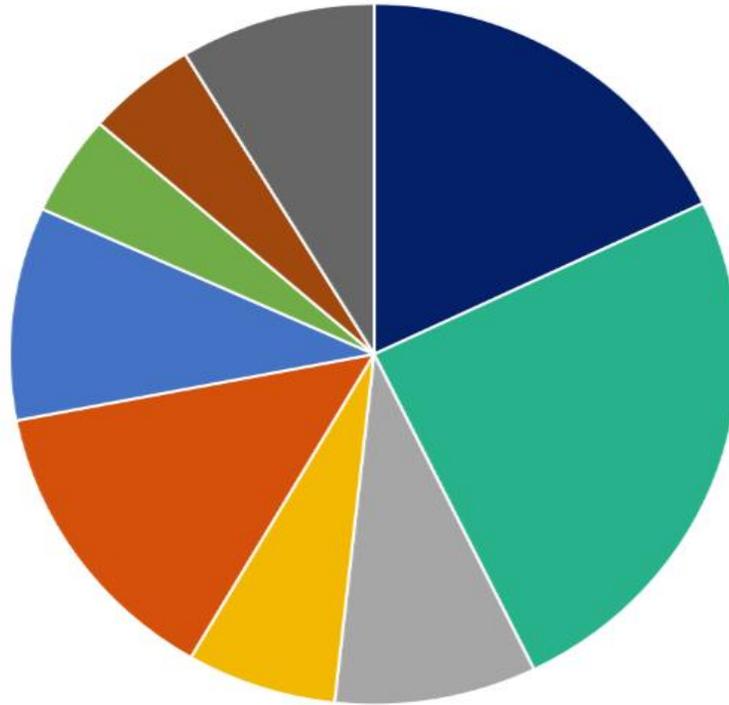- https://trialinnovationnetwork.org

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.
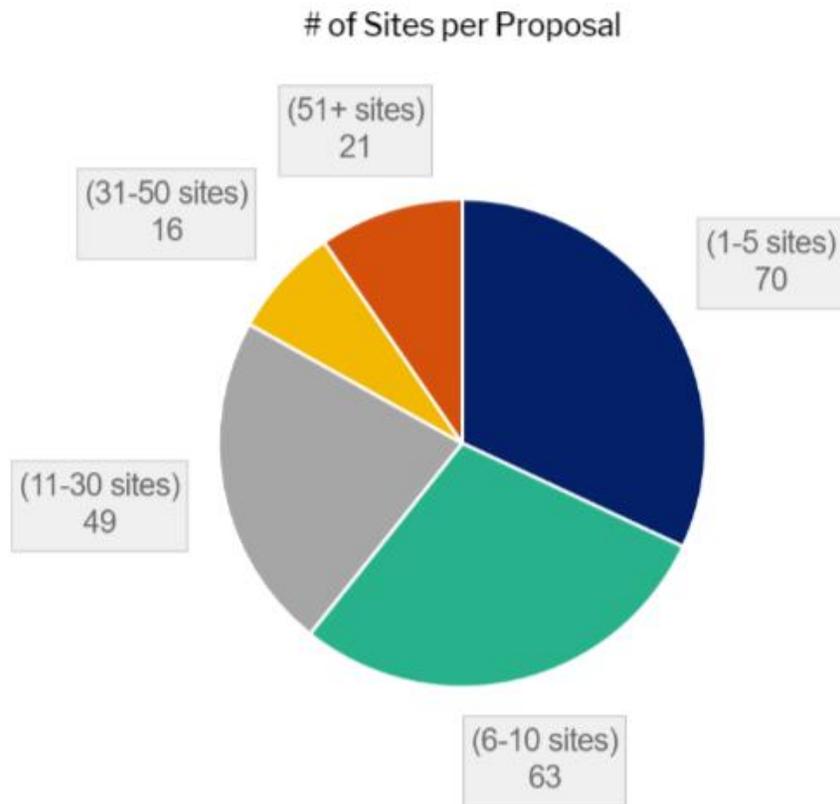
Some TIN Services:

- 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

Requested TIN Support

- ■ Initial Consultation (62)
- ■ SIRB (86)
- ■ Standard Agreements (31)
- ■ Recruitment Feasibility Assessment (23)
- ■ Recruitment & Retention Planning (47)
- ■ Recruitment Materials (34)
- ■ Community Engagement Studio (16)
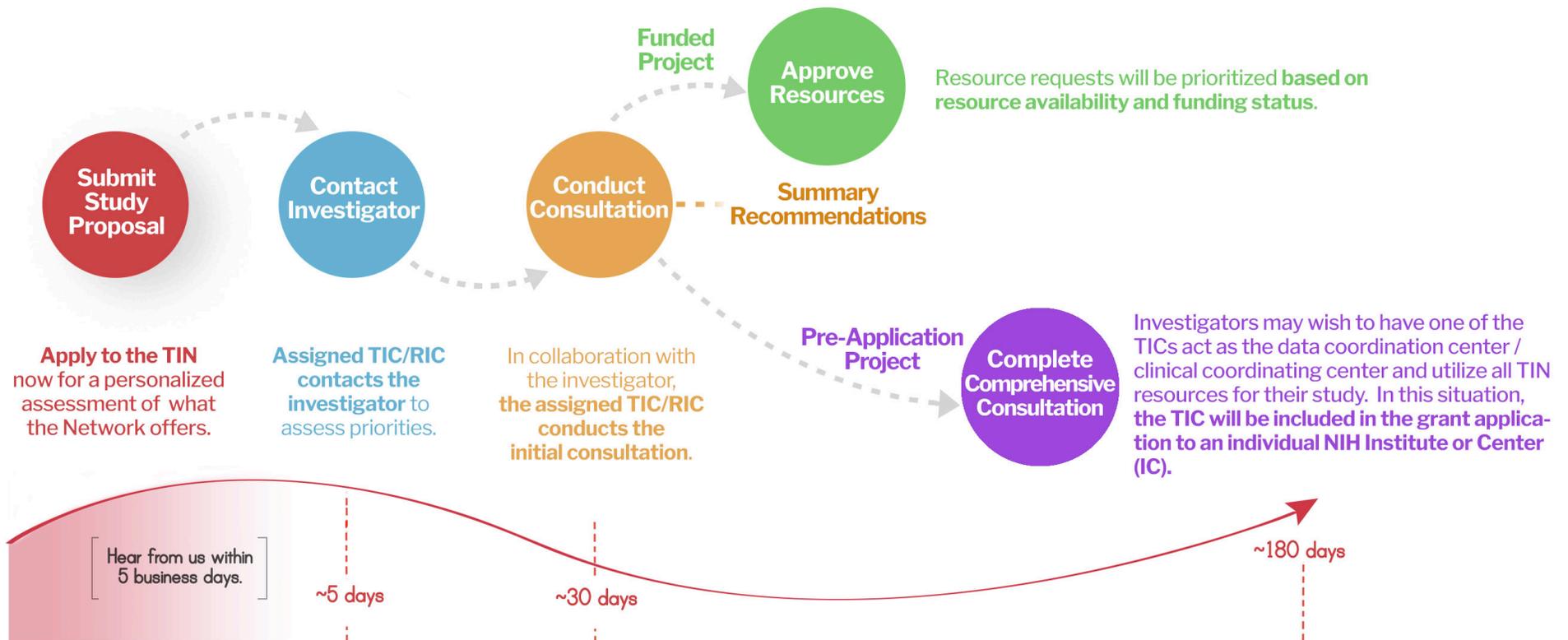- ■ EHR Cohort Assessment (17)
- ■ Other (30)

Number of Sites Recruited for Trials:

# of Sites per Proposal

(51+ sites) 21

(31-50 sites) 16

(1-5 sites) 70

(11-30 sites) 49

(6-10 sites) 63

Steps to Submit

Using the Trial Innovation Network to Plan Your Trial

Submit Study Proposal

Apply to the TIN now for a personalized assessment of what the Network offers.

Contact Investigator

Assigned TIC/RIC contacts the investigator to assess priorities.

Conduct Consultation

In collaboration with the investigator, **the assigned TIC/RIC conducts the initial consultation.**

Funded Project

Approve Resources

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

Summary Recommendations

Pre-Application Project

Complete Comprehensive 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).**

Hear from us within 5 business days.

~5 days

~30 days

~180 days

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

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*

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*](mailto:clinicaltrialsfinder@ucsf.edu)

UCSF Catalyst Program

Translational accelerator advancing UCSF discoveries with clinical relevance & commercial potential

Therapeutics   **Diagnostics**   **Medical Devices**   **Digital Health**   **Biotools**

- **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?