



Institute for Translational Neuroscience

Competitive Research Program Request for Applications July 1st, 2015

COLLABORATIVE TRANSLATIONAL PROGRAM AND RESEARCH GRANT OPPORTUNITY

The problem of alcohol and substance use disorders (AUD/SUDs) in the US Armed Forces is now a public health crisis. SUDs in the military often present with comorbid psychological health and neurological conditions such as post-traumatic stress disorder (PTSD), major depression, and traumatic brain injury (TBI). Research programs of the Institute for Translational Neuroscience (ITN) will be designed to accelerate development of new, medication-based treatments to mitigate the impact of SUDs, particularly in the military/veteran context.

An FY2013 congressional appropriation via the Congressionally Directed Medical Research Program (CDMRP) of the US Army/Department of Defense (DoD) will fund the grants under this RFA. The CDMRP organizes multidisciplinary, team-based translational research efforts to expedite the process of identifying promising beneficial compounds to conducting human proof-of-principle clinical trials. If successful, this approach could result in translation of contemporary basic science knowledge into enhanced clinical pharmacological treatment protocols for alcohol and substance use disorders.

The objective of the ITN is to bring together investigators, including basic, translational, and clinical scientists, into cooperative and synergistic working teams. The goals of these teams will be to **identify and develop new medications and protocols for treatment of SUDs in the military/veteran context**. The goal of this RFA is to identify the pre-clinical PoP projects with the most promise to be continued through Extend-and-Confirm (EC) Awards.

In this round we expect to commit up to \$2,500,000 to Pre-Clinical PoP Awards.

PoP Awards

Up to \$250,000 in total costs will be awarded for a first year of funding for each PoP award with an animal model or other, non-clinical focus. Collaborations between and among investigators are encouraged in formulating PoP proposals and conducting the funded studies. Although a strong rationale should be provided, unpublished preliminary data will not be required. Examples of potentially fundable PoP projects include: identification of interacting components that regulate the activity of a receptor and molecules that interact with these components; characterization of rodent behavioral responses to chemical compounds that alter the activities of regulatory components. Preclinical animal models for these comorbidities, which may support screening of new medications for their alcohol and substance use efficacies, are thus expected to model AUDs and/or SUDs in the context of, for example, recent exposures to traumatic stress.

The ITN is pleased to invite researchers from institutions that are members of the Coalition for Translational Research Centers in Alcohol and Substance Use Disorders to submit proposals for PoP Awards.

ITN CONSORTIUM MEMBER INSTITUTIONS

- Boston VA Research Institute, Inc.
- Boston University Medical Campus
- Columbia University
- Harvard Medical School
- Medical University of South Carolina
- Meharry Medical College
- Northern California Institute for Research and Education
- Oregon Health & Science University
- The Scripps Research Institute
- Seattle Institute for Biomedical and Clinical Research
- University of California, Berkeley
- University of California, Davis
- University of California, San Diego
- University of California, San Francisco
- University of Florida
- University of Pennsylvania
- University of Texas at Austin
- University of Washington
- VA San Diego Healthcare System
- Yale University

Collaborators from institutions other than the Consortium member institutions are allowed, and subcontracting to such institutions is permitted.

KEY DATES

Preproposals: Firm deadline is September 1, 2015, 5:00pm PST

Proposals: Firm deadline is October 15, 2015, 5:00pm PST

Planned Start Date: February 1, 2016

OBJECTIVE

The ITN Awards are designed for collaborative teams and individual investigators to develop innovative research directions in furtherance of the mission of the ITN Program. Specifically, EC Awards will be judged by their potential to accelerate the development of new treatments targeting SUDs in the military/veteran context. Additional Proof-of-Principle and/or EC Awards may be announced in future years, depending on funding.

MILITARY RELEVANCE

Alcohol and drug abuse among military personnel and veterans are increasingly recognized as serious challenges to military readiness and individual health. SUDs and comorbidities such as PTSD, for example, are interrelated conditions frequently affecting the same individual. Traumatic stress such as that from exposure to combat can promote heavy drinking, and recovery from PTSD is complicated by concomitant alcohol abuse. Alcohol and substance abuse confounds current therapeutic approaches to PTSD and other comorbid conditions. For many patients current treatments have limited efficacy. The close linkage and interaction between stress and alcohol abuse, for example, makes it imperative to understand how these conditions interact at the level of neurobiology and to develop treatment approaches that address both problems.

Successful applications will have been responsive to these issues and will have clearly indicated the relevance of their proposals to the development of new medications and protocols for the treatment of SUDs in the context of neuropsychiatric comorbidities.

PoP Award REQUIREMENTS

The proposals must adhere to the following guidelines:

- Proposals are expected to describe their relevance to the development of therapeutic medications for the treatment of AUDs and SUDs in the context of psychological and/or neurological health conditions impacting military personnel or veterans. Proposals should be directly relevant to a translational or clinical goal.
- Funding in future years may be increased or decreased depending on funding availability and significance of progress. Annual reviews and quarterly discussions of progress will be required.
- Awards may be terminated at the end of any funded year.

PREPROPOSAL

The Preproposal will essentially describe what the PoP project is intended to accomplish and what that accomplishment would mean in the context of the goals and mission of the ITN. The template for a Preproposal is included with this RFA. No deviation from this template will be accepted.

Title and Affiliations: Page 1 will include the title, names and affiliations of the Principal Investigator and Co-Investigators involved in the project.

Abstract: Page 2 will be an abstract that clearly includes a description of the area(s) of research that will be the focus of the PoP Award. The specific goals of the projects, including their potential general, as well as military, significance should be included.

Please submit preproposals via email **by 5:00pm (PST), September 1, 2015** to jennifer.mitchell@ucsf.edu.

APPROVAL OF THE PREPROPOSAL WILL LEAD TO AN OPPORTUNITY TO SUBMIT A COMPLETE RESEARCH PLAN FOR A POP AWARD.

PROPOSAL

The Complete Research Plan will adhere to the proposal instructions, which have been included with this RFA.

Institutional Approval. Approval and sign off by the appropriate institutional representative is required. Other compliance documents will also be required as per standard DoD requirements after the selection.

Proposal Submission Process

Please submit proposals via email **by 5:00 p.m. PST, October 15, 2015** to jennifer.mitchell@ucsf.edu.

If the Proposal is identified as one likely to be awarded, a request may be sent to the applicant organization requesting certain information and documents, including:

Updated Other Support

Use of Vertebrate Animals, including protocols
Certificate of Environmental Compliance
Facility Safety Director/Manager Assurance
Principal Investigator Assurance
Facility Safety Plan Status Report
Representations for Assistance Agreements
Certifications and Assurances for Assistance Agreements
IDC/F&A Rate Agreement.

POST-AWARD INSTRUCTIONS

Applicants are advised of the following requirements for post-award reporting:

Concise, quarterly reports on scientific progress at dates as advised by the ITN Program Manager;
Annual scientific reports;
Annual animal use reports;
Grant holders will be requested to attend annual product line review meetings with CDMRP in Washington, DC or another location to be determined;
Further report instructions will be disseminated to awardees.

REVIEW PROCESS

Proposals will be read and evaluated by DoD and ITN staff for compliance with submission requirements and military relevance. Proposals that meet these requirements will then be submitted to the ITN Advisory Council for review.

ITN Scientific and Technical Reviewers may serve in an advisory role to the ITN Advisory Council as needed.

For those projects that require animal and/or human subject's protocol approval, final acceptance will be contingent upon official DoD approval of the protocol submitted to the appropriate IACUC and/or CHR committee(s). Thus, if selected, investigators are encouraged to submit their supporting documentation and protocol approval letters to the DoD and the ITN Program Manager as soon as possible.

QUESTION & CONCERNS

Please direct any questions or concerns regarding this RFA to Connie D'Aura, Program Manager, or Jennifer Mitchell PhD, Director, Institute for Translational Neuroscience, UCSF.

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