

Please Note: This announcement is for two companion funding opportunities

UCSF May Submit 1 Application to each RFA

Internal Deadline: 11:59 PM, Monday, February 11th, 2019

PLEASE FORWARD THIS ANNOUNCEMENT TO ALL APPROPRIATE FACULTY AND RESEARCH ADMINISTRATORS

NIH NCI The Experimental Therapeutics Clinical Trials Network (UM1 Clinical Trial Required):

REQUEST FOR APPLICATIONS NUMBER: RFA-CA-19-007 (<https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-19-007.html>)

PURPOSE:

- To continue support for the Experimental Therapeutics Clinical Trials Network (ETCTN) for the efficient and comprehensive conduct of early phase clinical trials of NCI Investigational New Drug (IND) agents
- The ETCTN is designed to assure the availability of investigators and programs with expertise in early drug development and translational research for this purpose.
- This FOA solicits UM1 cooperative agreement applications from appropriate multidisciplinary groups that can assemble an appropriate infrastructure and conduct phase 0, phase 1, phase 2, pilot and other experimental therapeutics clinical trials involving agents for which the NCI's Division of Cancer Treatment and Diagnosis (DCTD), Cancer Therapy Evaluation Program (CTEP) received IND status

ELIGIBILITY:

- The FOA is open to any qualified applicant regardless of whether they have been previously associated with the ETCTN
- Individual(s) designated as PI on the applications for ETCTN awards are expected to be nationally- and internationally-recognized leaders in cancer-related clinical trials of novel therapeutic agents, translational research, and related clinical areas relevant to such studies. These individuals should also be recognized leaders in the relevant areas of science and have documented administrative leadership experience

BUDGET AND PROJECT PERIOD:

- Award Budget: up to \$1,250,000 direct costs per year
 - UCSF indirect cost policy will apply except for non-federal entities.
- Project Period: 6 years

NIH NCI The Experimental Therapeutics Clinical Trials Network (ETCTN) Pharmacokinetic Resource Laboratories (U24 Clinical Trial Not Allowed):

REQUEST FOR APPLICATIONS NUMBER: RFA-CA-19-008 (<https://grants.nih.gov/grants/guide/rfa-files/rfa-ca-19-008.html>)

PURPOSE:

- To create Pharmacokinetics Resource Laboratories (PK Laboratories) that will support the Experimental Therapeutics Clinical Trials Network (ETCTN)
- The PK Laboratories will be expected to organize specimen collection and subsequent analysis of pharmacokinetic endpoints, drug-drug interactions, cytochromes P450 (CYP) interactions, and food effects in ETCTN studies of NCI Investigational New Drug (IND) agents.
- The overarching goal of the ETCTN PK Laboratories is to advance the clinical development of NCI-IND agents through achieving comprehensive understanding of pharmacokinetic behavior of these agents studied in ETCTN protocols.
- The ETCTN Pharmacokinetic Resource Laboratories will assure the availability of physicians, clinical pharmacologists, nurses and scientists who have the appropriate expertise in pharmacokinetic studies for early drug development and translational research.
- This FOA seeks U24 cooperative agreement applications from multidisciplinary groups that will conduct all pharmacokinetic studies for ETCTN early phase clinical trials filed to the IND applications in NCI's Division of Cancer Treatment and Diagnosis (DCTD), Cancer Therapy Evaluation Program (CTEP)

ELIGIBILITY:

- Individual(s) designated as PI are expected to be national and international leaders in cancer-related pharmacokinetic studies for early phase clinical trials of novel therapeutic agents and translational research.
- Proposed investigators must be highly capable of inter- and trans-disciplinary team-based research with investigators involved in the design and conduct of clinical trials.

BUDGET AND PROJECT PERIOD:

- Award Budget: up to \$320,000 direct costs per year
 - UCSF indirect cost policy will apply except for non-federal entities.
- Project Period: 6 years

DUE DATES:

- **Internal: 11:59 PM**, Monday, February 11th, 2019. If multiple groups submit an LOI, an additional pre-application will be due Wednesday, February 20th, 2019.
- **Please note PIs may submit directly to the LSP; RMS does not get involved unless and until you are nominated**
- Sponsor: Wednesday, May 22nd, 2019.

Submit the attached Letter of Intent (LOI) by 11:59 PM, February 11th, 2019, to:
limitedsubmissions@ucsf.edu

To qualify for UCSF Limited Submission Program opportunities, applicants must have a paid UCSF appointment either at the time of application or anticipated by the time of award.

The LSP is a selection process, not an award process. As the LSP is under significant time constraints, all reviewer feedback is optional. We encourage you to seek other avenues for proposal feedback.

For information on all current LSOs, please visit: <http://rdo.ucsf.edu/limited-submission-program-lsp>

Sent by Lisa Howard on behalf of the Research Development Office (RDO), Limited Submission Program (LSP)