2019 Clinical and Translational Research Funding Program

Program Overview

The Washington University Institute of Clinical and Translational Sciences (ICTS) announces the 13th annual Clinical and Translational Research Funding Program (CTRFP). The primary purpose of this program is to advance medical knowledge by funding high quality, innovative proposals that promote the translation of scientific discoveries into improvements in human health. The CTRFP provides up to $50,000 direct costs for 1 year to support pilot projects that include a concrete plan for further steps beyond the pilot grant.

Annually, the CTRFP receives over 100 applications and awards approximately $1M for 20 investigator-initiated projects. These projects are supported with funding from the ICTS and our partner institutions: The Foundation for Barnes-Jewish Hospital, Saint Louis University, and the University of Missouri- Columbia. In addition to projects of broad clinical/translational interest, special topic area will be given special consideration, as outlined below:

- **General Clinical/Translational Projects** whose goals are to promote the translation of scientific discoveries into improvements in human health.
- **Collaborative Projects** involve multidisciplinary groups of research teams from at least two ICTS partner institutions. Each investigator must have a defined role in the research project. A lead PI must be identified and a subcontract must be included for the collaborating institution.
- **Community-Engaged Research Projects** involve established partnerships with communities and/or stakeholders whose health and well-being and/or service provision could be most impacted by the research.

Additional consideration will be given to proposals that address the national opioid epidemic, including early stage translational research (improve understanding of pain, discovery and evaluation of innovative treatments) and late stage research (strategies to restrict opioid supply, influence prescribing practices, preventing addiction and overdose fatalities).

Applications for start-up costs for new Clinical Research Cores will not be considered this year.

SUBMISSION & REVIEW PROCESS

Notification of Intent Deadline:	Monday, July 22, 2019 (5 pm, CT)
Application Deadline:	Monday, August 19, 2019 (5 pm, CT)
Proposal Peer Review:	October 2019
Award Decisions:	December 2019
Award Start Date:	Sunday, March 1, 2020

Step 1, NOI:
PI submits required electronic Notification of Intent (NOI) Form through the online submission process at https://wucrtc.az1.qualtrics.com/jfe/form/SV_3f3FEzQAdghcJBH by **5:00PM (CT)** on **Monday, July 22, 2019**. (See NOI Instructions and Form). This deadline is strict with **NO exceptions.** Program Committee reviews NOI on a rolling basis and will respond to applicant by July 26, 2019 regarding eligibility of the project for submission of full proposal.

Projects identifying as “community-engaged” will be reviewed by investigators with expertise in this area. Reviewers will assess the appropriateness and role of the proposed partner, relevance of the research topic to the community of interest, and sustainability.

Step 2, Application:
After NOI review, the PI will be provided access to the online application to submit a full proposal which is due on **Monday, August 19, 2019 at 5:00PM (CT).** The electronic application *must be received by this date/time.* This deadline will be strictly adhered to with **NO exceptions**.

Step 3, Review:

- **General Pilot and Collaborative Grants:** Proposals will be assigned to three experienced scientific reviewers and evaluated in a full review panel similar to NIH Study Section. A member of the Biostatistics, Epidemiology, and Research Design (BERD) Program also submits a written review and is a standing member of the panel. Applicants will receive a Summary Statement including comments from the scientific peer reviewers and will be notified of funding decisions in December.

- **Community-Engaged Research Projects**: Projects using a participatory approach with community and/or stakeholder partners will be reviewed by a panel of non-academic representatives and investigators with expertise in community and stakeholder engagement.

Step 4, Award:
Awardees must obtain all regulatory approvals (e.g. IRB, IACUC) and meet all compliance requirements prior to receiving funds for the March 1st start date.

PROGRAM CONSIDERATIONS

The scientific quality of the proposal will be the most important criterion used in the review process. In developing applications to this RFA:

- Projects that involve animal models must include a **DIRECT and CLEAR LINK** to human health or disease. Such proposals must identify how the project will allow direct translation of findings into human subjects, how human subjects or tissue will be used, and the importance of possible findings for understanding human disease/physiology.
- Applicants are strongly encouraged to seek **methodologic and study design consultation** with ICTS shared resources EARLY in the proposal development process. Requesting assistance after July 22nd may not allow sufficient time.
  Consider consulting with the following ICTS cores prior to submission of the NOI:
  - **Biostatistics, Epidemiology, and Research Design** (BERD) offers a BioStat Clinic, an hour-long consultation service that is fully subsidized for ICTS members. Online appointment scheduling available.
  - **Center for Community Health Partnership and Research** (CCHPR) can assist with developing key stakeholder and community engagement activities, from planning through dissemination. Submit a consultation request here.
  - **Center for Administrative Data Research** (CADR) serves to provide training in the use of health services administrative data in clinical epidemiologic, health series and outcomes research.
  - **Dissemination and Implementation Research Core** (DIRC) provides expertise to advance translational (T3 and T4) research to move health practices from clinical knowledge into routine, real-world use.
- Applicants are encouraged but not required to include use of ICTS cores & services to support their proposed research and to consult with core personnel during the development of their proposal to discuss application of available ICTS tools and services. Information about available cores & services can be found on the ICTS website or through email (icts@wustl.edu).
- BJC employees without prior experience in applying for research funds should collaborate with an experienced university or hospital-based researcher in order to create a more competitive application.

INVESTIGATOR CATEGORIES

Investigators in the following categories are encouraged to apply.

- New & Early Stage Investigators: A New Investigator (NI) is an NIH research grant applicant who has not yet competed successfully for a substantial, competing NIH research grant. For a complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator, see the NIH Definition of New Investigator. An Early Stage Investigator (ESI) is a new investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant.
- Established investigators who are working in other fields, but are interested in exploring new directions in clinical and/or translational research.
- Established investigators already active in the field of clinical and/or translational research, but whose proposed project is different from their previous work.

TYPES OF STUDIES SUPPORTED

This program is designed to support a broad range of clinical and translational studies including, but not limited to, the following:

- **Novel Methodologies and Technologies:**
  Funds may be requested to develop new technologies with strong promise for being introduced into humans in the short term (< 5 years). Funds may also be used to develop methods that could be applied in humans, e.g. methods to improve the phenotyping of human subjects (mass spectrometry in biomarker development, novel imaging approaches, stable isotope turnover methods). Methodologies that are not technologically based are also eligible for funding (e.g. new methodological approaches to problems in biostatistics and clinical trial design, novel approaches to implementing community-engaged research and outcomes studies).
- **First-in-Human Studies:**
  These funds are specifically intended to support costs related to bringing new technologies (diagnostic or therapeutic) into humans for the first time.
- **Process Improvement:**
  Funds may be requested for pilot programs aimed at demonstrating the value of new processes to facilitate clinical research or for research related to process improvement. Research intended to develop improvements in study design, statistical analytic approaches, research ethics, or harmonization of regulatory processes would all come under this category.
- **Collaborative Projects:**
  The WU ICTS is interested in promoting inter-institutional collaborations between WU and the ICTS partners. Pilot funds are available for investigator teams with proposed projects that consist of multidisciplinary groups of research teams from at least 2 partner institutions working on a common clinical or translational research project. A lead PI must be identified and a subcontract must be included for the collaborating institution.
- **Community-Engaged Research Projects:**
  Projects are sought that involve established partnerships with communities and/or stakeholders whose health and well-being and/or service provision could be most impacted by the research. Stakeholders and community members may include: patients and their families; community leaders and staff in community-based organizations; health and mental health care providers, support staff and administrators in locations like clinics, hospitals, long-term care facilities, schools, non-profit organizations, and home-based programs; governmental agencies; individuals and/or groups who influence or enact healthcare policy. *These projects require a participatory approach: communities and/or stakeholders whose health and well-being and/or service provision could be most impacted by the research must have an active role in the development, implementation, and dissemination of the research.*

Regardless of the type of study, we encourage investigators to consider involving groups that are frequently underrepresented in clinical and translational research.

PROPOSAL FOCUS

The following definitions for the stages of translational research are used when categorizing proposals for review (T1-T4):

- **T1 Research – Translation to Humans:**
  The translation of new understandings of disease mechanisms gained in the laboratory into the development of new methods for diagnosis, therapy, and prevention, and their initial testing in proof-of-concept studies in humans
- **T2 Research – Translation to Patients:**
  Translation of initial research findings to test initial hypotheses and/or approaches in clinical applications, encompasses early stage clinical trials through larger scale, multi-center trials
- **T3 Research – Translation to Practice:**
  Effectiveness, cost effectiveness, and comparative effectiveness studies conducted in practice sites, ensuring the translation of results from clinical studies into clinical practice settings
- **T4 Research – Translation to Population:**
  Dissemination and implementation research, which identifies and resolves barriers to implementation of evidence-based guidelines into community practice

Please refer to the Application Instructions document for specifics regarding eligibility, how to apply, and budgetary guidelines.