

Clinical and Translational Research Funding Program

2017 Program Overview

The Washington University Institute of Clinical and Translational Sciences (ICTS) announces the 11th 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.

PROGRAM PROCESS OVERVIEW

Letter of Intent Deadline:	Wednesday, July 26, 2017 (5 pm, CT)
Application Deadline:	Friday, September 8, 2017 (5 pm, CT)
Proposal Peer Review:	October, 2017
Award Decisions:	December, 2017
Award Start Date:	March 1, 2018

Town Hall for Applicants (information sessions):

Webinar Option 1: **Thursday, July 6th** from 5:00 – 6:00 p.m.

<https://wustl.adobeconnect.com/ctrfp-town-hall-1/>

Webinar Option 2: **Friday, July 7th** from 11:00 a.m. – 12:00 p.m.

<https://wustl.adobeconnect.com/ctrfp-town-hall-2/>

If you have never attended an Adobe Connect webinar before, please test your connection prior to the meeting: https://wustl.adobeconnect.com/common/help/en/support/meeting_test.htm

Step 1: PI submits required electronic Letter of Intent (LOI) Form through the online submission process at <https://is.qd/2017CTRFundingProgram> by **5:00 p.m. (CT)** on Wednesday, July 26, 2017. (See [LOI Instructions and Form](#)). This deadline will be strictly adhered to with **NO exceptions**.

Step 2: Program Committee reviews LOI and responds to applicant by August 2, 2017 regarding whether the LOI is eligible for submission of full proposal.

- Projects involving a community partner or taking place within the community will be reviewed by an investigator with expertise in Community-Engaged Research. Reviewers will assess appropriateness of the proposed partner, relevance of the research topic to the community of interest, and sustainability. Feedback from this review will be shared with the PI by August 2, 2017. If invited to submit a full proposal, recommendations raised during the preliminary review must be addressed.

Step 3: If invited, PI will be provided access to the online application to submit a full proposal. (See [Application Instructions section and Forms](#)). **Deadline: Friday, September 8, 2017 at 5:00 p.m. (CT)** The electronic application *must be received by this date/time*. This deadline will be strictly adhered to with **NO exceptions**.

Step 4: Projects involving a community partner or taking place within the community will be reviewed by a panel of community representatives and investigators with expertise in Community-Engaged Research. **A summary of this review will be shared at the scientific study section.**

Step 5: Proposals will be assigned to three experienced scientific reviewers and then evaluated in a full review panel similar to an NIH Study Section. A member of the Research Design and Biostatistics Group (RDBG) 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.

Step 6: Awardees must obtain all regulatory approvals (e.g. IRB) and meet all compliance requirements prior to receiving funds for a March 1st start date.

AVAILABLE FUNDING

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 including The Foundation for Barnes-Jewish Hospital, Saint Louis University, and the University of Missouri-Columbia.

Awards will be made for:

- **Pilot Grants:** Provide up to \$50,000 direct costs for 1 year to facilitate the planning of a new clinical and/or translational research project. Pilot grants are typically used to fund developmental or early stage work, including pilot data, and should describe a concrete plan for further steps beyond the pilot grant.

ELIGIBILITY

- Applicants must be a registered member of the ICTS **before submitting a LOI**. [Online registration](#) takes less than 5 minutes and is available along with eligibility information. For assistance with registration, contact the ICTS Administrative Core office through email (icts@wustl.edu) or by calling 314-362-9829.
- Applicants from WU or its ICTS Partner academic Institutions must hold a faculty level appointment. Fellows in the final year of training with a letter of commitment from their department head for a faculty position effective by the time of award are also eligible.
- Employees of BJH, Goldfarb School of Nursing, or SLCH (MD, PhD, nurse, or allied healthcare professional) may apply with the permission of their department director.
- Community-based organizations or Affiliate Institutions (Southern Illinois University Edwardsville School of Nursing and University of Missouri at St. Louis College of Nursing) may apply in collaboration with an investigator from one of the ICTS partner institutions. (The PI of the proposal must be from an ICTS partner institution.) If interested in forming new collaborations, contact the ICTS Administrative Core (email icts@wustl.edu or 314-362-9829).
- Applicants may be the Principal Investigator on **only one LOI and one proposal**. There can be only ONE Principal Investigator on an application. The program does not allow for co-PIs or multi-PIs.
- PIs with active awards under the previous Clinical and Translational Research Funding Programs are not eligible to apply unless their current funding will expire by 3/1/18 when the new awards will begin. **If previously funded through this program, it is unlikely that a PI will be successful in obtaining funding in the same area of research for a second submission.**
- There is no specific citizenship requirement for the applicant.

INVESTIGATOR CATEGORIES

Investigators in the following categories are encouraged to apply.

- New investigators in either clinical or translational research who do not yet have their own peer-reviewed research support. NIH 'New Investigator' definition: The individual has not competed successfully for a significant independent research award. In terms of NIH awards, the PI still fits into the New Investigator category if he/she only received such awards as a Mentored Career Award (K08, K12, K23, etc.) or small or early stage research awards, including R03, R15, R21, etc. This same logic would also apply to funding from other agencies.
- 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.
- Investigators collaborating with community-based organizations.
- Investigators developing inter- or multidisciplinary groups working on novel methodologies or research teams working on a clinical problem of interest and importance.

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 August 2nd may not allow sufficient time to provide suggestions. Consider consulting with the following ICTS cores prior to submission:
 - Research Design and Biostatistics Group ([RDBG](#)) offers a BioStat Clinic, an hour-long consultation service that is fully subsidized for ICTS members. On-line [appointment scheduling](#) is available and is strongly recommended during the planning phase of project development prior to the LOI deadline.
 - 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.
 - Community Health Partnership and Research ([CCHPR](#)) works to reduce disparities and improve health and wellness in the St. Louis region by fostering bidirectional communication and supporting community-academic partnerships and research endeavors
- 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.

Acceptable Research Themes

Applications must address at least one of the following research themes (propose to advance science in at least one of the following areas of program interest)

- Improving the Quality of Patient Care: Increasing the likelihood of achieving outcomes valued by patients and their families, including exceptional disease-specific survival rates, minimum hospital readmission rates for chronic diseases, superior patient satisfaction with care, improved patient functional status, best possible quality of life consistent with patient needs, and patient/family understanding of, and involvement in, their medical care.
- Enhancing Patient Safety: Exploring reliable care processes to prevent all errors that result in preventable mortality, health care acquired infections, adverse drug events, falls with injury, pressure ulcers, venous thromboembolism, wrong site/wrong person procedures, or other preventable surgical and procedural complications.
- Improving Patient Outcomes: Research where the results from hypothesis testing will potentially impact desirable health outcomes. For example: more accurate or earlier diagnosis, reduced disability, increased survival, decreased morbidity, identification of risk factors, and design of reliable and effective care delivery processes.
- Improving Transfer to Practice: Conduct comparative effectiveness and dissemination and implementation research to improve the transfer of clinical research discoveries into practice.
- Translating Genetic/Genomic Findings: Translate the findings of genetic/genomic research into studies that advance biomedical knowledge and improve human health, including tools for prevention, diagnosis, and treatment of human diseases.
- Development/Evaluation of Therapeutics: Accelerate the development and evaluation of new therapeutics, including drugs, biologics, devices, diagnostics, and behavioral therapies to improve human health.

Proposal Focus

The following definitions for the stages of translational research will be 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

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.
- Community-Engaged Projects: Projects are sought that are jointly conducted with a community-based organization and performed in an outpatient setting or in community-based settings rather than health care settings. Community-engaged projects should seek to better define risk factors for health and disease, or to perform interventions aimed at reducing health risks, improving health behaviors, or producing measurable changes in health status.
- Active Partnerships

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

SUBMISSION AND REVIEW PROCESS

Letter of Intent – Applicants must complete the LOI Form and submit through the online submission process no later than **5:00 p.m. (CT)** on Wednesday, July 26, 2017 at <https://is.qd/2017CTRFundingProgram>. (See [LOI Instructions and Form](#). *Early submission, prior to July 26th, is encouraged so PIs invited to submit a full application have more preparation time.*

Each letter of intent (LOI) will be reviewed to determine the eligibility of the PI and whether the anticipated project is relevant to clinical and/or translational research and is within the scope of the RFA. If the LOI is judged appropriate by these criteria, the applicant will be notified that a full proposal may be submitted.

Full Proposal – Upon notification that the LOI has been approved, the PI may submit a full proposal using the required forms and instructions. (See [Application Instructions section and Forms](#)). The electronic copy of the entire proposal (submitted through the online application process) must be received by the ICTS Admin Core office **no later than 5:00 p.m. (CT)** on September 8, 2017.

Review Process – Proposals involving a community partner or taking place within the community will be reviewed by a panel of community representatives and investigators with expertise in Community-Engaged Research. These proposals will be evaluated for 1) relevance of the research question to the community of interest, 2) the role of and benefit to the community partner/organization, 3) approach and methodology, and 4) whether the research presents an opportunity for sustained impact. **A summary of this review will be shared at the scientific study section.**

All proposals will be assigned to three experienced scientific reviewers and then evaluated in a full review panel similar to an NIH Study Section. Assigned reviewers and panel will include individuals from Washington University as well as the various ICTS partner institutions. A member of the RDBG (Research Design and Biostatistics Group) also submits a written review and is a standing member of the panel. The Biotechnology and Life Science Advising (BALSA) group provides a written analysis of translation and commercialization of research findings. Each applicant is provided a critique of their proposal in the form of a Summary Statement, which will include comments from the assigned reviewers. Reviewers will be asked to consider the following key criteria: 1) application to acceptable theme(s), 2) translational aspect, 3) significance, 4) approach, 5) innovation, 6) environment and 7) investigators. For details and complete list of review criteria, refer to the [Review Criteria](#) reference document.

AWARD PROCESS/TERMS

Awards will be issued in accordance with the mission and priorities of each partner institution and in compliance with funding source guidelines. The Notice of Award will detail budget information, publication citation language, progress report requirements, etc.

QUESTIONS

Questions and/or assistance with proposal development may be addressed to icts@wustl.edu, Andi Cox (acox23@wustl.edu or 314-362-7707) or Jaimee Stagner (jstagner@wustl.edu or 314-362-6325).

For questions and/or assistance with online submission: Contact icts@wustl.edu or Beth Mott (emott@wustl.edu or 314-362-1539).