2019 Clinical and Translational Research Funding Program

Application Instructions

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

ELIGIBILITY

- Applicants must be a registered member of the ICTS before submitting a NOI. Online registration takes less than 5 minutes. For assistance, contact the ICTS Administrative Core (icts@wustl.edu) or by calling 314-362-9829.
- Applicants from WU or 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. A letter of support from the director is required in the application.
- Community-based organizations or Affiliate Institutions (e.g. 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. If interested in forming new collaborations, contact the ICTS Administrative Core (icts@wustl.edu 314-362-9829).
- Applicants may be the Principal Investigator on only one NOI 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 2/29/20, prior to the new award start date. If previously funded through this program, it is unlikely that a PI will be successful in obtaining funding in the same area of research under a second submission.
- There is no specific citizenship requirement for the applicant.

proposalCentral Information

proposalCentral will be used to collect a portion of the required data for this application submission.

Project Start/End Dates: 03/01/2020 – 02/28/2021

Resource Sharing, (See PI certification checkbox on Title Page.):
The ICTS considers the timely release and sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with ICTS funds and the associated research findings published, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. Investigators applying for ICTS assistance are required to affirm that they will share data, research resources, model organisms, or software that will be developed, or to explain why data-sharing is not possible.

Investigators are expected to participate in the timely release and sharing of final research data from all studies that are carried out with the assistance and/or support of the ICTS. The definition of "timely release and sharing" is no later than the acceptance for publication of the main findings from the final data set.

Shared research data will be required to have "low re-identification potential", by removing the 18 demographic data elements listed by the HIPAA as person-identifiable. More description of NIH data sharing policies is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html and http://grants.nih.gov/grants/gwas/.

If there are issues surrounding compliance with the ICTS Resource Sharing Plan (provided below), include justification after section "I".

Signatures:

- Principal Investigator - The signature of the PI is required on the Face Page for all applications.
- Other Approval Signatures - Official Signing for Applicant Organization:
  - Washington University (WU) applicants do **not** need a signature under "Official Signing for Applicant Organization".
  - For investigators from institutions other than WU, approval signatures must be provided from the Institutional Official of the applicant organization. (Note: Barnes-Jewish Hospital (BJH) applicants are required to obtain BJH Office of Research Affairs approval signature prior to submission.)
    - The signature of the "Official Signing for Applicant Organization" on the Face Page signifies that the applicant organization understands and agrees to the following statement:

      The appropriate programmatic and administrative personnel of each organization involved in this grant application are prepared to establish the necessary contractual agreement consistent with applicable policies.

Note: If a WU application is selected for funding through The Foundation for Barnes-Jewish Hospital (FBJH), institutional review and signature will be required through the WU Office of Sponsored Research Services before funds will be released**.**

The signed face page should be uploaded to the proposalCentral system for submission. *Do not upload a printout of other proposalCentral webpages.*

Regulatory Approvals:
If the research involves the use of animals (IACUC) and/or human subjects (IRB), the Investigator must provide a copy of the IACUC and/or IRB approval letter to the awarding institution before award funds will be released. **Note: 'Pending' approvals at the time of application submission are acceptable.** Please use the date of 01/01/2000 in proposalCentral, if your approval is still pending.

Research Theme(s) (check all that apply): Provide a description of how your proposed project is relevant to one or more of the ICTS Research Themes. *See Program Overview for Theme descriptions.*

Established Investigators: Be prepared to describe how this project will lead to a new direction in your research or is different from your previous work (if applicable). *See Program Overview for Investigator definitions.*

Short project description: Please use layman's terms. This will be used on the website, if awarded.

Abstract: Provide abstract of project.

Impact: Considering the significance, approach, innovation and the environment as described in your proposal, describe the potential impact for this project to exert a sustained influence on the research field(s) involved. Be specific about the steps necessary for this project to reach human application using language easily understood by reviewers outside of your area of specialty

Estimate of percentage of activity in a laboratory setting vs. a non-laboratory/other setting *(this is for administrative purposes only, and will not be considered during scientific review)*

Performance site/short resource description: Indicate where the work described in the Research Plan will be conducted. Include the name of the organization(s) and the city. In addition, provide a ***brief*** listing or description of any specifically required resources or facilities you will be using to carry out the proposed project so that reviewers will see that you have access to the necessary resources to conduct your project.

Previous Funding: If you or one of your collaborators previously received funding from the CTRFP for the same project, describe how the proposed project differs from that which was already funded.

Stakeholders and Active Partnerships: Describe active partnerships with key stakeholders and community members in the context of this research proposal. 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. Discuss 1) the relevance of the research question to the stakeholders or communities of interest; and 2) your active partnerships with key stakeholders in the context of this research proposal.

Budget Summary: Complete the Budget Summary Page for the period of 03/01/2020 - 02/28/2021. Costs submitted on this page **must be identical** to those on the Detailed Budget Page (uploaded below) with the exception of salary/fringe detail. Only the Budget Summary Page will be shared with reviewers for confidentiality purposes.

PDF uploads for proposalCentral, FORMAT SPECIFICATIONS

- For non-form pages, use Arial 11 point font size or larger; minimum 0.5 inch for all margins
  - Figures, Graphs, Diagrams, Charts, Tables, Figure Legends and Footnotes: you may use a smaller type size, but it must be readily legible.
- On all PDF uploads, it is best to include the PI's name at the top of each page, when possible.
- **The form pages will retain their format by tabbing through the form fields**. *Pressing 'Enter' while in a form field may cause the document format to shift.*

FORM PAGE 1: PERSONNEL

List of key personnel/other significant contributors

- **Key Personnel** are key individuals, typically faculty, who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. (These individuals will have effort included on the budget or will be a paid consultant.)
- **Other Significant Contributors** are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. Unpaid consultants/collaborators should be included if they meet this definition.

FORM PAGE 2: DETAILED BUDGET PAGE(S)

Complete the ICTS Detailed Budget Page for the year requested.

- See the ICTS Budget Guidelines (pages 8-9) for detailed instructions and allowable budget items.
- This page will be submitted as a separate attachment during the online application process since it **will not be shared with reviewers for the sake of confidentiality.**

BUDGET JUSTIFICATION

Using the Continuation Format Page, **provide a justification for all costs** (both personnel and non-personnel).

- Describe the role and effort of each individual listed on the project. Do NOT include any salary figures in the justification.
- For non-personnel costs, itemize the expenses and describe how they will be used to conduct this project.

BIOSKETCHES

Submit biosketches in the current NIH format for Key Personnel and Other Significant Contributors. The biosketch is limited to five (5) pages and includes 4 sections: Personal Statement, Positions and Honors, Contribution to Science, and Research Support and/or Scholastic Performance.

RESEARCH PLAN

If this is a Resubmission application: An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and critiques noted in the Summary Statement. (Reviewers will receive a copy of the Summary Statement.) The Introduction should be placed immediately before the Specific Aims of the Research Plan, should be no longer than one page in length, *and is not part of the 5-page limit for the Research Plan.*

The Research Plan is limited to a maximum of 5 single-spaced pages for sections A - C (described below) including tables and/or figures; follow Format Specifications previously noted. A Continuation Page template is provided. The following headings should be used noting "N/A" for non-applicable sections:

A. Specific Aims: State concisely the hypothesis to be tested and the specific aim(s) to be achieved during the pilot award. The aims must be reasonable to achieve during the one-year period of the grant.

B. Research Strategy:

i) Significance:
- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field will be changed if the proposed aims are achieved.

ii) Innovation:
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

iii) Approach:
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plan as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Discuss inclusion of participants across the lifespan, or the scientific justification for exclusion.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation, and Approach for each Specific Aim individually, or may address Significance, Innovation, and Approach for all of the Specific Aims collectively.

Preliminary Studies. If applicable, include relevant information on Preliminary Studies. Discuss the PI's preliminary studies, data, and/or experience pertinent to this application as part of the Research Strategy, keeping within the sections listed above: Significance, Innovation, and Approach.

C. Next Stage Funding: Identify potential funding sources for the next stage of this project. If known, include all four of the following: name of PI for external grant submission; 2) funding agency; 3) funding mechanism; and 4) anticipated date of submission.

D. Bibliography and References Cited: Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.
The references should be limited to relevant and current literature. While there is no page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

E. Protection of Human Subjects (follow NIH guidelines): Use the NIH's Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy. Include a **Planned Enrollment Report** and a **Data and Safety Monitoring Plan,** if applicable to your project.

F. Vertebrate Animals (follow NIH guidelines): Use the NIH's Instructions for Grant Applications using PHS 398, Page 36, Section 5.5.5, "Vertebrate Animals" for guidelines. Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.

G. Select Agent Research: Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and Animal APHIS Select Agent Programs jointly maintain a list of these agents.
If the activities proposed in the application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The list of exclusions is available here.
If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of the request or the intent to apply for an exclusion and provide a brief justification for the exclusion.
If any of the activities proposed in the application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.

i) Identify the Select Agent(s) to be used in the proposed research.
ii) Provide the registration status of all entities* where Select Agent(s) will be used.
- If the Project/Performance Site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.

**An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."*

iii) Provide a description of all facilities where the Select Agent(s) will be used.
- Describe the procedures that will be used to monitor possession, use, and transfer of the Select Agent(s).
- Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).
- Describe the biocontainment resources available at all performance sites.

Questions associated with Select Agent research will need to be addressed prior to award.

H. Consortium/Contractual Arrangements:
Proposed subagreements (includes associated community organizations) must be approved by the ICTS Administration prior to submission of the application.

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). Refer to the ICTS Budget Guidelines (pages 8-9) for submission details.

The signature of the authorized organizational official on the Consortium Face Page signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the funding institution's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

I. Consultants:
List the names of consultants here. Appropriate letters confirming their roles in the project must be included in the Letters of Support Section for any paid consultants (see below).

LETTERS OF SUPPORT

Address Letters of Support to the **ICTS Funding Program Review Committee**.

- All PIs must provide a Letter of Support from the Department Head/Division Head (academic institutions) or Director/Vice President (i.e. applicable supervisor) (BJC), including a commitment that the salary support requested will be used to **protect the PI's time for research**.
- Applicants in their final fellowship year must provide a letter from their Department or Division Head detailing the intent to offer the applicant a faculty position that would be effective by the time a CTRFP award would be made and confirming the Department/Division supports an overall plan to establish an independent research career for the applicant, including allocation of protected research time.
- Support letters from paid consultants *must* be provided, while letters from unpaid consultants/collaborators are *optional*.

CHECKLIST

- ☐ Abstract, Themes & Impact, Resources, (proposalCentral)
- ☐ Key Personnel (Form Page 1)
- ☐ Detailed Budget page (Form Page 2)
- ☐ Budget Justification
- ☐ Biographical Sketch (maximum 5 pages each)
- ☐ Introduction page, ***only if this is a resubmission application***
- ☐ Sections A-C: Research Plan (5-page maximum)
- ☐ Sections D-I: Bibliography, Protection of Human Subjects, Vertebrate Animals, Select Agent Research, Consortium/Contractual Costs, Consultants, Resource Sharing (Note N/A for non-applicable sections)
- ☐ Copy of IRB or IACUC approval letter if project involves human or animal subjects
  (If approvals are marked as "pending" on the face page, this is not applicable)
- ☐ Letter of Support from Department Head/Division Head or Director/Vice President
- ☐ Letter(s) of Support from consultants/collaborators, as applicable
- ☐ Additional materials submitted as an appendix (2 appendices maximum, may be more than 2 pages in length)

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 provide detailed budget information, publication citation language, progress report requirements, etc.

CONTACTS FOR QUESTIONS

Proposal development:
ICTS Administrative Core at icts@wustl.edu.

Online submission, financial, or program guidelines:
Angie Crawford, Sr. Grant Specialist at 314-362-7707 or angelacrawford@wustl.edu.
Or
Jaimee Stagner, Associate Director of Finance at 314-362-6325 or jstagner@wustl.edu.

BUDGET GUIDELINES

ALLOWABLE DIRECT COST ITEMS

Funding provided for items essential to the conduct of the project.

Personnel

- Allowable personnel expenses include salary and applicable fringe benefits for: the principal investigator, co-investigator(s), postdocs and graduate students if employees receiving a salary, and other professional and technical staff.
- **The PI must devote effort**, even if no salary requested. Cost sharing must be described in the budget justification.
- The current NIH salary cap must be used, if applicable. Cost sharing of salary is necessary when using the salary cap or in other situations where the effort exceeds the amount of salary being requested.
- Current KL2/K12 scholars may not request support for effort already supported by their K award. This effort should be shown as cost shared on the budget form pages (show effort, no dollars) and described in the budget justification.

Consultant Costs

Provide the names and organizational affiliations of all consultants other than those involved in consortium/contractual costs and provide any expected compensation, travel and other related expenses. When applicable, signed agreements which meet all compliance requirements of the individual grantee organization must be in place prior to any project-related consultant work being performed.

Equipment

Only equipment *essential* to the conduct of this project is allowed. A detailed description must be provided with an explanation as to how it directly relates to this project and is not otherwise available.

For budget submission purposes, equipment should be defined as items ≥ $5,000 and having a useful life of more than 2 years. Upon award, a grantee institution may re-categorize items to meet internal definitions. *Items costing less than $5,000 should be included in the Supply category.*

Travel

Travel must adhere to the grantee's established travel policy and is only allowable if needed to conduct the project. ***Travel to general scientific meetings is not allowable.***

Other Expenses

Publication costs are limited to $1,000.

Consortium/Contractual Costs

Proposed sub-agreements **must be approved by the ICTS Administration prior to submission of the application**. The participating consortium organization must submit a separate face page, detailed budget page(s), and budget justification to the PI who will include it as part of the overall application submission.

Other allowable budget categories include: Supplies and Patient Care Costs.

UNALLOWABLE DIRECT COST ITEMS

Funding will not be provided for the following:

- Administrative personnel
- Stipends for students/trainees
- Dependent Tuition Fringe Benefit
- Administrative supplies/services normally considered indirect costs (office supplies, phone, network lines, etc.)
- Office equipment and furniture
- Tuition
- Purchasing and binding of periodicals and books
- Dues and membership fees

UNALLOWABLE DIRECT COST ITEMS – *cont'd*

- Honoraria or travel expense for lectures
- Maintenance/Service Contracts
- Construction, alteration, maintenance or rental of buildings or building space
- Faculty/Staff recruiting /relocation expenses
- Entertainment/Social Expenses
- Pre-award costs
- Any expense contrary to applicant's institutional reimbursement policies

FACILITIES & ADMINSTRATIVE COSTS (F&A)

Do not include F&A Costs in the applicant or consortium organization budgets. F&A costs are expected to be a contribution to the program by institutions outside of WU. Any exceptions will be identified in the Notice of Award.