

Clinical and Translational Research Funding Program -Biostatistics, Epidemiology, and Research Design Projects-

2019 Program Overview & Request for Applications Instructions

The ICTS is soliciting applications for funding of Biostatistics, Epidemiology, and translational Research Design (BERD) pilot projects. The pilot grant program is intended to provide seed funding to facilitate new research and future funding. At least one grant will be funded for a maximum of \$25,000 for 1 year. Only one submission from a faculty member as PI is permitted in response to this RFA. Applicants must submit an online notification of intent. Full proposal will be submitted after recommendation and an invitation from the review committee.

It is critical that the proposal is written in a way that a non-expert can understand the ideas and appreciate their significance and potential impact. Additionally, it must be clear that the specific aims of the project can be completed within the allowed time period (12 months).

GOALS OF THE PROGRAM

The principal goal of this program is to promote innovative methodology development to enhance the validity, rigor, accuracy, and ease of use, of the analytical methods for clinical, translational, genetics, informatics, and health service data. Research areas of interest include biostatistical, epidemiological, genetic, and bioinformatics methods. The pilot funding will be targeted at research proposals that match new methodology with clinical and translational science needs. Priority will be given to research that addresses one or more of the following:

- Novel, cross-disciplinary collaborative research programs within the ICTS;
- Research projects that have high potential to obtain external funding;
- Methodology development within the context of solving a real problem in a relevant area of importance;
- Applications that support precision medicine.

SUBMISSION AND REVIEW PROCESS

Notification of Intent Deadline:	Monday, July 22, 2019 (5:00 PM, CT)
Application Deadline:	Monday, August 19, 2019 (5:00 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 will be strictly adhered to with **NO exceptions**. Program Committee reviews NOI on a rolling basis and responds to applicant by July 26, 2019 regarding whether the project is eligible for submission of full proposal.

These projects will be reviewed by members of the Biostatistics, Epidemiology, and translational Research Design (BERD) core. Reviewers will assess the innovation and impact of the proposed methodology, and interdisciplinary collaboration.

Step 2, Application:

If invited, PI will be emailed access to the online application to submit a full proposal 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:

Members of the Biostatistics, Epidemiology, and translational Research Design (BERD) core and researchers associated with other CTSA's will submit written reviews. Applicants will receive a Summary Statement including comments from the scientific peer reviewers and will be notified of funding decisions in December.

Step 4, Award:

Awardees must obtain all regulatory approvals (e.g. IRB) and meet all compliance requirements prior to receiving funds for a 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 to provide suggestions. Consider consulting with the following ICTS cores prior to submission:
 - **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](#) is available and is strongly recommended during the planning phase of project development prior to the NOI deadline.
 - **Center for Administrative Data Research (CADR)** serves to provide training in the use of health services administrative data in clinical epidemiologic, health services 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.

ELIGIBILITY

- Applicants must be a registered member of the ICTS before submitting a NOI. [Online registration](#) takes less than 5 minutes. 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. A letter of support from the director is required in the application.
- 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. 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 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 2/29/2020, 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 for a second submission.
- We encourage applications from teams that have expertise in both a quantitative field (e.g. biostatistics) and a clinical one.
- There is no specific citizenship requirement for the applicant.

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

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:

1. Principal Investigator - The signature of the PI is required on the Face Page for all applications.
2. Other Approval Signatures - Official Signing for Applicant Organization:
 - Washington University (WU) applicants do **not** need an additional 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.

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.

Established Investigators: Describe how this project will lead to a new direction in your research or is different from your previous work (if applicable).

Short project description: using layman’s terms. This will be used on the website, if funded.

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 can 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: KEY 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 11-12) 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: Only one resubmission of a previously submitted proposal is allowed. 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 (1 page, maximum):** 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 budget 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.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

iv) Timeline of Key Milestones

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 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 not a 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): Not applicable to this RFA.

G. Select Agent Research: Not applicable to this RFA.

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 10-11) 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. Appropriate letters confirming their roles in the project must be included in the Letters of Support Section (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

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.

Requirements if funds are awarded:

1. IRB Approval: All Human Subject protocols must be approved prior to expenditure of any funds.
2. Delayed Onset Human Subjects Research: The NIH requires that the ICTS obtain explicit approval from the NIH for any pilot-funded research involving human subjects. Accordingly, the IRB-approved protocol and other materials must be submitted to the NIH at least 30 days prior to the project start date. ICTS personnel will work with awardees to meet these requirements.
3. Publications: All publications that benefit in whole or in part from support provided by the ICTS must do the following:
 - a. Comply with the NIH Public Access Policy: Assistance with the compliance process is available through the Library. Information regarding the Public Access Policy is located at <https://publicaccess.nih.gov/policy.htm>
 - b. Acknowledge ICTS grant funding. We recommend the following language: "Research reported in this publication was supported by the Washington University Institute of Clinical and Translational Sciences grant UL1TR002345 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official view of the NIH."

CONTACTS FOR QUESTIONS

For questions and/or assistance with *scientific and peer review*, contact BERD rt-berd@rt.biostat.wustl.edu

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.

ACCEPTABLE RESEARCH THEMES

Applications must propose to advance science in at least one of the following areas of program interest:

- 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.
- Improving the Quality of Patient Care
Increasing the likelihood of achieving outcomes valued by patients and their families. For **example**:
 - 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
 - Patient/family understanding of, and involvement in, their medical care
 - Medical team training or dynamics
- Enhancing Patient Safety
Exploring reliable care processes to prevent all errors that result in issues **such as**:
 - Preventable mortality
 - Health care acquired infections (ex. surgical site infections)
 - Adverse drug events
 - Falls with injury
 - Pressure ulcers
 - Venous thromboembolism
 - Wrong site/wrong person procedures
 - 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
 - Design of reliable and effective care delivery processes
 - Patient-centered outcomes from the patient's perspective (patient perception of care)

BUDGET GUIDELINES

ALLOWABLE DIRECT COST ITEMS

Funding will be 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. Costs may include funding computer simulations or software development.

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 the purpose of this grant, applicable costs include purchasing resources on a high capacity computer, and purchase of data.

For budget submission purposes, equipment should be defined as items \geq \$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 (i.e. office supplies, phone, fax and modem line charges, etc.)
- Office equipment and furniture
- Tuition

UNALLOWABLE DIRECT COST ITEMS – *cont'd*

- Purchasing and binding of periodicals and books
- Dues and membership fees
- Wet lab expenses
- 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 & ADMINISTRATIVE 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.

REVIEW CRITERIA REFERENCE FOR PROPOSAL REVIEWERS

This is meant to be a reference tool for reviewers to provide criteria to consider during proposal review. Do NOT return with the Evaluation Form.

Key Review Criteria (Also see Program Specific considerations on page 2.)

Significance:

- Does this study address an important problem in clinical and/or translational research?
- If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field?
- What is the intellectual merit of the proposed activity to advance knowledge across its own field and across different fields? Are there broader impacts to the clinical and/or translational project to benefit society and advance desired societal outcomes?
- Is there a strong scientific premise for the project?

Innovation:

- To what extent do the proposed activities suggest and explore creative, original and potentially transformative concepts? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?
- Does the project plan develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

Approach:

- Are the conceptual or clinical framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims of the project?
- Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple investigators, is the leadership approach, including the designated roles and responsibilities, consistent with and justified by the aims of the project and the expertise of each of the investigators?
- Does the applicant identify the next steps in research or clinical endeavor to move the concept forward in the translational continuum?
- Has the investigator presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the investigator presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Environment:

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Does the proposed study benefit from unique features of the environment, or subject populations, or employ useful collaborative arrangements?

Investigator(s):

- Are the investigators appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level of the investigator? Do the investigators bring complementary and integrated expertise to the project (if applicable)?
- If the applicant is a new or junior investigator, is there adequate supervision and mentorship described and how does the proposed work fit with his/her overall professional development?
- If the applicant is an established investigator, is there clear description about how this project is different from their previous work?

Additional Review Considerations

Human/Animal Use:

Have protections for human subjects and/or appropriate use of animals been addressed?

Success/Potential for Subsequent Funding:

Is there a plan or set of criteria by which to judge whether the proposal has been successful?

If this project is successful, would it likely lead to external peer-reviewed funding?

Budget: (Budget does not contribute to the priority score)

Does the documentation demonstrate that the funds requested will meet the research needs?

Is the proposed budget and duration reasonable in relation to the proposed project?

Is there potential funding overlap?

Is it clear how funds will be used to uniquely advance the proposed clinical or translational research?

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, are the proposed plans for identifying and ensuring the validity of those resources appropriate?

PROGRAM SPECIFIC CONSIDERATIONS

Priorities for awarding funding include:

Quality and scientific rigor of the proposal;

Innovation of the proposed methodology;

Impact on clinical and translational sciences, e.g., the ability to solve a real issue in an important area;

Potential to lead to new funding from NIH or other extramural funding agency;

Interdisciplinary collaboration to foster cross-bridging training and interaction

Does the project have the potential to promote the translation of scientific discoveries into improvements in human health?

Are the aims appropriate for a 1-year grant?

Does the project clearly describe how this research applies to one or more of the acceptable research themes?

- Improving Quality of Patient Care
- Enhancing Patient Safety
- Improving Patient Outcomes
- Improving Transfer to Practice
- Translating Genetic/Genomic Findings
- Development/Evaluation of Therapeutics

If the investigator or collaborators have previously received funding for this same project through the CTRFP, are the goals and aims of this project sufficiently different from that which was previously funded?

Does the project promote team science?