Clinical and Translational Research Funding Program
Pilot and Community-Engaged Projects

2018 Program Overview & Request for Application Instructions

The Washington University Institute of Clinical and Translational Sciences (ICTS) announces the 12th 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.

Annually, the CTRFP receives over 100 applications and awards approximately $1M for 20 investigator-initiated projects. These projects are supported along 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.

- **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.

- **Community-Engaged Research Projects**: Provide up to $50,000 direct costs for 1 year to fund active partnerships with stakeholders and communities (including patients, patient organizations, governmental agencies, community-based clinicians), and other groups whose health, well-being and service provision may be influenced by the results of the proposed study.

---

**SUBMISSION & REVIEW PROCESS**

*These guidelines are modeled after those required for standard NIH research grant submissions.*

**Notification of Intent Deadline:** Monday, July 23, 2018 (5 pm, CT)
**Application Deadline:** Friday, August 24, 2018 (5 pm, CT)
**Proposal Peer Review:** October 2018
**Award Decisions:** December 2018
**Award Start Date:** Friday, March 1, 2019

Step 1: PI submits required electronic Notification of Intent (NOI) Form through the online submission process at [https://wustl.az1.qualtrics.com/jfe/form/SV_9GEsvkv8ph9UAWp](https://wustl.az1.qualtrics.com/jfe/form/SV_9GEsvkv8ph9UAWp) by 5:00 p.m. (CT) on Monday, July 23, 2018. (See NOI Instructions and Form). This deadline will be strictly adhered to with NO exceptions. Early submission, prior to July 23rd, is encouraged so PIs invited to submit a full application have more preparation time.

Step 2: Program Committee reviews NOI and responds to applicant by July 25, 2018 regarding eligibility of the project 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.

Step 3: If invited, PI will be provided access to the online application to submit a full proposal. **Deadline: 5:00 p.m. (CT) on Friday, August 24, 2018.** The electronic application must be received by this date/time. This deadline will be strictly adhered to with NO exceptions.

Step 4: Review Process:
- **Pilot Grants**: 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 Biostatistics, Epidemiology, and Translational 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 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. Applicants will receive a Summary Statement including comments from the scientific peer reviewers and will be notified of funding decisions in December.

Step 5: 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 23rd may not allow sufficient time to provide suggestions. **Consider consulting with the following ICTS cores prior to submission of your NOI:**
  - Biostatistics, Epidemiology, and Translational Research Design (BERD) offers a BioStat Clinic, an hour-long consultation service that is fully subsidized for ICTS members. Online appointment scheduling is available.
  - 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.
  - 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.

### ELIGIBILITY

- Applicants must be a registered member of the ICTS **before submitting a NOI.** [Online registration](icts@wustl.edu) 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 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 3/1/19 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 substantial, competing NIH research grant. In terms of NIH awards, the PI still fits into the New Investigator category if the PI 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.

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 active partnerships with stakeholders and communities (including patients, patient organizations, governmental agencies, community-based clinicians), and other groups whose health, well-being and service provision may be influenced by the results of the proposed study.

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

---

**FORMAT SPECIFICATIONS**

- proposalCentral will be used to collect most of the required data
- Research Plan (described below) cannot exceed 5 single-spaced pages.
- Use Arial 11 point font size or larger; minimum 0.5 inch for all margins for all pages.
  - Figures, Graphs, Diagrams, Charts, Tables, Figure Legends and Footnotes: you may use a smaller type size, but it must be readily legible.
- Include the PI’s name at the top of each page and consecutively number all pages in the application at the bottom of each page.

**Using the ICTS Form Pages:**
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.*

---

**Project Start/End Dates**: 03/01/2019 – 02/28/2020

**Resource Sharing:**
(See PI certification checkbox on Title Page.) If unable to comply with the ICTS Resource Sharing Plan (provided below), include justification.

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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html) and [http://grants.nih.gov/grants/gwas/](http://grants.nih.gov/grants/gwas/).

**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.
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.

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.

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

Abstract: of project

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

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

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

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 brief 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 BJHF/ICTS Funding Program for the same project, describe how the proposed project differs from that which was already funded

Stakeholders and Active Partnerships: Describe active partnerships with stakeholders and communities in the context of this research proposal. Stakeholders and communities include patients, patient organizations, caregivers and families, online communities, non-profit organizations, governmental agencies, community-based clinicians, and other groups whose health, well-being and service provision may be influenced by the results of your proposed study. Discuss 1) the relevance of the research question to the stakeholders or communities of interest; and 2) how stakeholders and communities will be involved in your proposed research.

Budget Summary: Complete the Budget Summary Page for the period of 03/01/19 - 02/28/20. 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.
Using the required CTRFP formatted pages, provide the following:

**FORM PAGE 1: KEY PERSONNEL**

**List of key personnel/other significant contributors**

- **Key Personnel** are individuals 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.

**BUDGET JUSTIFICATION**

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

Biosketches: Submit biosketches in the new 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. A sample form has been provided.

**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 criticism raised 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 budget period of the grant.

- **B. Research Strategy:**
  1) 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.

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 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):** Go to the [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):** Go to [Instructions for Grant Applications using PHS 398, Part I-49, Section 5.5.10, “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:
Subagreements proposed to organizations other than ICTS partner institutions (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 7-8) 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**

Letters of Support should be addressed 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 BJHF/ICTS 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.
- Support letters from unpaid consultants/collaborators should be provided, if possible.
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
- Additional materials submitted as an appendix (2 maximum)

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

For questions and/or assistance with proposal development, contact the ICTS Administrative Core at icts@wustl.edu.

For questions and/or assistance with financial and program guidelines, contact Denise Zurliene, Senior Grant Specialist (314-362-7707 or dzurliene@wustl.edu) or Jaimee Stagner, Associate Director – Finance (314-362-6325 or jstagner@wustl.edu).

For question and or assistance with online submission, contact Beth Mott, Project Manager (314-362-1539 or emott@wustl.edu).
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)
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 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**
Sub-agreements proposed to organizations other than ICTS partners (includes associated community organizations) 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.**

**ALLOWABLE DIRECT COST ITEMS**

**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
- 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 & 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**
___ 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?

For Community-Engaged Research proposals:
- Is the research question relevant to the community of interest? Is the project a community-defined priority?
- What is the role of the partner? Are there benefits for the partner?
- Does the research present an opportunity for sustained impact?
- Does the research team have a track record in building and sustaining community partnerships?