

# Clinical and Translational Research Funding Program

## Application Instructions

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

### FORMAT SPECIFICATIONS

- 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.*

### FORM PAGE 1: FACE PAGE

Complete the Face Page.

### 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 BJHF, institutional review and signature will be required through the WU Office of Sponsored Research Services before funds will be released.

### FORM PAGES 2-5

Using the required CTRFP formatted pages, provide the following:

- **Abstract** of project
- **Short project description**, using layman's terms
- **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 activities will be influenced by the results of your proposed study. Examples of stakeholder engagement are assessments of patient or community needs that lead to a research question, a recognized gap in knowledge that will lead to development of a new therapeutic or diagnostic, or development of a new method or technique that will be applied by others to answer important questions. Basically, we are asking you to identify who wants to see the findings from

your proposed study, and to describe the next translational step that will occur if your study works as planned.

- **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
- **Community-Engaged Research Projects (involving a community partner and/or taking place within the community)** describe 1) the relevance of the research question to the community of interest, 2) the role of and benefit to the community partner/organization for each partner, and 3) how the research presents an opportunity for sustained impact (if applicable)

#### FORM PAGE 6: 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 7A: REVIEWER SUMMARY BUDGET PAGE(S)

Complete the ICTS Reviewer Summary Budget Page for the period of 03/01/18 - 02/28/19. Costs submitted on this page **must be identical** to those on the Detailed Budget Page with the exception of salary/fringe detail. Only the Reviewer Summary Budget Page will be shared with reviewers.

#### FORM PAGE 7B: DETAILED BUDGET PAGE(S)

Complete the ICTS Detailed Budget Page for the year requested. See the ICTS Budget Guidelines (pages 7-8) 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:**
- 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.

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.

1. Identify the Select Agent(s) to be used in the proposed research.
2. 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."*
3. 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).

#### **J. Resource Sharing:**

(See PI certification checkbox on Face 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> and <http://grants.nih.gov/grants/qwas/>.

### **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

- \_\_\_\_\_ Face Page (Form Page 1)
- \_\_\_\_\_ Abstract, Themes & Impact, Resources, Additional Project Specifics, Personnel (Form Pages 2-6)
- \_\_\_\_\_ Reviewer Summary Budget page (Form Page 7A)
- \_\_\_\_\_ Detailed Budget page (Form Page 7B)
- \_\_\_\_\_ 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-J: 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)

## SUBMISSION PROCESS

**Submit the following by Friday, September 8, 2017 at 5:00 p.m. CT**

**The online application submission will NOT be accepted after this date and time** (*must be received by this date/time*).

Electronic copy of the entire proposal including summary budget pages must be submitted as a single pdf document and the detail budget page(s) as a second pdf document by online application through the URL provided with invitation to submit.

## 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 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  $\geq$  \$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

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.**

### 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.

## QUESTIONS

**For questions and/or assistance with proposal development,** contact the ICTS Administrative Core.

Andi Cox, Grant Specialist II 314-362-7707

Jaimee Stagner, ICTS Associate Director - Finance 314-362-6325

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