

## **2020 Tufts CTSI Pilot Studies Program Application Instructions**

**Applications due: Friday, September 27, 2019 at 11:59PM.**

### **GENERAL GUIDANCE AND REQUIREMENTS**

- ✓ A complete application and any accompanying materials must be submitted online using REDCap.
- ✓ Internet Explorer 11 and below will not support the application. All other browsers are supported. Google Chrome is recommended.
- ✓ The REDCap application consists of fields to be filled in online and four (4) application-specific forms, which must be completed and uploaded as part of the application.
- ✓ Applicants are required to use the application-specific templates provided by Tufts CTSI. These templates can be downloaded from REDCap.
- ✓ Templates (applicant certification and authorization form, budget forms, and biosketch template, in particular) are protected to preserve formatting. They should not be modified.
- ✓ For uploaded documents, all margins must be set at 0.5 inches (top, bottom, left, and right). Applicants must use Arial at a font size of 11 points. Smaller font size is acceptable only in figures, graphs, diagrams, and charts.
- ✓ Documents may be uploaded as Word or PDF files except for the applicant authorization and certification form, which must be a PDF scan of the printed and signed document.
- ✓ Letters of support are optional. They can be uploaded in the Additional Supporting Documents section.
- ✓ Appendices should not be included and will not be reviewed.
- ✓ All documents should be no larger than 10MB. Any documents larger than 10MB will not be accepted.
- ✓ Applicants will have the option to save their progress and return to their applications at a later time (up to the submission deadline). Refer to the “Save and Return Later” instructions provided in REDCap.

### **APPLICATION SUBMISSION FORM**

- ✓ Application Guidance and Document Templates
- ✓ Project Information (Research Strategy and Applicant Certification and Authorization Form to be uploaded, one per project)
- ✓ Principal Investigator (PI) Information (PI's Biosketch to be uploaded)
- ✓ Collaborator Information, if applicable (Collaborator(s)' Biosketch(es) to be uploaded, one per named senior/key personnel)
- ✓ Budget Information (Budget Form(s) to be uploaded, one per eligible site)
- ✓ Additional Supporting Documents
- ✓ Research Team and Project Questions
- ✓ Certification and Authorization
- ✓ Submission Review Section

### **ELIGIBILITY REQUIREMENTS AND BUDGET CONSIDERATIONS**

- ✓ Eligible applicants include members of [Tufts CTSI partner or collaborator organizations](#), which span academic partners, affiliated hospitals, for-profit and not-for-profit collaborators, and community-based organizations.
- ✓ All PIs of single-site projects and PIs and Multiple PIs (Co-PIs) of multi-site projects must have a primary position or appointment at a Tufts CTSI partner or collaborator organization and be eligible to receive funding from NIH and other federal agencies.

- ✓ Both single-site and multi-site projects may include collaborators who are not affiliated with Tufts CTSI. While their institutions will not be considered as funded sites for a multi-site proposal, individual investigators and research teams have the option to subcontract services provided by and/or sign a professional service agreement with non-Tufts CTSI-affiliated collaborators.
- ✓ For-profit Tufts CTSI-affiliated organizations are eligible as participating sites. However, they may not receive funding.
- ✓ All schools and centers of Tufts University are considered one site for the purpose of this program. For example, if the project includes Tufts University School of Medicine and Tufts University School of Engineering, both schools count as one site, not two.
- ✓ Past Tufts CTSI pilot award recipients may re-apply to obtain funding for a new research project, but will not be considered for additional funding for a project previously awarded through the program.
- ✓ PIs or Multiple PIs (Co-PIs) who have received two Tufts CTSI pilot awards are not eligible to apply as PIs or Multiple PIs (Co-PIs) for another award until five years from the end date of their last award.
- ✓ To be considered for new funding, returning applicants must comply with all prior award reporting requirements.
- ✓ Eligible investigators or research teams may request up to \$30,000 per award. Multi-site projects including two eligible sites may request a total budget of up to \$45,000 and projects including three eligible sites a total budget of up to \$60,000.
- ✓ Research teams of multi-site projects may allocate funds across sites in accordance with project needs.
- ✓ If a pilot grant is awarded, a change in scope needs to be pre-approved by Tufts CTSI. A change of scope is a change in direction, aims, purpose, or type of research.
- ✓ The project period is May 1, 2020 through April 31, 2021. All budgeted funds must be expended by the end of the project period. Carryover is not allowed. Funds not expended by April 30, 2021 will revert to Tufts CTSI.

## **RESEARCH STRATEGY DOCUMENT GUIDANCE**

The PI will be prompted to upload a completed research strategy document in the PROJECT INFORMATION section of the online form.

- ✓ **Project Title**
- ✓ **Project Abstract (maximum 250 words)**  
The project abstract should provide a clear statement of the aims and their relevance to human health. It should also outline how the research meets the specified translational phase.
- ✓ **Project Summary (maximum one page)**  
The summary should describe how the proposed project will contribute to the next phase of research; include specific information regarding each investigator's role on the project (including aims and proposed contributions of each investigator); and provide detailed project timeline.
- ✓ **Background and Significance (maximum two pages)**  
This section should provide a clear statement of the proposed project's specific relevance to human health and establish the context for the proposed research. What is known? What is not yet known? How will this project make progress toward filling the existing knowledge gap?
- ✓ **Specific Aims (one page maximum)**  
This section should outline clear and measurable aims of the proposed project.
- ✓ **Research Procedures (three page maximum)**  
This section should describe proposed methods of study in adequate detail so that their appropriateness may be assessed. It should also detail the feasibility of successfully completing the work within the one-year time period. Specifically, what factors will facilitate successful completion of this pilot project? If novel methods or approaches are proposed, how will they be more effective than existing methods or approaches? If applicable, this section should provide information on human and/or animal subjects.
- ✓ **Stakeholder Engagement Plan (maximum one page)**  
This section should provide a general overview of the stakeholder engagement plan. Stakeholders may

include the general public and community members; healthcare providers; purchasers responsible for underwriting the cost of health care; individual payers and entities that finance or reimburse the cost of health services; policy makers; drug and device manufacturers; and/or other researchers and their funders. In which roles and what modes of interaction will the relevant stakeholders be engaged (e.g., in the conceptualization of research design, project implementation, interpretation of research results, and/or dissemination of study findings to improve clinical care and health)? When will these selected stakeholders be involved (before, during, and/or after the pilot award period)? (For additional guidance, please see the Pilot Studies Program Stakeholder Engagement Plan Toolkit.)

✓ **Alignment with Selected Translational Research Phase(s) (maximum half a page)**

This section should specify where the proposed research falls on the translational research spectrum. How does the proposed project align with the selected translational research phase(s)? How will the project findings be applied to various populations in the form of new and/or improved interventions, treatments, devices, practices and/or policies? How will the proposed project fit into future research efforts that will translate new scientific findings into measurable positive impacts on the public's health?

✓ **Leadership Plan for Multi-site and Single Site Multiple PI (Co-PI) Projects, if applicable (maximum half a page)**

The leadership plan should describe the roles, responsibilities, and the working relationship(s) of the identified PI and Multiple PI(s) (Co-PI(s)). It should also clarify how the inclusion of multiple sites or multiple PIs enhances the proposed project.

✓ **Description of Next Steps (maximum one page)**

This section should provide a defined plan and timeline for publication of results in the peer-reviewed literature, if the proposed project is successful and an outline of steps for reporting results if the project is not successful. What target journals will be considered? Describe the specific plans for dissemination of any research products beyond publication in peer-reviewed literature. This section should also outline a specific plan and timeline for seeking future extramural funding. What federal and/or non-federal funding opportunities or sources be sought after the pilot award period?

✓ **Bibliography (maximum one page)**

This section should list references of any publications or research products cited.

## **APPLICANT CERTIFICATION AND AUTHORIZATION FORM GUIDANCE**

The applicant certification and authorization form must be completed, signed, and dated by the PI. The PI-completed form must be reviewed by the Research Administrator and Department Chair/Chief of the primary (lead) site. If they approve the proposed project, they must check the box for Department Assurance and both must date and sign the signature page. Electronic signatures are acceptable, but must be attributable to a particular signee. The PI will be prompted to upload a scanned PDF file of the page with all three required signatures in the PROJECT INFORMATION section of the online form.

## **BIOGRAPHICAL SKETCH GUIDANCE**

A biographical sketch (biosketch) form must be completed by each named senior/key personnel who will contribute to the scientific development and execution of a proposed project in a substantive, measurable way. This may or may not include all members of a research team. The PI will be prompted to upload completed biosketch(es) of senior/key personnel, as applicable, in the PRINCIPAL INVESTIGATOR and COLLABORATOR INFORMATION sections of the online form.

### **General Biosketch Guidance**

- ✓ NIH requires to use the biosketch format pages that have been updated to reflect the new expiration date of 03/31/2020. For detailed biosketch instructions, format pages, and sample biosketches, please click [here](#).
- ✓ Investigators are encouraged to utilize a researcher profile system, [Science Experts Network Curriculum Vitae \(SciEncv\)](#), to help them develop their biosketches and automatically format them according to NIH requirements.

- ✓ The biosketch may not exceed five (5) pages per each named personnel. This five-page limit includes the table at the top of the first page.
- ✓ Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketches.
- ✓ Any publications or research products cited in the biosketches are required to comply with the NIH Public Access Policy. This policy applies to any peer-reviewed manuscripts accepted for publication in a journal on or after April 7, 2008 that arise from any direct funding from NIH. For more information on the NIH Public Access Policy, please click [here](#).

## **Biosketch Content**

- ✓ **Name**
- ✓ **Electronic Research Administration (eRA) Commons Username**  
All PIs and Multiple PIs (Co-PIs) are required to have an [eRA Commons username](#). If the proposed project is funded, other budgeted key personnel will be required to have their eRA Commons usernames as well. If necessary, these usernames may be obtained from the research administration office of the investigator's institution.
- ✓ **Position Title**
- ✓ **Education/Training**  
Each key investigator should complete the education block, beginning with the baccalaureate or other initial professional education. If applicable, postdoctoral, residency, and clinical fellowship training should be listed separately. Each entry must include the name and location of the institution; the degree received (if applicable); the month and year of end date (or expected end date) when the degree was (will be) received; and the field of study (or the area of residency training).
- ✓ **Personal Statement**  
Each key investigator should provide a brief description of why they are well-suited for the role in the proposed project. Relevant factors may include: aspects of training; previous experimental work on this specific topic or related topics; technical expertise; collaborators or scientific environment; and/or past performance in this or related fields.
- ✓ **Position and Honors**  
Each key investigator should provide a chronological list of past and current positions relevant to the proposed project. That list may include academic and professional achievements, fellowships, and honors.
- ✓ **Contributions to Science**  
Each key investigator should briefly describe up to five (5) of their most significant contributions to science. For each contribution, they may indicate the following: the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and their specific role in the described work. For each contribution, each key investigator may cite up to four (4) publications or research products relevant to the contribution. A link to a full list of published work may be provided. This link must be to a federal government website with a .gov suffix.
- ✓ **Research Support**  
Each key investigator should provide a list of ongoing and completed (federally and non-federally-funded) research projects from the past three (3) years that they would like to draw attention to. They should briefly indicate the overall goal(s) of the selected project(s), their responsibilities, and any accomplishments.

## **BUDGET and BUDGET JUSTIFICATION GUIDANCE**

Budget documents must be named using the following convention: "PI Last Name\_Budget\_Site#", for example: [Smith\\_Budget\\_Site2](#)". The PI will be prompted to upload budget and budget justification form(s) in the BUDGET INFORMATION section of the online form.

## Allowable and Unallowable Costs

- ✓ For all award types, applicants may only request direct costs that are necessary and reasonable to complete the work described in their applications. Direct costs are any costs and that can be directly assigned to the project with a high degree of accuracy.
- ✓ Examples of allowable budget expenses include:
  - PI, Co-PI, Co-I, and support staff (e.g., pre/post-doctoral student, research assistant, and/or technician) salaries and fringe costs associated with those salaries.
    - Each institution has its own specific fringe rates and, in some cases, these rates are different for various types of employees. Please contact your respective Office of Research Administration to confirm your institution's fringe rates.
    - Personnel salaries may not exceed the congressionally mandated salary cap of \$192,300.
  - Consultant or biostatistical/biomedical informatics services
  - Reasonable participant incentives
  - Laboratory supplies and services, animal costs and per diem housing expenses
- ✓ Examples of unallowable budget expenses include:
  - General office supplies and expenses, telephone, data plans, internet, etc.
  - Clinical equipment
  - Travel, unless specifically required for project
  - Computers, laptops, and other electronics, unless specifically required and justified (if approved, items must be purchased within the first 90 days of the budget period and be returned to Tufts CTSI at the end of the project period)
  - Graduate program tuition, stipends, membership dues or professional fees
  - Meals or refreshments (including alcohol)
  - Rent, Facilities and Administrative Costs (F&A) and/or Indirect Costs (IDC)

## Subcontracts

- ✓ Subcontracts, if necessary, should be budgeted separately in the research proposal. Subcontract expenses can include any of the allowable costs described above, including personnel, consumables, and/or other direct costs. Please list any subcontract costs as a total on the budget form, then clearly describe all subcontract costs in the budget justification.

## Cost-Sharing

- ✓ Cost-sharing is the portion of pilot project costs that are not paid for by the pilot project budget. Cost sharing for investigator salaries is discouraged and will be allowed only with written approval of both the investigator's department chair and senior administrator.

## Budget Justification

- ✓ Budget justification should describe the importance of any budgeted items or services.
- ✓ The personnel justification should include the name, role, and number of person-months devoted to this project for every person on the project. All salary support for existing personnel must describe past support and plans for future support after Tufts CTSI funds are exhausted. It is not necessary to include specific salary and fringe benefit rate figures in the justification.
- ✓ Supplies and other expenses justification should include explanations and descriptions of all consumables and other expenses requested.
- ✓ If applicable, subcontract justification should follow the guidelines for personnel and consumables and other expenses described above.

## RESOURCES AND SERVICES

- ✓ Refer to the [Request for Applications](#) and [Frequently Asked Questions](#) at the [Tufts CTSI](#) website.
- ✓ Request an in-person or virtual consultation (free of charge) with Tufts CTSI by [submitting a service request](#).
- ✓ Attend a [research help drop-in session](#) offered by the Tufts CTSI [Biostatistics, Epidemiology, and Research Design \(BERD\) Center](#) and [Research Process Improvement Program](#) on Wednesdays from 8:00 to 9:00AM at 35 Kneeland Street, 10<sup>th</sup> Floor Conference Room, Boston.
- ✓ Reach out for assistance by contacting the Pilot Studies Team at [pilots@tuftsctsi.org](mailto:pilots@tuftsctsi.org).