# CTSI Pilot RFA Fall 2019

# Application Instructions and Forms

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*Please carefully follow the Application Instructions below and use the forms provided. Proposals that are incomplete or otherwise do not follow instructions will be returned to the investigator without review.*

All pages of all items in your proposal must be consecutively numbered, use Arial 11 point font, single-spaced, on 8.5 x 11 pages, left justified, with ¾” margins on all sides.

# Cover Page

Complete all elements of the cover page:

* Trainees and junior faculty must provide the name, title and UFID of their mentor.
* Costs: Applicants must complete the NIH’s standard “Detailed Budget for Initial Budget Period” form, include a separate budget justification and include written cost estimates from requested CTSI Services. For a complete list of available resources, please visit the CTSI website at: [www.ctsi.ufl.edu/research](http://www.ctsi.ufl.edu/research). No-cost consultation(s) with service provider(s) is recommended. Be sure to list and include funds available for this project from non-CTSI sources. Funding for this pilot project from sources outside of the CTSI will strengthen the application.
* The completed cover page must be signed and dated by the principal investigator and the principal investigator’s department chair.

# Page 2

* Abstract (200 words or less): Provide the rationale for the work, usually in the form of a research question to be answered, and a description of the approach to be taken to answer the question.
* Translational Impact (200 words or less): Describe how the work will improve human health.
* External Funding Plan (200 words or less): Provide a specific plan for obtaining external support. What agency and funding program will be pursued with this pilot data? The clarity and feasibility of the external funding plan will be a strong determinant of funding.
* Trainee/Junior Faculty Mentoring Plan [if applicable] (200 words or less): Describe the approach being taken to mentoring and role of the proposal in the development of the career of the trainee and/or junior faculty.

# Research Plan

Describe your proposed project in a research plan of **no more than six pages**. You may submit the same research plan to the IRB/IACUC and the CTSI concurrently. The Research Plan should include the following sections:

* Project Timeline including current IRB/IACUC submission status
* Rationale
* Specific Aims
* Preliminary Studies
* Design and Methodology (For clinical proposals, include clear justification for the number of participants to be enrolled in the pilot and for the number of participants needed for an externally funded study.)
* Recruitment Strategy, if applicable. (For clinical proposals, specifically address feasibility, recruitment methods, and retention planning for success).
* Planned Enrollment Table, if applicable. (for clinical proposals)
* References (included in the six page limit)

**Required Attachments**

# Cover Sheet

* **Page 2** – Abstract, Translational Impact, External Funding Plan, Mentoring Plan
* **Research Plan**
* **Key Personnel**: Provide a list of key personnel. For each member of the research team, include name, title, UFID and role on the project.
* **NIH Biographical Sketches:** NIH-formatted biosketches for PI, investigator(s) and mentor(s). The NIH biosketch form is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Additional instructions for biosketches:
	+ Biosketches must be submitted using the new format and are limited to five pages.
	+ All biosketches should include eRA Commons User Names: <https://commons.era.nih.gov/commons/index.jsp>.
	+ **PIs:** Use the statement section to explain why you are well suited for the role of PI and how the project will contribute to your career development plan.
	+ **Mentors:** Personal statement should include mentor’s qualifications and role in the career development of the PI.
* **Budget:** Submit a detailed budget using the NIH’s standard “Detailed Budget for Initial Budget Period” form. The NIH “Detailed Budget for Initial Budget Period” form can be downloaded at <http://grants.nih.gov/grants/funding/phs398/phs398.html>.
* **Budget Justification Worksheet:** Applicants must include a separate budget justification for all line items. Include all costs associated with the project. Indicate the funding source for each line item (i.e. department, Gatorade, CTSI, etc.).
* **Cost Estimates:** CTSI services require cost estimates in writing from CTSI Service providers. No-cost consultations prior to submission of the proposal are encouraged.
	+ For a complete list of available resources, please visit the CTSI website at: [www.ctsi.ufl.edu/research](http://www.ctsi.ufl.edu/research)
* **Letters of Support:** Trainees and Junior Faculty must include letters of support from their mentor(s).

# Submitting your proposal

Email your complete proposal (including cover sheet and all attachments) as a single PDF to CTSI\_Pilot-Awards-l@lists.ufl.edu. Proposals that do not follow the instructions will not be reviewed. Please email CTSI\_Pilot-Awards-l@lists.ufl.edu with any questions.

 **Cover Sheet for CTSI Pilot Award Proposal – Fall 2019**

Proposal Title

**Please select the type of award for which you are applying:**

[ ]  Trainee (up to $7,500) [ ]  Junior Faculty (up to $20,000)

[ ]  Novel Technologies and Methodologies (up to $25,000)

**Please indicate whether you have been the PI on a previous CTSI Pilot Award:**

[ ]  No [ ]  Yes

|  |  |
| --- | --- |
| Principal Investigator Name |  |
| Position/Title |  |
| UFID |  |
| Email |  |
| Fiscal / Admin Contact (Name & Email) |  |

|  |  |
| --- | --- |
| Co-investigator Name (if applicable) |  |
| Position/Title |  |
| UFID |  |

|  |  |
| --- | --- |
| Mentor Name (if applicable) |  |
| Position/Title |  |
| UFID |  |

|  |  |
| --- | --- |
| Number of participants to be enrolled |  |
| Total cost of proposed work\* |  |
| Funding amount available from non-CTSI sources  |  |
| **Total funds requested from CTSI\*** |  |

**\*Please use attached CTSI Budget Justification Worksheet to document costs.**

**Human/Vertebrate Animal Subjects and Proprietary/Privileged Information**

***Note:*** Projects that are awaiting funding to begin may wait until after Notice of Award to submit protocols to IRB or IACUC, but applicants should demonstrate they have taken preliminary steps to prepare submissions so minimal time will be lost in securing approvals. Once approvals are received, please forward to CTSI\_Pilot-Awards-L@lists.ufl.edu

1. Are human subjects involved? [ ]  Yes [ ]  No
	1. If YES, does this project require IRB approval? Yes No

If YES,

Is the IRB’s review of your protocol in progress? [ ]  Yes [ ]  No

IRB approval date (mm/dd/yyyy): / /

IRB project # (if known):

Note: for assistance with determining the need for IRB approval for projects, you may contact Tiffany Pineda, Research Navigator, at tiffany.danielle@ufl.edu

1. Are vertebrate animals used? [ ]  Yes [ ]  No
	1. If YES,

Is the IACUC’s review of your protocol in progress? [ ]  Yes [ ]  No

IACUC approval date (mm/dd/yyyy): \_\_/\_\_\_\_/

IACUC project # (if known):

1. Is proprietary/privileged information included in the application? [ ]  Yes [ ]  No

**Signatures**

Principal Investigator Department Chair or Representative

Name Date Name Date

**Page 2 of CTSI Pilot Award Proposal**

 **Abstract** *(200 words or less)*

**Translational Impact** *(200 words or less)*

**External Funding Plan** *(200 words or less)*

**Mentoring Plan** *(200 words or less)*

**Research Plan** *(no more than 6 pages)*

# Project Timeline; including proposed IRB/IACUC submission date

**Rationale**

**Specific Aims**

**Preliminary Studies**

**Design & Methodology**

**Recruitment Strategy (Clinical Research Only)**

**Planned Enrollment Report (clinical research only)**

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| --- | --- |
| **Racial Categories** | **Ethnic Categories** |
| **Not Hispanic or Latino** | **Hispanic or Latino** | **Total** |
| **Female** | **Male** | **Female** | **Male** |
| American Indian/ Alaska Native |  |  |  |  | **0** |
| Asian |  |  |  |  | **0** |
| Native Hawaiian or Other Pacific Islander |  |  |  |  | **0** |
| Black or African American |  |  |  |  | **0** |
| White |  |  |  |  | **0** |
| More Than One Race |  |  |  |  | **0** |
| **Total** | **0** | **0** | **0** | **0** | **0** |

# References

**Key Personnel**

|  |  |
| --- | --- |
| Name of Project Member |  |
| Position/Title |  |
| UFID |  |
| Role on Project |  |

|  |  |
| --- | --- |
| Name of Project Member |  |
| Position/Title |  |
| UFID |  |
| Role on Project |  |

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| Name of Project Member |  |
| Position/Title |  |
| UFID |  |
| Role on Project |  |

CTSI Pilot Budget Justification Worksheet

|  |  |
| --- | --- |
| P.I. (Last, First): |  |
| Proposal Title: |  |

Refer to the CTSI Pilot Awards Fall 2019 RFA for allowable costs. Some line items from the NIH Detailed Budget for Initial Budget Period form might not qualify for CTSI Pilot funding. Be sure to list non-CTSI resources - Funding from sources outside of the CTSI will strengthen the application. In addition to this worksheet, written cost estimates are required attachments.

|  |
| --- |
| **Personnel. List all Key Personnel i.e. PI, Co-I, Mentor, etc., Describe study role and amount of effort for each. Include source of funding for effort and pilot funding request if applicable (i.e. CTSI, Dept., Grant, etc.)** |
|  |
| **Consultants. (Line item from NIH Detailed Budget for Initial Budget Period form). List all non-CTSI consultants, if applicable. Describe study role. Include source of funding and pilot funding request if applicable (i.e. CTSI, Dept., Grant, etc.)** |
|  |
| **Equipment. (Line item from the NIH Detailed Budget for Initial Budget Period form). Major equipment is not an allowable budget item for this RFA. In order to evaluate the request for funding, provide description, purpose, total cost, useful life information and funding source (i.e. CTSI, Dept., Grant, etc.)** |
|  |
| **Supplies. (Line item from the NIH Detailed Budget for Initial Budget Period form). In order to evaluate the request for funding, provide description, purpose, total cost, and funding source (i.e. CTSI, Dept., Grant, etc.)** |
|  |
| **Travel. (Line item from the NIH Detailed Budget for Initial Budget Period form). Travel is typically not an allowable budget item for this RFA. In order to evaluate the request for funding, provide description, purpose, location, total cost, and funding source (i.e. CTSI, Dept., Grant, etc.)** |
|  |
| **Inpatient Care Costs. (Line item from the NIH Detailed Budget for Initial Budget Period form.) Inpatient Care Costs are not an allowable item for this RFA budget. Indicate non-CTSI funding source, if inpatient care costs are applicable to this project.** |
|  |
| **Outpatient Care Costs. (Line item from the NIH Detailed Budget for Initial Budget Period form). Outpatient Care Costs are not an allowable item for this RFA budget. Indicate non-CTSI funding sources, if outpatient care costs are applicable to this project.** |
|  |
| **Other Expenses (Line item from NIH Detailed Budget for Initial Budget Period form). Use this category and list all requested CTSI Services and attach written cost estimates.** ***requested CTSI Services and attach written cost estimates.*** |

|  |  |  |
| --- | --- | --- |
| **CTSI Services:** | **Cost:** | **How will this be funded: (i.e. CTSI, Dept., Grant, etc.)** |
| **Biorepository** |  |
| **Biostatistics** |  |
| **CRC Coordinator Support** |  |
| **Clinical Research Center** |  |
| **CTS-IT** |  |
| **HealthStreet** |  |
| **Integrated Data Repository (IDR)** |  |
| **Investigational Drug Services (IDS)** |  |
| **Recruitment Center** |  |
| **REDCap** |  |
| **Regulatory Support – IND/IDE** |  |
| **Regulatory Support - IRB** |  |
|  |  |
|  |  |
| **Other Non-CTSI Expenses:** |  |