**Cover Sheet for Spring 2021 UF-FSU Pilot Project Award Application**

|  |  |
| --- | --- |
| Project Title |  |

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

[ ]  No [ ]  Yes

|  |  |
| --- | --- |
| Full Name of PI |  |
| Position/Title |  |
| Institution & UF or FSU ID# |  [ ]  UF [ ]  FSU |
| College/Department |  |
| Department ID |  |
| Fiscal/Admin Contact |  |
| Campus Mailing Address/PO Box |  |
| Phone/Fax # |  |
| E-mail |  |

|  |  |
| --- | --- |
| # of Participants to be enrolled (if applicable) |  |
| Total cost of proposed work |  |
| Funding amount available from non UF-FSU CTSA sources (i.e. departmental or Opportunity Funding) |  |
| Total Amount of Funding Requested minus external funding |  |
| Start/End Date | July 1, 2021 - December 30, 2022 |

|  |  |
| --- | --- |
| Co-Investigator/Mentor*(as applicable)* |  |
| UFID/FSUID |  |
| College/Department |  |
| Campus Mailing Address/PO Box |  |
| Phone/Fax |  |
| E-mail |  |

**\***If more than one Co-I and/or mentor, please continue on an additional page.

**Human Subjects, Animal Research, and Proprietary/Privileged Information**

***Note:*** For projects requiring IRB and/or IACUC approval, applicants should demonstrate they have taken preliminary steps to prepare submissions so minimal time will be lost in securing approvals.

1. Are human subjects involved? [ ]  Yes [ ]  No
	1. If YES, does this project require IRB approval? [ ] Yes [ ]  No
	2. If YES, which IRB will your project be associated with (choose one)?
	 [ ]  UF [ ]  FSU [ ]  OneFlorida

If YES,

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

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

IRB project # (if known):

For assistance with determining the need for UF IRB approval for projects, please contact Tiffany Pineda, CTSI Research Navigator, at tiffany.danielle@ufl.edu.

For FSU IRB-related questions, please contact the FSU Office of Human Subjects at humansubjects@fsu.edu.

1. Is proprietary/privileged information included in the application? [ ]  Yes [ ]  No
2. Is Animal Research involved in your project? [ ]  Yes [ ]  No
	1. If YES, does this project require IACUC approval? [ ] Yes [ ]  No
	2. If YES, which IACUC will your project be associated with (choose one)?
	 [ ]  UF [ ]  FSU

If YES,

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

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

IACUC project # (if known):

For UF IACUC-related questions, please contact <https://iacuc.ufl.edu/secure/>.

For FSU IACUC-related questions, please contact <https://www.research.fsu.edu/research-offices/acuc/>.

***Principal Investigator:***

 Date:

Printed Name Signature

***Department Chair (or designee):***

 Date:

Printed Name Signature

**Application Instructions**

**Application Checklist and Submission**

Submit your application by 5:00 p.m. on Monday, April 12, 2021, to CTSI\_Pilot-Awards-l@lists.ufl.edu. Applications that do not follow the instructions or are submitted after the deadline will not be reviewed. Please confirm the following documents are included:

***Uploaded as a single PDF in the following order (max file size of 2MB):***

[ ]  1. Signed Cover Sheet

[ ]  2. Abstract, Translational Impact, External Funding Plan, Mentoring Plan

[ ]  3. Project Proposal/Research Plan

[ ]  4. Key Personnel and NIH Biosketches for Key Personnel

[ ]  5. Budget, Budget Justification, and Cost Estimates

[ ]  6. Letters of Support (as applicable)

**Formatting Your Application**

Applications must be formatted as follows:

* Use Arial font, size 11
* Single spaced, left justified
* Use ¾” margins and standard 8.5’’x11’’ paper
* No appendices are allowed

**Applications Must Include the Following:**

**Cover Sheet**

List the project’s title, all key personnel, and signed by the PI and the PI’s department chair (or designee)

**Abstract (200 words or less)**

Provide the rationale for the work, usually in the form of a research question to be answered or specific methodology problem to be addressed, and a description of the approach to be taken.

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

Describe how the proposed project will contribute to improved human health.

**External Funding (one page or less)**

List the sources of external support that will be pursued following the UF-FSU CTSA Pilot Award, including the RFA/RFP/solicitation number, agency, tentative date of submission and why/how pilot project is aligned with solicitation requirements.

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

Summarize the mentoring plan and environment(s) for the project team’s trainee(s) and/or junior faculty.

**Project Proposal/Research Plan (6 pages or less)**

Describe the proposed project and research plan and include the following sections:

* Rationale and Specific Aims/Objectives
* Background/Significance
* Innovation
* Approach (including Preliminary Studies, Design, Methodology, and Analysis Plan)
	+ For NIH-defined clinical research projects:
		- Clearly justify the number of participants to be enrolled in the pilot and the number of participants needed for an externally funded study.
		- Include a recruitment strategy that addresses feasibility, recruitment methods, and retention planning for success.
* Planned Enrollment Table (if applicable) 
* Project Timeline; please use general timeframes (e.g., Month 1)
* References (NIH formatted; not included in the 6-page limit)

**Additional Information Required**

**NIH Biographical Sketches**

NIH-formatted biosketches for PI, Co-I(s), and mentor(s). The NIH biosketch form can be downloaded at <https://grants.nih.gov/grants/forms/biosketch.htm>. Additional instructions for biosketches:

* + Biosketches must be submitted using the new format (Rev. 03/2020 Approved Through 02/28/2023) and are limited to 5 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 (as applicable).
	+ **Mentors:** Personal statement should include mentor’s qualifications and role in the career development of the PI (as applicable).

**Budget, Budget Justification, and Cost Estimates**

* **NIH Detailed Budget for Initial Budget Period:** Submit a detailed budget and justification of expenses using the NIH’s standard “Detailed Budget for Initial Budget Period,” the form can be downloaded at <https://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, UF-FSU CTSA, etc.)
* **Cost Estimates:** UF CTSI Services require cost estimates in writing from UF CTSI Service Providers. No-cost consultations prior to submission of the proposal are strongly encouraged. For a complete list of available resources, please visit the UF CTSI website at: [www.ctsi.ufl.edu/research](http://www.ctsi.ufl.edu/research).

For questions about allowable costs and constructing a budget, contact Angela Hunter-Edwards at afhunter@ufl.edu (UF).

**Letters of Support**

Trainees and Early Stage Investigators must include letters of support from their mentor(s).

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**UF-FSU CTSA Budget Justification Worksheet**

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

Refer to the UF-FSU CTSA Pilot Awards Spring 2021 RFA guidelines for allowable costs. Some line items from the NIH Detailed Budget for Initial Budget Period form might not qualify for Pilot funding. Be sure to list non UF-FSU CTSA resources - Funding from sources outside of the UF-FSU CTSA will strengthen the application.

|  |
| --- |
| **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.*** |

In addition to the worksheet above, written cost estimates are required attachments for all UF CTSI Services included in this submission. Please detail all UF CTSI Services included in your application below.

|  |  |  |
| --- | --- | --- |
| **UF 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 - IDE/IND:** |  |
| **Regulatory Support – IRB:** |  |
|  |  |
|  |  |
| **Other Non UF-FSU CTSA Expenses:** |  |