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**Cover Sheet for 2021-22 CTSI Learning Health System 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 [ ]  FSU |
| College/Department |  |
| Department ID |  |
| Fiscal/Admin Contact |  |
| Campus Mailing Address/PO Box |  |
| Phone/Fax # |  |
| E-mail |  |

|  |  |
| --- | --- |
| Total Amount of Funding Requested |  |
| Start/End Date | July 1, 2021 – June 30, 2022 |

|  |  |
| --- | --- |
| Co-Investigator*(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 and Proprietary/Privileged Information**

***Note:*** For projects requiring IRB 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.

For assistance with OneFlorida IRB-related questions, please contact the OneFlorida Front Door team at OneFloridaOperations@health.ufl.edu.

1. Is proprietary/privileged information included in the application? [ ]  Yes [ ]  No
2. Answer the following questions to determine if your study meets the [NIH definition](https://grants.nih.gov/ct-decision/index.htm) of a clinical trial.
* Does the study involve human participants? [ ]  Yes [ ]  No
* Are the participants prospectively assigned to an intervention? [ ]  Yes [ ]  No
* Is the study designed to evaluate the effect of the intervention on the participants?

[ ]  Yes [ ]  No

* Is the effect being evaluated a health-related biomedical or behavioral outcome?

[ ]  Yes [ ]  No

If the answer to all four questions is yes, your research is considered a clinical trial.

1. National Clinical Trial (NCT) number (if available):

**Signatures**

***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 Friday, April 2, 2021, to katherineblackbu@ufl.edu. Applications that do not follow the instructions or are submitted after the deadline will not be reviewed. Contact Katie Blackburn at katherineblackbu@ufl.edu with questions. 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

**Applications Must Include the Following:**

**Cover Sheet**

Listing the project’s title, all key personnel, and signed by the PI and the PI’s department chair.

**Abstract (500 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 the Learning Health System and improved health outcomes.

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

List the sources of external support that will be pursued following the CTSI 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 Early Stage Investigator(s).

**Project Proposal/Research Plan (4 pages PLUS up to 2 pages of references)**

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

* Hypotheses and Specific Aims/Objectives
* Background/Significance
* Innovation and anticipated impact on practice-based healthcare, hospital care or the translational research process
* Approach (including Preliminary Studies, Design, Methodology, and Analysis Plan)
* Engagement strategies: include strategies for engagement of key stakeholders (e.g., patients, health system leaders, community clinicians).

**Project Timeline (1 figure)**

Please use general timeframes (e.g., Month 1)

**Appendices**

Letters of Support from relevant partners or institutions will be considered.

**Additional Information Required**

**NIH Biographical Sketches**

NIH-formatted biosketches for PI and Co-I(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).

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

Submit a detailed budget and justification of expenses using the NIH’s standard “Detailed Budget for Initial Budget Period” form. The NIH “Detailed Budget for Initial Budget Period” form PHS 398 (Rev. 03/2020 Approved Through 02/28/2023) can be downloaded at <https://grants.nih.gov/grants/funding/phs398/phs398.html>.The following guidelines should be considered when developing your budget:

* + Funds may not be used to support faculty salaries.
	+ There will be limits on use of award funds for travel.
	+ Funds cannot be used to buy computers or equipment that is not in direct support of the pilot.
	+ Funds can be used only for direct costs (indirect costs are not allowed), such as:
* Graduate student assistance to be hired on as OPS.
* Programming time, statistical support, and to support data collection activities.
* Travel support will only be funded to the extent that it is integral to the completion of the project; attendance at professional meetings will not be funded.
* A cost estimate for requested services should be included in the application. For example, if you are requesting funds for UF Health Integrated Data Repository or Southeast Center for Integrated Metabolomics services, we will expect an estimate detailing the cost of service from the provider of the service.

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