

Cover Sheet for Spring 2020 CTSI Precision Health Initiative Pilot Project Award Application

Project Title	
Please select the area in	which you are applying:
Precision medicine	Precision public health
Please indicate whether	you have been PI on a previous CTSI Pilot Award:
No Yes	
Full Name of PI	
Position/Title	
Institution	
College/Department	
Department ID	
Fiscal/Admin Contact	
Campus Mailing Address/PO Box	
Phone/Fax #	
E-mail	
Total Amount of Funding Requested	
Start/End Date	
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.

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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.

í aj	 Are human subjects involved? Yes No a) If YES, does this project require IRB approval? Yes No b) 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?								
		IRB approval date (mn						
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.							
 2) Is proprietary/privileged information included in the application? Yes No 3) Answer the following questions to determine if your study meets the <u>NIH definition</u> 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 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. 								
Sign	atures							
Princ	cipal Inve	estigator:						
Printe	ed Name		Signature	[Date:			
Depa	artment (Chair (or designee):						
Printed Name			Signature	Date: Signature				

Application Instructions

Application Checklist and Submission

Submit your application by 5 p.m. on Friday, May 15, 2020, to elizabetheddy@ufl.edu (UF) or terra.bradley@med.fsu.edu (FSU). Applications that do not follow the instructions or are submitted after the deadline will not be reviewed. Contact Elizabeth Eddy, MPH at elizabetheddy@ufl.edu or Terra Bradley, PhD at terra.bradley@med.fsu.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 ³/₄" margins and standard 8.5"x11" paper
- No appendices are allowed

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 (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 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 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:

- Hypotheses and Specific Aims/Objectives
- Background/Significance
- Innovation
- Approach (including Preliminary Studies, Design, Methodology, and Analysis Plan)

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- 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.
 - Include a planned enrollment table.
- Project Timeline (including IRB submission if necessary). 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 <u>https://grants.nih.gov/grants/forms/biosketch.htm</u>. 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: <u>https://commons.era.nih.gov/commons/index.jsp</u>.
- **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, 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

<u>https://grants.nih.gov/grants/funding/phs398/phs398.html</u>. 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 <u>afhunter@ufl.edu (UF)</u> or Ellen Potts at <u>ellen.potts@med.fsu.edu (FSU)</u>.

Letters of Support

Junior faculty who are applying as a PI must include a letter(s) of support from their mentor(s).