# Instructions for Patient-Oriented Clinical Research Pilot Proposals Submitted April 1, 2018 – March 31, 2019

*Please carefully follow the 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.
* Include the IRB protocol number and date of approval. If you have not yet obtained IRB approval for your work, enter “NA”.
* 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). Be sure to list 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 should 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 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.

# Research Plan

Describe your proposed project in a research plan of **no more than five pages**. You may submit the same research plan to the IRB and the CTSI. Your plan should include the following sections:

* Project Timeline including current IRB submission status
* Rationale
* Specific Aims
* Preliminary Studies
* Design and Methodology. 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 (Feasibility, recruitment, retention planning)
* Planned Enrollment Table
* References (included in the five 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:
  + Each biosketch is 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. 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 [CTSIClinicalRFA-L@lists.ufl.edu](mailto:CTSIClinicalRFA-L@lists.ufl.edu). Applications in response to this RFA will be accepted on a rolling basis until March 31, 2019. Proposals that do not follow the instructions will not be reviewed. Please email [CTSIClinicalRFA-L@lists.ufl.edu](mailto:CTSIClinicalRFA-L@lists.ufl.edu) with any questions.

**Cover Sheet for Patient-Oriented Clinical Research Pilot Project Proposal**



Proposal Title

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

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

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

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| IRB/IACUC Protocol Number |  |
| IRB/IACUC Approval Date (mm/dd/yy) |  |

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| Number of participants to be enrolled |  |
| Total cost of proposed work\* |  |
| Funding amount available from non- CTSI sources (e.g., departmental or Opportunity Fund support). |  |
| Total funds requested from CTSI |  |

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

Signatures

Principal Investigator Department Chair or Representative

Name Date Name Date

**Page 2 of Clinical Research Pilot Project 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 5 pages)*

# Project Timeline; including proposed IRB submission date

**Rationale**

**Specific Aims**

**Preliminary Studies**

**Design & Methodology**

**Recruitment Strategy**

**Planned Enrollment Report**

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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** |

PHS 398 / PHS 2590 (Rev. 08/12 Approved Through 8/31/2015) OMB No. 0925-0001/0002

# References

**Key Personnel**

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| Name of Project Member |  |
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| Role on Project |  |

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Please refer to the RFA guidelines for allowable costs; some line items from the NIH Detailed Budget for Initial Budget Period form might not qualify for CTSI Patient-Oriented Clinical Pilot funding. Be sure to list funds available for this project from non-CTSI sources. Funding for this pilot project from sources outside of the CTSI will strengthen the application. Funds requested for use of CTSI Services should be listed under "Other Expenses."

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| **Personnel (list the Key Personnel included in this study i.e. PI, Co-I, Mentor, etc.)** | | | | |
| **Name** | **Role in Project** | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., Grant, etc.)** | **For Office Use Only** |
|  | Principal Investigator | $0.00 |  |  |
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| **Consultants (from NIH Detailed Budget for Initial Budget Period)** | | | | |
| **Name** | **Role in Project** | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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| **Equipment (from the NIH Detailed Budget for Initial Budget Period; refer to RFA)** | | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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| **Supplies (from the NIH Detailed Budget for Initial Budget Period; refer to RFA)** | | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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| **Travel (from the NIH Detailed Budget for Initial Budget Period; typically not applicable, refer to RFA)** | | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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| **Inpatient Care Costs (from the NIH Detailed Budget for Initial Budget Period; typically not applicable)** | | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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| **Outpatient Care Costs (from the NIH Detailed Budget for Initial Budget Period; refer to RFA)** | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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| **Other Expenses (Itemized by Category) *include requested CTSI Services in this section;* list of available resources** [**www.ctsi.ufl.edu/research**](http://www.ctsi.ufl.edu/research) | **Total Funding Requested** | **How will this be funded (i.e. CTSI, Dept., etc.)** | **For Office Use Only** |
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