**The Ohio State University Center For Clinical and Translational Science
Pilot Translational & Clinical Studies Program Application Document Order**

Applications submitted without elements included per order below may not be reviewed or considered for funding.
- Use single spacing and a consistent 12 point font throughout the document.
- All applications are to be completed online through the REDCap platform. Additional information can be found on ccts.osu.edu

Consult the Pilot Translational & Clinical Studies Information and Instructions Document for additional details regarding eligibility, project requirements, and funding criteria.

Application Document Order for single PDF Upload

1. **Cover Letter** – Address Cover Letter to the Review Committee

2. **Abstract -** Describe and state the project's broad, long term objectives and specific aims.
   - Not to exceed 500 words

3. **Protocol/Proposal -** The protocol/proposal **must** include the following sections.
   - The proposal should not exceed 5 pages; however, additional reference pages over the page count are allowable.

   ➢ **Specific Aims/Objectives** - Concisely describe what the specific research is intended to accomplish. List any hypothesis to be tested along with research goals.

   ➢ **Feasibility Analysis** – How likely is it that the objectives and activities planned will be achieved within the scope of the funded project.

   ➢ **Background and Significance** – Briefly provide background for the proposal. Critically evaluate existing knowledge and identify and address scientific gaps. State the importance of the proposed research by relating it to the research project objectives.

   ➢ **Integrating Special Populations*** – Applications for Integrating Special Populations Pilots must include a description of the special populations to be included.

   ➢ **Preliminary Studies** – Include any information or data from previously conducted work.

   ➢ **Experimental Design and Methods** - Outline the experimental design and the procedures necessary to accomplish the objectives. Discuss any potential difficulties with the proposed research and list possible alternative pathways to achieve the goals of the study in a timely manner. It is **critical** to have a well thought-out recruitment plan and detailed study feasibility assessments, i.e. data on NCH patient population, approach/consent planning, etc. The CCTS may be able to offer recruitment planning and feasibility assistance.

   ➢ **Statistical Analysis -** Include statistical information, such as goal enrollment and sample size (with justification), power analysis, data to be collected, analysis and

*May not be required

interpretation. *Applicants should discuss statistical study design with a biostatistician for completion of this section and submission.*

➢ **Evaluation** – Describe the project evaluation plan. What metrics will be measured?

➢ **Cited Literature and References**

4. **NIH Biosketch for Key Personnel:**
   - Principal Investigator
   - Co-PI and Co-I
   - Collaborating Investigators
   - Research Mentor

5. **Grant Budget** - Applicant must include budget from the Sponsored Projects Office and a written budget justification supporting the requested funds.

6. **Signature Attestation Page**

7. *****Letter(s) of Support** - Applications indicating that subjects will be recruited in an area outside of the direct patient care area of the investigator must include a **Letter of Support (LOS)** from a member of the department/division of the applicable patient population which includes confirmation of adequate eligible subjects and staff, and also that the proposed project does not overlap with other, ongoing division research.

   - **Community/Stakeholder Letter of Support*** - Community Engagement Pilot Applications must include a Letter of Support from the community/stakeholder partner.

8. **Project Timeline** - A successful project will include an outline that can be completed within 1 year of funding. We encourage applicants to display a thoughtful clinical research study design.

9. **Future Plan Statement** - Include a statement of how the proposed project will lead directly to a publication and external grant support.

A completed application will include a PDF document of all items listed above as well as a PDF document of the research abstract. Both files must be uploaded into the REDCap application platform; emailed submissions will not be accepted.

Please contact the Pilot Translational & Clinical Studies Program with any questions or for application assistance: ccts-pilots@osumc.edu

*May not be required
The Ohio State University Center for Clinical and Translational Science
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