

Program Overview and Application Instructions

Pilot and Collaborative Translational and Clinical Studies Program

PROGRAM OVERVIEW

A. PURPOSE

The purpose of The Ohio State University Center for Clinical & Translational Science (CCTS) Pilot and Collaborative Translational and Clinical Studies Program is to cultivate outstanding new research at OSU. The specific goal of the program is to stimulate preliminary data in novel research directions, and ultimately to launch new nationally-funded research programs. To this end, preference is given to new and unfunded ideas. These grants are not intended to provide additional support for established areas of research or previously funded projects. Established investigators, however, are encouraged to apply for the initial funding of unique research directions. Translational investigation is of special interest. The CCTS specifically encourages interdisciplinary research, in which investigators from disparate scientific areas collaborate to bring unique approaches to human health issues.

The CCTS supports both clinical research and basic research intended to have human applications. In this context "translational" investigation is broadly defined. It includes laboratory research with potential human applications, "bench to bedside" research in which laboratory findings are studied in the human context, the interaction of small human studies with those in larger populations, and the translation of research into clinical practice and health policy. Examples of "interdisciplinary" research include basic investigators teaming with clinician scientists to launch a bench-to-bedside project, clinical investigators teaming with population researchers to understand how molecular or physiological events are manifested in larger cohorts, or clinician scientists collaborating with outcomes investigators to examine the process of translating research into practice. When investigators from many institutions and disciplines come together to collaborate on developing a new diagnostic or a novel approach to treatment or prevention, that is the measure of success.

B. PILOT PROJECT FUNDING DETAILS

1. Pilot and Collaborative Studies Projects

- a. Funding: Amounts up to \$30,000 in direct costs per year.
- b. Eligibility: All OSU faculty researchers may apply. Applicants must fit the general OSU guidelines for Principal Investigator eligibility.
(<http://rf.osu.edu/development/piqualifications.cfm>)
- c. Projects to be funded: 3-4 projects are expected to be funded.

2. Novel Methodology Initiatives

- a. Funding: Amounts up to \$30,000 in direct costs per year.
- b. Eligibility: All OSU faculty researchers may apply. Applicants must fit the general OSU guidelines for Principal Investigator eligibility.
(<http://rf.osu.edu/development/piqualifications.cfm>)

c. Projects to be funded: 2-3 projects are expected to be funded.

3. Allowable costs

- a. Personnel *, supplies, travel, and other expenses, such as research beds, nursing or bionutrition staff, routine laboratory measures, and generation of preliminary data.
- b. Travel funds that are needed for study conduct (e.g. participant travel) are allowed if essential.
- c. Equipment that is essential for the study, and is not otherwise available, may be requested, but large equipment expenditures are discouraged.

*CCTS Pilot Grants will not cover the salary of faculty members (salary support for students, graduate students, clinical trainees, post-doctoral and clinical fellows will be permitted)

C. KEY ELEMENTS OF PROPOSALS FUNDED BY THE PILOT AND COLLABORATIVE STUDIES PROGRAM

- Addresses an important problem in human clinical and/or translational research or in an area that impacts human health
- Includes interdisciplinary and/or cross-institutional collaborative research
- Includes a team of faculty members with appointments in different departments, colleges, or institutions
- Proposes a high risk, high impact field of investigation that is new to the faculty member(s) and that requires pilot funds to generate preliminary data
- Is used as seed money rather than continuing support for ongoing projects
- Includes junior faculty or new investigators mentored by senior investigators

D. KEY DATES

RFA released	November 17, 2008
Application deadline	January 10, 2009
Review of applications completed	February 15, 2009
Earliest funding start date	February 28, 2009

E. CCTS INFRASTRUCTURE SERVICES

To request CCTS biostatistics study design consultation for a Pilot Project application, applicants must contact the Center for Biostatistics (<http://www.biostatistics.osu.edu/>) at least 4 weeks in advance of the application deadline to schedule an appointment.

Investigators are encouraged to make use of the extensive core resources of the CCTS after receiving pilot funding. These services include:

- Consulting services to assist in planning and identifying Biomedical Informatics support
- Biostatistics services to assist in study design and data analysis

- Technical help with IRB submissions including consent documents and HIPAA forms, and access to a Research Subject Advocate as needed
- Nursing, bionutrition and laboratory services through the Clinical Research Center
- Resource materials for developing community-based studies
- Research training through an approved university course on Clinical Research Methods (IBGP692)

F. APPLICATION INSTRUCTIONS

The application must be submitted online to ccts-admin@osumc.edu as a Word or PDF document using the following guidelines:

1. Cover Page (1 page)

- Name, affiliation and role of the Principal Investigator, Co-Investigators and Mentor(s) (as applicable)
- Problem to be solved
- Abstract: brief description (maximum 350 words) of the proposed project

2. Research proposal (8-pages maximum; follow Format Specifications listed below).

- Specific Aims/Objectives
- Hypothesis
- Background and Significance (include translational and collaborative aspects of the project)
- Preliminary Data
- Research Design & Methods (also include the approach to statistical analyses, power estimates, etc.)
- Proposed Timeline and milestones for completion of the project within the one-year funding period
- Plans for future grant submissions utilizing data from the project
- Literature Cited (not included in total page counts)

3. Project Budget and Budget Justification (1 page)

4. Biographical Sketch(es) for PI and Key Personnel (maximum 3 pages/investigator)

- Use the most recent version of the NIH Biographical Sketch Format Page.
- Consolidate multiple biographical sketches into a single document, with the biosketch for the project PI first.

5. Letters of Support (maximum of 3)

G. FORMAT SPECIFICATIONS. All applications must adhere to the following guidelines:

1. Font

- Use Arial 11 points or larger
- Type density, including characters and spaces, must be no more than 15 characters per inch.

- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.

2. Page Margins

- Use at least one-half inch margins (top, bottom, left, and right) for all pages

3. Application Paging

- The application must be single-spaced.
- Consecutively number pages in the Research Proposal.

4. Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

- You may use a smaller type size but it must be in black ink, readily legible, and follow the font typeface requirement.
- Do not include figures or other materials that are not inserted directly into the body of the application. Any separate pages will be counted as part of the 8 page limit.

5. Documents and file names

- Documents can be in any of the following formats: *.doc, *.docx, *.xls, *.xlsx, *.pdf
- Turn off tracked changes and accept all changes before uploading documents.
- Documents should be named according to the following naming conventions (with appropriate file extension):
 - 1) Cover page: [PI last name]_cover.doc (e.g. Edwards_cover.doc)
 - 2) Research proposal: [PI last name]_researchplan.doc
 - 3) Project budget: [PI last name]_budget.doc
 - 4) Biosketch(es): [PI last name]_biosketch.doc [NOTE: combine all biosketches into a single document with the project PI's biosketch first]
 - 5) Letters of support: [PI last name]_support.doc

H. CTS REVIEW CRITERIA

- Is the project innovative, focused, and achievable?
- Do the investigators have the requisite skills and experience to carry out the project successfully? Is adequate supervision and mentoring provided for trainees who will carry out the project?
- Does the proposed project stimulate collaboration across institutions? Does the funding stimulate collaborations that otherwise might not have taken place?
- Does the project bring together investigators who have not worked together in the past?
- Does this support junior faculty?
- Does the project involve studies that can translate experimental findings to patient care, community engagement or population health?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- Is the application likely to lead to new RO1 applications (or similar national grant requests)?

I. AWARDEE RESPONSIBILITIES

- IRB approval (if needed) is required prior to release of funds.

- A 6-month progress report is required.
- A final report describing project accomplishments must be submitted within 60 days of the project end date.
- The OSU CCTS itself is evaluated by the NIH on its effectiveness in stimulating new research findings and publications. The following support acknowledgement should be included on all publications that result from CCTS support.

“The project described was supported by Award Number UL1RR025755 from the National Center for Research Resources, funded by the Office of the Director, National Institutes of Health (OD) and supported by the NIH Roadmap for Medical Research. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.”

J. FURTHER INFORMATION

Please direct all questions to Kim Toussant at 614-688-3722.