The Center for Clinical and Translational Science Pilot and Innovative Program
Longitudinal Track Pilot Program
Request for 4-page Pre-Proposal

Deadline for Pre-Proposal Submission: August 4, 2015, at 8:00AM
Full Application Deadline October 1, 2015, at 8:00 AM

PROGRAM OVERVIEW
A. PURPOSE

The Longitudinal (L-Pilot) mechanism is aimed at incentivizing the long-term development of a promising project towards a major success story (i.e. significant extramural programmatic funding and/or commercialization). The L-pilot program is looking for investigators with interest in forming interdisciplinary teams (multi-college) that have the clear potential to transform health care or translational science through patient-based (may include pre-clinical component as supporting research) innovative clinical and translational research.

A town hall meeting will be held on July 10, 2015, at 10:00 am at the Prior Health Science Library 6th floor seminar room. This meeting will serve to answer all questions about the program and applications.

The L-Pilot Program is broken down into three Phases:

Phase 1:
1. Recognize the problem to be studied from an interdisciplinary perspective
2. Develop a pilot study approach and establish feasibility data
3. Identify pointed deliverable milestones, including appropriate regulatory and/or institutional approval(s)
4. Teams must bring a minimum match of $5K. The match funds are further defined in the funding section of the RFA. Teams may request a 1:2 match with a minimum contribution of $5K. Examples of the match setup:

<table>
<thead>
<tr>
<th>Team</th>
<th>CCTS</th>
<th>Total Award</th>
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<tbody>
<tr>
<td>$5K</td>
<td>$10K</td>
<td>$15K</td>
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<tr>
<td>$10K</td>
<td>$20K</td>
<td>$30K</td>
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<tr>
<td>$16.5K</td>
<td>$33K</td>
<td>$49.5K (maximum request)</td>
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The CCTS anticipates funding up to 4 teams at the Phase 1 funding level of up to $49.5K for no more than one year. Advancement of Phase 1 to Phase 2 funding will be dependent on meeting Phase 1 expectations and the collection of convincing preliminary data. It is anticipated that no more than half of Phase 1 projects will advance to Phase 2. Advancement to Phase 2 will be a competitive external review process. *2014 Phase 1 teams that did not advance to Phase 2 are eligible to compete in this Phase 2 grant cycle.

Phase 2:
1. Project has advanced from preliminary to final mode. That is, a translational component of the project is developed and initiated.
2. Set new milestones demonstrating project progress
3. Team must set and meet itemized deliverables (awarded funds will be distributed based on meeting these milestones)
4. Award of up to $100K total over 1-2 years
5. The awardee team must match $50K towards this project. The match funds are further defined in the funding section of the RFA.

It is anticipated that 1/3 of Phase 2 projects will advance to Phase 3. Advancement to Phase 3 will be a competitive external review process. *Phase 2 funding will be dependent upon the CCTS’s continued internal and external grant funding levels.

**Phase 3:**

1. Stringent requirements will be aimed at commercial success and/or substantial translation/clinical value/extra mural funding prospect(s)
2. Award funds will be based on meeting itemized deliverables (awarded funds will be distributed based on meeting these milestones)
3. $150K for 1-2 years
4. The awardee team must match $50K towards this project. The match funds are further defined in the funding section of the RFA.

*Phase 3 funding will be dependent upon the CCTS’s continued internal and external grant funding levels.

**B. KEY DATES**

<table>
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<tr>
<th>Event</th>
<th>Date</th>
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<tr>
<td>RFA release</td>
<td>June 23, 2015</td>
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<tr>
<td>Town Hall Meeting</td>
<td>July 10, 2015</td>
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<tr>
<td>Pre-Proposal Deadline</td>
<td>August 4, 2015</td>
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<tr>
<td>Application Workshop (mandatory)</td>
<td>August 25, 2015</td>
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<tr>
<td>Full Application Deadline</td>
<td>October 1, 2015</td>
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<tr>
<td>Earliest Phase 1 funding start date</td>
<td>November 15, 2015</td>
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**C. PILOT PROJECT FUNDING DETAILS**

**Funding**

For Phase 1 projects, up to 4 awards are expected in the amount of (up to) $49,500 in total direct costs including match for up to one year. Projects not meeting stated goals in one year will be eliminated from further consideration.

**Allowable costs**

- Salary and fringe support for students, graduate students, clinical trainees, post-doctoral, project staff such as clinical coordinators and lab technicians, and clinical fellows is permitted.
- Salary and fringe support for faculty and administrative personnel are not permitted.
- Supplies and other expenses, such as research beds, nursing or bionutrition staff, routine laboratory measures, and generation of preliminary data.
- Travel funds that are needed for study conduct (e.g. participant travel) are allowed if essential.
- Equipment that is essential for the study, and is not otherwise available, may be requested, but large equipment expenditures are discouraged.

**Cost Match**

Matching funds are mandatory. This helps the CCTS demonstrate its leveraging of institutional resources towards final productivity that far exceeds the direct investment made by the NIH to the CCTS. Matching funds can come from any combination of team members’ startup funds, departments, chairs, or colleges. Examples for match include, but are not limited to:
• Direct research money
• Dollars toward salary of key non-faculty personnel whose effort either in whole or part is dedicated to the project
• Industry sponsored research
• Philanthropic donor/gift development funds

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

Eligibility
• Project leaders must have principal investigator status at OSU or NCH (with extramural funding track record). Eligibility information can be found at the Ohio State Office of Research website and the NIH website.
• The project team should have senior faculty leaders and must include two junior faculty members in mentee roles with clearly defined tasks.
• Applicants and mentors must become CCTS members by completing a CCTS membership form.
• Past CCTS Pilot awardees are eligible; except past L-pilot PIs and Co-PIs. They may serve as consultants to new teams.
• Project must include a team of researchers from at least two different OSU Colleges or Nationwide Children’s Hospital.
• It is highly recommended that each team includes both a basic scientist and a clinician in the leadership
• Projects must be patient centric.
• Project must address an important problem in human clinical and/or translational research or in an area that impacts human health.
• Project must include transdisciplinary and/or cross-institutional collaborative research.
• Project teams may be either new teams or teams that have worked together in the past, but cannot have received large programmatic funding (e.g. PPG or SPORE). RO1 funding and group publications are allowable. Already established teams must present a new idea or how they are taking a past project to a new translational level.
• Investigators may only submit one proposal or be a part of one proposal.
• Funding will be used as seed money rather than additional funding for ongoing funded projects.
• Research may not go beyond Phase 2A.

E. CCTS INFRASTRUCTURE SERVICES

Pilot investigators are encouraged to take advantage of the many CCTS resources as a way to extend their research capacity. A list of the provided services can be found on the OSU Computerized Research Record Website.

Selected projects will participate in project management, guidance, and consulting from Battelle and the CCTS.

F. APPLICATION INSTRUCTIONS

The Pre-proposal must be submitted to cctspilots@osumc.edu as a single Word or PDF document no later than August 4, 2015 at 8am. All pre-proposals will undergo administrative and scientific review. If selected for full application a representative of the team will be required to present at the Application Workshop on August 25, 2015. You will be notified by August 11, 2015 if you application has been accepted to present at the Application Workshop.

A. Pre-Proposal Contents
• Team member names and contact information including title/department/division/era Commons name/
Administrative departmental contact (name, phone, email)

• Project title

• Graphic Summary (1000 words and up to 2-4 summary figure; cannot exceed 4 pages)
  - Question to be addressed – Clinical Impact – 50 words
  - Breadth of proposed interdisciplinary team and unique expertise involved – 100 words
  - How the project will fit a well-defined significant void – 100 words
  - Project innovation (describe how the project is transformative and impactive) – 100 words
  - Feasibility – 150 words
  - Science/approach – 500 words

• Letters of Support from funding source committing matching funds (as described above).

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

1. Font
   a. Use Arial 11 points or larger
   b. Type density, including characters and spaces, must be no more than 15 characters per inch.
   c. Type may be no more than six lines per inch.

2. Documents and file name
   a. A single combined PDF file is acceptable and should be named using the following guideline
      [last_first_LPilotpreproposal_013114]

G. AWARDEE RESPONSIBILITIES

• Upon receipt of your pre-proposal, the CCTS will send you an email confirmation. Please inquire within 24
hours if you do not receive this email. The program will not be responsible for late submissions if not
notified.

H. FURTHER INFORMATION/Town Hall Meeting
A Town hall meeting to answer all questions about this application cycle will be held on July 10, 2015, at 10:00am in
the Prior Health Sciences Library 6th floor seminar room. This one hour meeting will discuss the overall Longitudinal
Program and what is expected in applications. Please direct questions to the pilot program manager, Amy Dworkin
(Amy.Dworkin@osumc.edu) (614-366-5856) or Chandan K. Sen, the Director of the CCTS Pilot and Innovative
Program.