Request for Applications

Pilot Project Funding for Investigations into the Ethical Conduct of Research

Full application deadline: December 21, 2009*

The Oregon Clinical & Translational Research Institute (OCTRI) is now accepting applications for Pilot Project Funding for Investigations into the Ethical Conduct of Research. The purpose of this funding mechanism is to stimulate research on ways to improve and expand how we conduct and oversee human subject research.

Review criteria include scientific excellence, applicability to clinical and translational research, innovation, feasibility and a likelihood of meeting successful benchmarks (i.e., publication and/or grant submission). Successful applications will draw from techniques in qualitative and quantitative research and borrow from program evaluation methodology and the practice of quality assessment and process improvement. Proposed projects should consider ways to improve and expand how we conduct and oversee research. Examples of such would include but not be limited to examining novel approaches to obtaining consent, proposing new models for oversight that allow for equivalent protections, questioning the added-value of extra-regulatory activities, and/or studying the effects of reviewer biases on the quality of research. As part of the successful execution of the pilot project, awardees are expected to submit one or more manuscripts to a peer-reviewed, scientific journal and/or submit a grant application to one or more external agencies. OCTRI should be notified in a timely manner of submitted manuscripts and/or grant applications.

We expect to fund 1-2 applications at $10,000 each. Members of OCTRI’s leadership team and program directors may not submit for pilot project funding. Project funding can be used to support any direct expenditure appropriate to furthering the research goals. Funding will not be awarded as bridge funding for ongoing projects or to purchase large equipment for use as a core resource. In addition to financial support, OCTRI has extensive infrastructure services that may be beneficial to funded Pilot Projects; investigators are encouraged to take advantage of these services as a way to extend their research capacity.

*Optional Proposal Review: Although a Letter of Intent is not required, potential applicants are invited to submit a brief study proposal (2-4 sentences) in advance of the full application deadline for limited feedback to ensure their project represents true collaboration between the institutions, makes appropriate use of institutional resources, is consistent with OCTRI's current strategic goals, and to verify that a full application is warranted at this time. Proposals should be submitted via email to octri@ohsu.edu.

MORE INFORMATION AND COMPLETE INSTRUCTIONS ARE AVAILABLE ON THE OCTRI WEBSITE (WWW.OCTRI.ORG/FUNDING).

Please direct all questions to the OCTRI Front Door (503-418-9790, octri@ohsu.edu)
Program Overview and Application Instructions

Pilot Project Funding

PROGRAM OVERVIEW

A. PURPOSE

The purpose of the Oregon Clinical & Translational Research Institute (OCTRI) Pilot Project program is to cultivate outstanding new research at OHSU and Kaiser Permanente Center for Health Research (KPCHR). 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. OCTRI also encourages interdisciplinary research, in which investigators from disparate scientific areas collaborate to bring unique approaches to human health issues. Joint OHSU-KPCHR projects are encouraged.

OCTRI 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. Other variations are certainly possible.

Bridge/infrastructure funding: OCTRI Pilot Project program is designed to support the gathering of key data essential to future research endeavors. As such, funding will not be awarded as bridge funding for ongoing projects or to purchase large equipment for use as a core resource.

B. PILOT PROJECT FUNDING DETAILS

1. Traditional Pilot Projects
   a. Funding: Amounts up to $10,000 in direct costs per project are available.
   b. Eligibility: OHSU faculty at the rank of Assistant Professor or higher and KPCHR investigators or doctoral-level Research Associates.
   c. Projects to be funded: 1-2 projects are expected to be funded.

2. General Principal Investigator eligibility
   a. OHSU: Applicants must fit the general OHSU guidelines for eligibility (http://www.ohsu.edu/research/rda/documents/PI_Eligibility_Awards.pdf).
   b. Kaiser Permanente: Applicants must be a KPCHR investigator or doctoral-level research associate.

3. Allowable costs
   a. Personnel, supplies, travel, and other expenses, such as research beds, nursing or bionutrition staff, routine laboratory measures, biostatistics and informatics support, and generation of preliminary data.
   b. Investigator salary is allowed, but a clear justification of why it is necessary should be provided (i.e., funds should be used principally to directly support the research).
c. Travel funds that are needed for study conduct (e.g. participant travel) are allowed if essential.
d. Equipment that is essential for the study, and is not otherwise available, may be requested, but large equipment expenditures are discouraged.

C. KEY DATES

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>RFA released</td>
<td>November 20</td>
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<tr>
<td>Letter of intent deadline*</td>
<td>LOI is optional</td>
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<tr>
<td>Review of letters of intent</td>
<td>Nov - Dec</td>
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<tr>
<td>Full application deadline*</td>
<td>December 21</td>
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<tr>
<td>Scientific / administrative review of full applications</td>
<td>Dec - Jan</td>
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<tr>
<td>Earliest funding start date</td>
<td>February 1</td>
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* Electronic submissions must be successfully received by OCTRI no later than 5:00 pm (Pacific Time) in order to be considered “on time.” When a submission date falls on a weekend or Federal holiday, the date will be extended to the next business day.

D. OCTRI INFRASTRUCTURE SERVICES

1. OCTRI has extensive infrastructure services that may be of use to funded Pilot Projects (e.g. core laboratory, nursing and bionutrition support, informatics support, biostatistical services). Due to limited availability, OCTRI cannot automatically offer free services to projects. The costs for these services can be included in the Pilot Project budget. Alternatively, applicants interested in requesting that OCTRI subsidize the costs of infrastructure services should consult with OCTRI Front Door before the application is submitted and describe those needs briefly in the application.

2. To request OCTRI biostatistics study design consultation for a Pilot Project application, applicants must contact OCTRI Front Door at least 4 weeks in advance of the full application deadline to schedule an appointment.

3. For more information about OCTRI services, visit www.octri.org or contact OCTRI Front Door directly.

APPLICATION INSTRUCTIONS

A. LETTER OF INTENT: The letter of intent is optional for applicants and should be submitted via email to the OCTRI Front Door (octri@ohsu.edu). OCTRI will review the letters of intent to ensure the proposed research meets the basic requirements for OCTRI funding eligibility.

1. Online application form
   - Name, affiliation and role of the Principal Investigator and Co-Investigators
   - General project information
   - Abstract: brief description of the proposed project

2. Letter of intent (2 pages maximum)
   - Brief summary of the scientific plan.
   - Why is this a “pilot” application and how will the data from this project be applied to future funding applications?
   - How does the proposed project fit into the PI’s career plan?
• How does the proposed project differ from the PI’s current research?

• For projects that involve OHSU-Kaiser Permanente collaborations: Have the Co-Investigators been contacted regarding participating in the project? [NOTE: A letter of support from the OHSU or Kaiser Permanente Co-Investigators will be required at the time of application, indicating support of and role on the project.]

• Which OCTRI infrastructure services will be needed to complete this project? [See Section D above.]

• One avenue for translating research into practice is through commercialization. Have you filed an invention disclosure on this technology or idea? Please describe any commercialization opportunities from your perspective.

B. FULL APPLICATION. The full application must be submitted online using OCTRI secure online application (see “Submission” below).

1. **Online application form**
   - Name, affiliation and role of the Principal Investigator and Co-Investigators
   - General project information
   - Abstract: brief description of the proposed project

2. **Cover letter** (2 pages maximum). This should address each of the following:
   - Significance and innovation of the proposed research.
   - Translational and collaborative aspects of the project.
   - Proposed timeline for completion of the project within the one-year funding period.
   - Other active funding available for the project. If there is corporate support, explain how OCTRI support would be synergistic and how intellectual property resulting from the study would be handled. Established investigators should clearly state how the proposed work is distinct from their ongoing efforts and how it will lead to an independently funded program. In addition, please describe how other resources would be leveraged to ensure a successful outcome.
   - Plans for future grant submissions utilizing data from the project (e.g. how will Pilot Project funding lead to future funding?).
   - Does this project involve collaborations with investigators at other CTSA institutions (see www.CTSAweb.org)? If so, there may be opportunities for trans-CTSA collaborations that could enhance the project’s attractiveness.
   - Specify whether OCTRI-subsidized infrastructure services are being requested in addition to the Pilot Project funding.
   - If the application is a resubmission of a previously unfunded Pilot Project application, one additional page should be added to the cover letter (for a maximum of 3 pages) describing how the application has been modified in response to the previous review. Applicants may only resubmit an application one time.

3. **Research proposal** (4-pages maximum; follow Format Specifications listed below). This should contain the following components:
   - Specific Aims
   - Hypothesis
4. **Project budget** (use the form available on the OCTRI website)
   - Page 1: Detailed Budget
   - Page 2: Budget Justification (list an explanation of all costs)
   - **Subaward/Consortium Expenses**: If the application involves multiple institutions, a separate budget should be submitted for each institution. On the budget for the project PI’s institution (primary site), the **total** subaward/consortium expenses should be listed in the appropriate location.
   - **Indirect costs**:
     1) **OHSU and Kaiser Permanente**: Indirect costs should **not** be included on the budget.

5. **Biographical Sketch(es) for PI and Key Personnel**
   - 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.

6. **Letters of Support** (combined into a single document)
   - A letter of support from the Department or Division Chair, including a description of institutional resources and partnerships dedicated to the project.
   - For projects that involve OHSU-Kaiser Permanente collaborations: a letter of support from the OHSU or Kaiser Permanente Co-Investigators (not needed from research staff) indicating the role and degree of involvement on the project.
   - Other letters of support, as appropriate.

7. **Proposed Project Questionnaire (OHSU only)**
   - A Proposed Project Questionnaire (PPQ) is **not** required at the time of the Pilot Project Funding application. The application, also, does not need to go through the OHSU Research Grants and Contracts office prior to application. Awardees, however, will be required to submit a PPQ to OCTRI.

C. **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, including continuation 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 4 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 letter**: [PI last name]_cover.doc (e.g. Orwoll_cover.doc)
     2) **Research proposal**: [PI last name]_researchplan.doc
     3) **Project budget**: [PI last name]_budget.doc [combine all budget pages into a single document]
     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

D. **SUBMISSION**
   1. Full applications must be submitted online by the deadline specified in the RFA using OCTRI secure application website (go to www.octri.org and click on Funding Opportunities).
   2. Previous applicants can access the site using their existing account.
   3. New applicants can create an account online.
   4. Applicants who have forgotten their password or have difficulty accessing the site should contact OCTRI Front Door (octri@ohsu.edu). Technical support for accessing the site is not available outside normal business hours; applicants should, therefore, plan accordingly.

E. **REVIEW PROCESS** (for applicants invited to submit a full application)
   1. Traditional Pilot Project applications will be reviewed by OCTRI Scientific Review Committee, which will be supplemented with reviewers in more specialized content areas to ensure that each application is appropriately evaluated. All reviewers are experienced, funded investigators with expertise in evaluating research applications.
   2. Several reviewers will read each application and all members of the committee will discuss them. Approximately 50% of the top scoring applications will be discussed in detail by the Committee. Any application will be discussed in detail at the request of any Committee member.
3. Top-scoring applications will also be reviewed by a biostatistician (a statistical plan is required, however, for all applications).

4. Scores (using the NIH scale) will be assigned by each committee member and mean scores will be calculated for each application.

5. All applicants invited to submit a full application will receive a brief summary statement explaining the rationale for the scores.

6. Final funding decisions will be made by OCTRI leadership.

F. OCTRI REVIEW CRITERIA

Overall scientific excellence; qualifications of the research team (40%)

- Are the conceptual framework and specific aims, study design, methodology, data analysis and interpretation, feasibility, etc. of high scientific quality?
- Are the investigators appropriately expert?
- Are the resources available to make the project successful?

Innovation (20%)

- How will this application provide results that are novel and likely to open new avenues of investigation at OHSU and KPCHR or beyond?
- Is the application in an exciting new direction apart from the work already ongoing in the investigator’s research group?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Significance (10%)

- Does this study address an important problem?
- If the aims are achieved, will scientific knowledge and/or clinical practice be advanced?

Translational/multidisciplinary (10%)

- A priority for OCTRI is to stimulate translational research. Translation is not required but translational approaches will be given some priority.
- Multidisciplinary collaboration among scientists of diverse backgrounds is also a plus, but not essential.

Likelihood of leading to new national funding (20%)

- An overt goal of the Pilot Project Program is to stimulate new science. Hence, applications that are likely to lead to new RO1 applications (or similar national grant requests) are of higher priority.
- All applicants should describe how the proposed studies are related to future funding plans.

G. AWARDEE RESPONSIBILITIES

1. IRB and IACUC approval (if needed) are required prior to release of funds.

2. A 6-month progress report is required.

3. A final report describing project accomplishments must be submitted within 60 days of the project end date.
4. OCTRI 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 OCTRI support (funding and/or infrastructure services)

This publication was made possible with support from the Oregon Clinical and Translational Research Institute (OCTRI), grant number UL1 RR024140 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research.

H. FURTHER INFORMATION

Please direct all questions to OCTRI Front Door at (503) 418-9790 or octri@ohsu.edu