Request for Applications:
Pilot Project Funding for Catalyzing Translational Research Opportunities

KEY DATES

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<th>Event</th>
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<td>Full application deadline</td>
<td>March 31, 2015</td>
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<tr>
<td>Presentations to Scientific Review Committee (if invited)</td>
<td>May 6, 2015</td>
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<td>Notification of award</td>
<td>May 7, 2015</td>
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<td>Window of award availability</td>
<td>July 1, 2015 – June 30, 2016</td>
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No-cost extensions will not be available for this funding cycle. All spending must be done by 6/30/2016.

PROGRAM OVERVIEW
The Oregon Clinical & Translational Research Institute (OCTRI), in close collaboration with the SOM Research Roadmap, is now accepting applications to apply for Pilot Project Funding for projects designed to enhance translational research at OHSU. This funding mechanism is open to all OHSU faculty.

The primary purpose of this program is to support new clinical and translational research initiatives at OHSU. OCTRI expects to support the novel, collaborative, transdisciplinary projects of 4-6 awardees (total amount available - $400,000). The funding is specifically intended to enable the development of subsequent grant applications that will sustain the awardees’ research activity and/or the dissemination of an impactful novel research methodology.

Applications that are responsive to any one of the following three areas will be accepted:

1. Development of Large, Transdisciplinary Grants
2. Development of Novel Research Methodologies
3. T1 Translational Research/First in Human Studies

Applicants may request a budget of up to $100,000, but only if at least $25,000 is allocated for OCTRI services. If no OCTRI services are requested on the application, then applicants may request a budget of
up to $75,000; these funds would be used for non-OCTRI direct costs. Note that, due to the structure of
the OCTRI pilot fund, indirect costs are not allowable.

A portion of this funding is made available through NIH grant support via the CTSA mechanism, and from
the Office of the Vice President of Research’s institutional support of OCTRI. The School of Medicine
Research Roadmap provides $200,000 for support of mechanism 1, listed above (Development of Large,
Transdisciplinary Grants).

AVAILABLE OCTRI SERVICES
OCTRI supports investigators, administrators and research staff with expertise, equipment, and facilities
for every stage of the research process.

- The Clinical Translational Research Center (CTRC)
  - Nursing – adult and pediatric inpatient and outpatient units, skilled nursing support for
    phlebotomy, intravenous access, medication administration, intensive phenotyping,
    pharmacokinetic sampling, etc.
  - Bionutrition/research kitchen – bionutritionist consultation for diet design and dietary
    intake analysis, metabolic kitchen for testing and administering research diets, body
    composition measurements, energy expenditure measurements.
  - Study coordinators – recruitment and enrollment of subjects, conduct of study
    procedures at OHSU and in the community
  - Core laboratory - sample processing and storage, DNA and RNA isolation, analytic
    assays, genetic assays
- Biomedical Informatics Program (BMIP)
  - OHSU Research Data Warehouse (RDW) – epic data for research purposes such as
    identifying patients for potential recruitment, clinical phenotyping, etc.
  - Data management consultation
  - Custom-developed databases & software development
  - Data coordination for clinical research & clinical trials
  - REDCap survey tool and REDCap customized research databases
  - Translational Bioinformatics Methodology development
  - Computational Workflow development and dissemination
  - Multi-omics and Imaging consultations
  - Statistical genetics consultation
  - Experimental design and analysis
- Biostatistics and Design Program (BDP)
  - Study design sample size and power analysis
  - Statistical analysis planning
  - Statistical analysis
  - Data preparation and data management
  - Statistical support with grant and manuscript preparation and review
- Investigator Support and Integration Services (ISIS)
  - IRB protocol preparation and application services are provided with all pilot awards at
    no cost to the investigator
  - Clinical trial and grant budget development
  - IND and IDE submission assistance and consultations
Visit the OCTRI website (www.octri.org) for a listing of services or contact the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu) with questions. OCTRI cost estimates are required only for those applications that are selected for presentation to the Scientific Review Committee. A detailed budget is not required at the time of initial application.

**FUNDING TYPES**

1. **Development of Large, Transdisciplinary Grants (e.g. Centers and Program Projects)**
   These awards support the SOM Research Roadmap goal to catalyze outstanding multidisciplinary collaborations, further the development of strong foci of biomedical research, and enhance the core resources available to OHSU investigators. The intent is to launch a new scientific direction or accelerate growth in an existing area of clinical and translational research. For example, this pilot award can be used to generate data to enhance submission of a compelling application for larger collaborative grants such as multi-PI, PPG, and Center awards, or to evolve an existing R01 into a grant submission for one of these larger awards. **It is expected that submission of one of these large grant applications will occur within 12-18 months of the start of this pilot award.**

   **The purpose of the OCTRI award is not to support the development of individual grant proposals (e.g. R01).** Strong preference will be given to applications that build on collaborations/projects that are ready to launch into larger programs, that are likely to result in successful national funding applications, and that have implications for human health, including research involving patients or human samples.

2. **Development of Novel Research Methodologies**
   The development of new methodologies is critical to the advancement of translational and clinical research. OHSU investigators have often been actively involved in creating translational research methods, and this program provides a dedicated funding mechanism to accelerate such work. **The goal is to facilitate development of state-of-the-art tools for translational research and to make them rapidly available to investigators.**

   Novel Research Methodology Development Awards support the development of novel clinical and translational methods and can encompass a wide range of techniques. Examples of pilot projects that would be viewed as responsive include but are not limited to:

   - New methods for phenotyping
   - Predictive toxicology
   - Novel and effective clinical subject recruitment techniques
   - Ethics research specific to populations
   - Clinical informatics for longitudinal studies
   - Novel comparative effectiveness research methodologies
   - Mass spectrometry-based techniques
   - Innovative use of imaging and/or biomarkers to assess treatment prognosis
   - Genomics research methodology
   - Improved methods for community outreach
   - Design or implementation of assays in medium throughput screening for drug discovery
   - Innovative experimental design and development of statistical methodologies for clinical and translational research applications including innovative clinical trial design
   - Technologies for clinical decision support
Proposed methods should have wide applicability and should be ready for broad dissemination to the research community by the end of the one-year award period. Specifically, methods whose feasibility is questionable should not be developed via this award, since the emphasis in this mechanism is the development of tools that are applicable in a relatively short period of time.

3. T1 Translational Research/First in Human Studies
The purpose of this funding mechanism is to help pre-clinical investigation cross over into human subjects research. Although this does not necessarily preclude the use (or development) of non-human models, proposals should be clear about how the research is expected to quickly lead to a clinical phase. **All proposed projects should have a clinical component.** It is expected that OCTRI funding will lead to external grant applications for continued project support within 12-18 months. Such funding could be through typical investigator initiated funding sources (e.g. NIH) or via alternative sources (e.g. public private partnerships). Teams composed of basic and clinical investigators are encouraged to apply.

**APPLICATION INSTRUCTIONS**

1) Fill out the online application at [https://octri.ohsu.edu/redcap/surveys/?s=AWNJT7J3LT](https://octri.ohsu.edu/redcap/surveys/?s=AWNJT7J3LT).

Application components include:

a) Project Title

b) Principal Investigator Contact Information

c) Project Information

d) Abstract - Provide a 250-word paragraph providing a clear and concise description of the project’s objectives, proposed methodology and anticipated results in layman terms.

e) Upload Research Plan and Key Personnel & Biosketches

i) **Font:** Use black ink, Arial font, 11 points or larger

ii) **Page Margins:** Use at least one-half inch margins (top, bottom, left, and right) for all pages.

iii) **Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes (included in page limit):** 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 page limit.

iv) **Documents and file names**

   (1) Documents can be in any of the following formats: *.*.doc, *.*.docx, *.*pdf

   (2) Turn off track changes and accept all changes before submitting documents.

   (3) Documents should be named according to the following naming conventions (with appropriate file extension):

   (4) **Research Plan:** PI last name_plan.doc

   (5) **Biosketch(es):** PI last name_biosketch.doc [Please combine all biosketches into a single document with the project PI’s biosketch first]

2) **Research Plan – 6 page limit**

   a) **Specific Aims:** Clearly articulate the hypotheses or objectives and specific aims of the study.

   b) **Proposal Narrative** (Please adhere to the following outline, including headers for each section):

      i) **Background and Significance:** Describe the scientific context of the proposed work with reference to other relevant work in the relevant field(s) and, in that light, the significance of the project. What is the major opportunity that drives the proposal? Why is the project innovative? Describe how the project could overcome existing barriers and open up new possibilities, or how it otherwise merits attention. Explain how the proposal is responsive to
the identified Funding Type. Highlight any unique combination of background, prior experience, and capabilities that will be brought to bear on the project. Explain why this project is a good opportunity for the people who are involved. Briefly describe the current status of related research at OHSU, including existing strengths and opportunities.

(1) For First in Human proposals, describe the preclinical work that led to the human research proposed. How will the proposed studies translate basic research? Why are the human studies compelling, and how will they yield ongoing opportunities in clinical research?

ii) Preliminary Data: Describe the work that supports the scientific worth and feasibility of the proposal, and thus enables the project.

(1) For Development of Large, Transdisciplinary Grant and First in Human proposals, it is expected that prior work and preliminary data will form a firm foundation for the expected submission of a competitive application for national funding.

(2) For Development of Novel Research Methodologies proposals, there must be sufficient preliminary data that establish feasibility in the approach.

iii) Project Plan: Against the background provided in the previous sections, describe the work you plan to undertake and its expected outcomes. Make it clear to reviewers that you have devised a well-crafted plan including how background information and preliminary data will be utilized in support of the project. This should include sufficient details of the science proposed to judge the feasibility of the plan. After reading this section, reviewers should appreciate how expected outcomes would address the critical opportunities and barriers that you identified in the previous section.

iv) Milestones and Timeline: Provide a timeline for completion of the proposed work in a simple, readable form such as a table or diagram. If your plan includes enrolling human subjects, one of your milestones must specify the enrollment period and recruitment goals. Include no fewer than 3 and no more than 10 project milestones. Project progress reports will include queries as to milestone progress. At six months post-project launch, milestone progress will be reviewed. Applications without measurable milestones will not be considered. Please direct any questions regarding this section to octrievaluation@ohsu.edu.

v) Plans for continuation: This is a key section. Explain how the science proposed will lead to the stated goals of the specific Funding Type.

(1) For the Development of Large, Transdisciplinary Grants proposals, priority will be given to those proposals that are likely to result in significant NIH or other national funding that will continue and expand the research program. Describe plans for how the requested OCTRI funding will yield this national funding. Identify specific and expected sources of extramural support. Include the agency or organization to which you plan to apply, and any known submission deadlines. Include specific plans (funding target (e.g. RFA), submission date and brief description of the proposed grant project) for submitting an application; provide specific plans (funding target, submission date and brief description of the proposed grant project) for submitting an application for a multi-PI, PPG Center grant or equivalent award. We are most interested in the development of large, impactful grant proposals that facilitate growth in an area of research. Describe the key collaborators and their expected roles in this future proposal. The most attractive proposals are likely to yield collaborative projects that bring ongoing research resources to OHSU.

(2) For Development of Novel Research Methodologies proposals, priority will be given to those proposals that are likely to result in publication in high impact peer reviewed journals or similarly impactful alternative means of dissemination (e.g., project website,
conference presentations, workshops, etc.). For dissemination funding, a specific target journal or dissemination method must be clearly specified.

(3) For First in Human proposals, priority will be given to those proposals that are likely to result in significant NIH or other national funding that will continue and expand the research program. Describe plans for how the requested OCTRI funding will yield additional funding. Identify specific and expected sources of extramural support. Include the agency or organization to which you plan to apply, and any known submission deadlines. Include specific plans (funding target (e.g. RFA), submission date and brief description of the proposed grant project) for submitting an application, and provide specific plans (funding target, submission date and brief description of the proposed grant project) for submitting an application.

c) **References and Letters of Support:** These documents do not count toward the page limit and should be added at the end of the proposal narrative.

**BUDGET CONSIDERATIONS**
Detailed budgets will be required only once an applicant has been asked to present. As part of the application form you will be asked if your budget will meet the following award constraints:

- Not more than $75,000 in non-OCTRI direct costs.
- Not more than $100,000 for both OCTRI services and direct costs.
- All funds must be spent by June 30, 2016. This restriction is due to our constraint to provide no extensions during the 5th year of the OCTRI grant.
- The project will pass all regulatory requirements (such as IRB, IACUC, IBC) no later than mid-July, 2015. To ensure that this process goes as quickly as possible, applications that include human subject research and are selected for presentation will be required to have a full protocol by the time of presentation to the Scientific Review Committee.
- Cost sharing or partnerships with other funding sources will be favorably considered and should be discussed as part of the proposal.

**REVIEW CRITERIA**
An expert panel of senior research scientists appointed by OCTRI will review applications and subsequent presentations. The primary review criteria will be the responsiveness to the specific requirements laid out in the above instructions. Additionally, submissions will be scored on their strengths in the following categories:

1. **Likelihood of future funding or effective dissemination of new methodology.** Will this funding enable the development of compelling new grant applications or industry investment that will sustain the proposed research activity? Or, in the case of the Development of Novel Research Methodology, will the proposed research activity provide impactful dissemination of an important new research methodology?

2. **Significance.** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
3. **Investigator(s).** Are the PIs, collaborators, and other researchers well suited to the project? If early-stage investigators, new investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise; is their leadership approach, governance, and organizational structure appropriate for the project?

4. **Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

5. **Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities, members of both genders, and children justified in terms of the scientific goals and research strategy proposed?

6. **Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

7. **Overall impact.** Reflects all scored criteria, plus additional criteria regarding the protection and inclusion of human subjects, vertebrate animal care and welfare, biohazards, and criteria specific to this funding opportunity.

The inclusion/exclusion of a request for OCTRI services will not impact the scientific review.

**Application SUBMISSION AND QUESTIONS**
Submit your application to OCTRI via a redcap survey at: [https://octri.ohsu.edu/redcap/surveys/?s=AWNJT7J3LT](https://octri.ohsu.edu/redcap/surveys/?s=AWNJT7J3LT)

Please direct all questions to the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu).