



OREGON CLINICAL
+ TRANSLATIONAL
RESEARCH INSTITUTE
OCTRI

Request for Applications

Oregon Clinical and Translational Research KL2 Program

Letter of Intent deadline: **January 13, 2014**

The OCTRI Education Program is now accepting letters of intent for a KL2 award funded by NIH/NCATS. This opportunity supports the research training and career development of clinical and translational researchers for a maximum of 2 years. All research proposed for this program must involve either clinical or translational research defined as research with human subjects or populations or with direct application to human health. The scholar is expected to apply for an independent career development award such as a K23, K08, or VA CDA, or an independent grant such as an R01 or equivalent.

KEY DATES

RFA released	Monday, November 18, 2013
Letter of Intent deadline	Monday, January 13, 2014
Notification of full application invitees	Wednesday, January 29, 2014
Full applications deadline	Monday, March 3, 2014
Notification of invitation to present	Monday, April 8, 2014
Presentations to selection committee	TBD
Notification of award	Prior to July 1, 2014

OCTRI KL2 scholars receive annual support not to exceed \$75,000 salary support per year plus OPE plus \$25,000 research and travel funds for a maximum of 2 years. KL2 scholars, their mentors, and their department chairs must guarantee that at least 75% FTE is spent in research and training. The scholar's research must be conducted in a mentored environment while pursuing career development which may include advanced training in research methods, such as in the Human Investigations Program at OHSU. The benchmark of success for each scholar selected is advancement to an independent career development award such as in the NIH K series or other independent funding, such as an R01.

OCTRI KL2 scholars receive a tuition waiver for courses in the [OHSU Human Investigations Program](#) which offers a Master of Clinical Research or Certificate in Human Investigations. In addition, scholars will have priority access to OCTRI faculty and programs to provide expertise in research design, quantitative and qualitative measurement, grant writing, program management, data management, statistical analysis, and scientific writing.

What qualifies as multidisciplinary clinical and translational research?

Clinical and translational research is defined as patient-oriented research, that is, research conducted with human subjects or on material of human origin such as tissues, specimens and cognitive phenomena. Clinical research embraces a spectrum of scientific disciplines (e.g. epidemiology, biostatistics, pharmacology, biology and psychology), methodologies (e.g. observational, experimental), health professions (e.g. radiology, nursing, clinical psychology),

specialties and subspecialties (e.g. internal medicine, surgery, pediatrics, obstetrics/gynecology, oncology, cardiology, nephrology and others), in addition to basic sciences. Translational research is defined as the process of applying ideas, insights and discovery to the diagnosis, treatment or prevention of human disease.

Multidisciplinary research is defined as an approach that brings together experts from diverse disciplines to collectively address a complex problem, with each expert addressing the issues from the perspective of his or her own discipline.

SUPPORT AND RESOURCES

The following resources are provided to each scholar selected:

- At least 75% of the scholar's salary (not to exceed a cap of \$75,000 plus OPE) for 2 years. It is expected that the scholar's department will provide additional salary support if the overall salary exceeds \$100,000.
- A firm commitment of 75% FTE protected time for research and career development for up to 2 years.
- \$25,000 per year in research and travel funds
- Tuition-waiver costs for participation in the Human Investigation Program (www.ohsu.edu/hip), including the Master of Clinical Research or Certificate in Human Investigation tracks. Courses or conferences outside of this program must be paid from research funds.
- Participation in OCTRI-supported networking and mentoring activities such as offered by the OCTRI Scholars Program (www.ohsu.edu/scholars).
- Priority support from OCTRI cores and services.

At least 75% of the Scholar's full time professional effort must be devoted to the KL2 program for research and career development for 2 years. The scholar's department will be expected to provide the additional salary support to augment the KL2 salary. The total salary (KL2 plus departmental support) cannot exceed the NIH salary cap. The remaining 25% FTE can be divided among other activities, including clinical work, teaching, and administration. Restrictions exist on using other federal research support to cover this additional 25% FTE, whether or not is awarded to a scholar; please consult with OCTRI KL2 program staff.

The second year of funding is contingent on satisfactory progress toward the scholar's individual benchmarks and career goals, continued support from the scholar's mentors and department, and participation in career development activities. Extensions of support or leaves of absence are possible only under exceptional circumstances.

OCTRI Resources

The educational leaders of OCTRI, including Drs. Jacoby and Morris will augment input that the KL2 scholars receive from their mentors. This includes support to refine research design and to identify resources within OCTRI to support research conducted as a KL2 scholar.

KL2 scholars may receive support from:

- The Biomedical Informatics Program to assist with applied informatics tools for bench research (bioinformatics), data management for clinical research studies, advanced computing, and data archiving.
- Biostatistics and Design Program for quantitative analysis of data.
- Clinical and Translational Research Center, an infrastructure core that includes inpatient and outpatient clinical space, bionutrition support, body energy and composition core, and access to protocol-based support personnel.
- Community and Practice Research program for collaboration with community organizations, health care practices and researchers.
- Investigator Support and Integration Services for research administration (IRB submission and monitoring), project management and regulatory compliance.

More information about OCTRI services can be found at www.octri.org/services.

EXPECTATIONS

Expectations of Mentors

Developing a successful clinical research career requires a strong relationship with a mentor team. Each scholar applicant must propose at minimum a lead mentor and at least one other mentor from a different discipline. This may commonly include a mentor in the focused area of research that the scholar proposes, as well as a mentor for specific research methods as appropriate, such as a basic scientist, biostatistician, clinical trialist, epidemiologist, pharmacologist, or health services researcher. An eligible lead mentor must have a substantial track record of research funding and should have independent research support to help cover costs of the proposed research project in excess of the allowable costs of the KL2. If awarded, the selection committee may suggest individuals to augment this mentor team.

The primary mentor and Drs. Jacoby and Morris will provide guidance to the scholar to assure that research and career development is moving satisfactorily on the path to publications and grant proposals. Mentors will provide advice about career direction, national networking, and academic promotion. They will also help to assure that 75% of the Scholar's total work week is protected from clinical and administrative duties and fully available for training and research. Co-mentors will be responsible for working with the primary mentor on these responsibilities and will provide guidance in one or more complementary areas of expertise.

Mentors are expected to provide quarterly reports on the progress toward the scholars' benchmark goals and to meet together with scholar and program directors twice yearly to review these benchmarks. In addition, mentors are required to submit annual progress reports to OCTRI for NIH required reporting.

Expectations of OCTRI KL2 Scholars

The benchmark of success for each OCTRI KL2 scholar is a career development award or independent funding by the end of his or her two-year funding period. In keeping with this, scholars will be expected to participate in monthly OCTRI Scholars group. KL2 scholars will participate in a Design Studio to present their research proposal to a group of experienced investigators for feedback.

Scholars are expected to pursue a curriculum of advanced didactic research training tailored to the individual's career development needs. The OCTRI KL2 program provides tuition-free access to the Human Investigations Program curriculum and may be taken for credit as part of a formal degree such as the Master of Clinical Research or Certificate in Human Investigations. Applicants may also propose an alternative didactic training plan that includes courses relevant to their research. Scholars must complete eight hours of formal training in the responsible conduct of research (RCR).

KL2 scholars will be expected to provide quarterly reports on the progress towards benchmark goals and to meet together with mentors and program directors twice yearly to review benchmarks. In addition, KL2 scholars are to submit annual progress reports to OCTRI for NIH required reporting. KL2 scholars are expected to update OCTRI on publications, grants and awards after appointment.

ELIGIBILITY

Applicants must meet all the following requirements:

- U.S. Citizen or Permanent Resident. Individuals with temporary or student visas are not eligible.
- Hold a clinical doctorate (e.g. MD/DO, DMD/DDS, DNS, PharmD, ND, OD, DC) or a research doctorate (PhD) and have a current or pending primary faculty appointment at OHSU as an Assistant Professor level or equivalent. Clinicians must have completed specialty or subspecialty training by the time of the award.
- No prior funding as principal investigator on an NIH research grant, including an R01 or any K series grant; or PI of a subproject of a program project grant (P01), center grant (P50, P60, U54); or other equivalent grant awards. Candidates are eligible if they have been supported by an NRSA grant (F or T) or an NIH small grant (R03 or R21).
- KL2 applicants may not simultaneously submit or have pending an application for any other PHS mentored career development award (e.g. K07, K08, K22, or K23) that duplicates the provisions of the KL2 program.

SELECTION CRITERIA

We expect to fund one scholar by June 30, 2014. A campus-wide OHSU KL2 selection committee will conduct the selection process in two steps and will follow the model of the NIH peer review process for K awards. Selection criteria will focus on the strength and potential of

the candidate to become a leading multidisciplinary clinical and translational investigator judged in five major domains:

- Potential of the applicant: potential to conduct multidisciplinary research judging by research expertise and prior training; publications; prior participation in research.
- Research Plan: Scientific value, potential clinical importance, and feasibility of the written multidisciplinary research plan.
- Training Plan: Quality, appropriateness, and composition of the multidisciplinary team of the proposed mentors; plan to gain didactic and other training at OHSU or elsewhere.
- Mentors: Tangible commitment and resources provided by the home department, including protected research time, and suitability of the available clinical and laboratory infrastructure and multidisciplinary team.
- Career Potential: Global assessment of the likelihood that the candidate will develop a career as an outstanding independent investigator and conduct research that will have an important impact on health. Individuals from underrepresented groups in research (women, ethnic minorities, and the disabled) are encouraged to apply. Special consideration will be given to individuals in disciplines traditionally under-represented in clinical research.

APPLICATION

1. LETTER OF INTENT

A letter of intent is required for all applicants. *This letter will be used to determine which applicants will be invited to submit a full application.* Applicants should submit a letter of intent and NIH biosketch via online application.

Letters of intent must address the following areas and questions:

- Research aims for the proposed project
- Preliminary data, if any
- Brief summary of the scientific plan
- Career development goals, long term and short term
- Brief details of proposed education and training plan
- Proposed mentor team and primary mentor

The research aims, preliminary data, and summary of the scientific plan must not exceed one page. Career development plans and proposed mentor team should not exceed a half-page. Applicants must follow NIH guidelines with 11-point font and one-half inch margins.

Invitations to submit a full proposal will be extended to applicants whose letters indicate that a full application will be competitive for funding. Due to the large volume of letters received and the difficulty in providing detailed assessment of a short proposal, applicants who are not invited to submit a full application will not receive reviewer comments.

2. FULL APPLICATION

If selected, applicants should prepare a complete application by the submission deadline. You may wish to meet with Drs. David Jacoby or Cynthia Morris to discuss this application.

All materials should be submitted as a single PDF to Karen McCracken (mccracke@ohsu.edu). The title of the project and applicant's full name should be clearly printed in the document header. The document should be named as follows: [Last name]_KL2Application.pdf (e.g. Jacoby_KL2Application.pdf). Mentors and department chairs may submit letters of reference independently or include with materials submitted by applicant.

A complete application consists of the following materials:

A. Abstract (no more than 300 words; not included in page limits). This should include both a brief description of the proposed project and your training plan.

B. Applicant's Statement (3 pages maximum; follow Format Specifications listed below). This should contain the following components.

- **Research experience.** Discuss previous and current participation in research, providing examples of opportunities to engage in research (basic or clinical) and your role in these projects. Discuss any research training that you have received through workshops or formal course work.
- **Career goals.** Discuss long-term career and research goals including plans to incorporate clinical practice (if applicable) with your career. Address the area of research in which you plan to focus, including the type of research you plan to conduct, the clinical problems your research will address, and the potential impact your research will have on public health or clinical practice.
- **Career development plans.** Provide a career development plan. Explain any additional training needed to achieve research career goals. Identify specific areas where and how this training will augment knowledge or skill deficiencies.
- **Mentor Roles.** Describe the roles each mentor will play. Be specific; cite examples from your proposed training or research plan whenever possible.
- **Preparation for federal funding.** Explain how conducting the research project proposed in this application will prepare you to compete successfully for an NIH grant (or equivalent) and provide a plan to achieve this funding.
- **Contribution of KL2 participation to career.** Explain how you will benefit from the OCTRI KL2 program and how it will contribute to your career in multidisciplinary clinical and translational research.

C. A research proposal (3 pages maximum; follow Format Specifications listed below). This should contain the following components. You should work closely with your mentors on writing the research plan.

- Title
- Specific aims (no more than 1 page)
- Background and significance

- Prior work by the investigators (if applicable)
- Design and methods (include the approach to statistical analysis, power estimates, etc.)
- Human subject considerations (not counted in the 3-page limit)
- Literature cited (not counted in the 3-page limit)

This proposal should be succinct and should not exceed 3 pages, exclusive human subjects consideration and of references. Please follow NIH formatting requirements (Standard 11-point Arial font and one-half inch margins). Refer to PHS 398 guidelines for other formatting questions. Figures and tables will be counted in the 3-page limit.

D. Letter in support from proposed lead mentor. This should address the following components.

- Plan to support applicant for the duration of the training period.
- Plan to support project financially if it exceeds the funds provided through this career development award (\$25,000 per year).
- Indicate support from the department/division for the applicant's research and specifically detail the space, number and kind of staff, clinical and lab resources, and funding available to the applicant.
- Discuss the mentor's experience with research mentoring in the past and outline support from other grants.

E. Letter in support from department chair or division head. This should address the following components.

- Long-term and short-term commitment to the applicant.
- Delineate any clinical, administrative, teaching, and other university commitments for the applicant.
- Describe the role that is expected of applicant as a leader in multidisciplinary clinical and translational research after completing the career development award.
- Indicate any support from the department/division for applicant's research, specifically commenting on cost sharing of salary above the cap of \$75,000, the amount of space, number and kind of staff, clinical and lab resources, and dollars available to the scholar.
- Discuss how a commitment to support at least 75% FTE protected time will be accomplished.

F. A biosketch (NIH format) of lead mentor as well as any other proposed mentor(s).

G. Applicant's biosketch (NIH format).

Applications will be reviewed by a campus-wide KL2 selection committee. This review will follow the model of the NIH peer review process for K awards.

3. ORAL PRESENTATIONS

As many as 5 applicants will be selected to present their proposal at a meeting of the KL2 selection committee. The applicant and his or her primary mentor must attend. The applicant will be given no more than 15 minutes to present the following (PowerPoint recommended):

- Research proposal (no more than 10 slides)
- Training and career (1-2 slides)
- Timeline of benchmarks (1 slide).

The applicant should be prepared to answer questions about these plans.

AWARDEE AND MENTOR RESPONSIBILITIES

- IRB or IACUC approval as appropriate is required prior to release of funds.
- Quarterly reports of progress against benchmarks are required from both KL2 scholar and mentor.
- Progress meetings with KL2 scholar, mentor and program directors are required every 6 months.
- An annual report describing project accomplishments from KL2 scholar and mentor must be submitted for OCTRI reporting to NIH.
- Awardees are expected to submit a grant application for a career development award or independent national funding to one or more external agencies as part of the successful execution of the pilot project. OCTRI should be informed of grant applications.
- OCTRI is evaluated by the NIH on its effectiveness in career development and research training. Important metrics for the success of KL2 scholars include subsequent funding, publications, licenses and patents. The OCTRI Evaluation Program will approach investigators for additional details related to the success of KL2 scholars.
- Support acknowledgement should be included on all publications that result from OCTRI support (funding and/or research services): *"This publication was supported by the Oregon Clinical and Translational Research Institute (OCTRI), grant number (KL2TR000152) from the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."*