

OCTRI KL2 Program 2024 RFA

Application Deadline: **Tuesday, July 16, 2024**

[Submit Application](#)

The OCTRI Education Program is accepting applications for a KL2 mentored career development award funded by NIH/NCATS. Faculty at OHSU, Portland State University, University of Oregon, and Oregon State University are eligible to apply. This opportunity supports the research training and career development of clinical and translational researchers for up to 2 years. All research proposed for this program must involve either clinical or translational research defined as involving human subjects or populations, or research that has direct application to human health. The scholar is expected to apply for an independent career development award such as a K01, K07, K08, K22, K23, K25, or VA CDA, or an independent grant such as an R01 or equivalent during year 1 of the KL2. KL2 scholars, their mentors, and their department chairs must guarantee that at least 75% effort is spent in research and training.

KEY DATES

RFA released	June 2024
Application deadline	Tuesday, July 16, 2024
Notification of presentation invitees	Aug 12-23, 2024
Presentation to selection committee	To schedule: September
<i>Pre-KL2 activities</i>	<i>To be completed Fall 2024</i>
Expected start date	January 1, 2025

CONTACT OCTRI KL2

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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 informatics), methodologies (e.g. observational, experimental), health professions (e.g. medicine, nursing, clinical psychology, dentistry, social science), specialties and subspecialties (e.g. internal medicine, surgery, pediatrics, obstetrics/gynecology, oncology, cardiology, nephrology, and others), in addition to basic sciences. Translational science is defined as the process of applying ideas, insights and discovery to the diagnosis, treatment, or prevention of human disease.

This KL2 emphasizes team science and promotes multidisciplinary research, defined as an approach that brings together experts from different disciplines to collectively address a complex problem, with each expert addressing the issues from the perspective of their own discipline. The KL2 provides training in translational science that includes searching for innovative ways to break down barriers in the translation process and ultimately deliver more interventions to more patients more quickly.

SUPPORT AND RESOURCES FOR KL2 AWARDEES

The following resources are provided to each scholar selected:

- 75% of the scholar's salary (not to exceed a cap of \$100,000 plus OPE) per year for 2 years with satisfactory progress. It is expected that the scholar's department will provide additional salary support if the scholar's overall salary exceeds \$100,000.
 - Total salary (KL2 plus departmental support) cannot exceed the NIH salary cap. The remaining 25% effort can be divided among other activities, including clinical work, teaching, and administration. Please consult with OCTRI KL2 program staff if there are questions.
- A firm commitment of 75% effort protected time for research and career development per year for up to 2 years, guaranteed by the KL2 scholar, their mentors, and their department chair.
Note: We will consider reducing this protected time to no less than 50% effort for individuals in procedure-intensive specialties upon approval by program leadership and NIH.
- Up to \$30,000 per year in research and travel funds, prorated for partial year appointments fitting with OCTRI's project period. No-cost extensions are not allowed.
- Participation in a weekly KL2 Work in Progress meetings are required. The primary objective is to build a collaborative learning community directed by the KL2 scholars and to illuminate successes and challenges related to research and career development through peer-mentoring.
- Tuition-waiver costs for participation in the [Human Investigation Program](#), including the Master of Clinical Research or Certificate in Human Investigation tracks. Courses or conferences outside of this program must be paid from research and travel funds.
- Participation in OCTRI-supported networking and mentoring activities such as offered by the [OCTRI Scholars Program](#).
- Priority support from OCTRI cores and services through [small grants](#) support.

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 under exceptional circumstances.

EXPECTATIONS

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 the two-year funding period. In keeping with this, scholars will be expected to:

- Submit an independent award proposal such as an NIH K or R01 during year 1 of their appointment. Support for this includes a mock review session.
- Co-lead the weekly KL2 Work in Progress meetings with fellow KL2 cohort to engage in peer-mentorship, including presenting their own work at least quarterly
- Publish 4 papers
- KL2 scholars will participate in OCTRI Scholar activities, including a [Design Studio](#) to present their next-step research proposal to a group of experienced investigators for feedback at the initiation of their research and at application for subsequent support
- Pursue a curriculum of translational science 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) as required by NIH
- Provide quarterly reports on progress towards benchmark goals and to meet together with mentors and program directors twice yearly to review benchmarks
- KL2 scholars are to submit annual progress reports to OCTRI for NIH-required reporting, describing project accomplishments and patient-level data enrollment table if human subjects research. KL2 scholars are required to update OCTRI on publications, grants and awards for 15 years after the appointment ends per NIH policy
- KL2 grant acknowledgement should be included on all publications that result from OCTRI support (funding and/or research services)

Pre-KL2 activities to begin Fall 2024

- Attend the weekly KL2 WIP, Monday's at 11am via Zoom
- Meet with experienced investigators of the Clinical Research and Development Team for guidance on KL2 study start up and implementation
- Develop IRB protocol and JIT documents for project approval in coordination with OCTRI Regulatory Knowledge & Support team (this process is expected to take several months)

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. Typically, this includes 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. Mentors may be internal or external to applicant's primary institution, but non-OHSU applicants will need an OHSU mentor to be the IRB PI ([see eligibility requirements](#)) – the KL2 program can help identify this mentor if needed.

The mentor team, along with Dr. Hough, 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 meet together with scholar and KL2 program director twice yearly to review progress toward the scholar's benchmarks. In addition, mentors are required to submit annual progress reports to OCTRI for NIH-required reporting.

KL2 STUDY STARTUP REQUIREMENTS

This process is expected to take several months to complete. OCTRI Regulatory Knowledge and Support team guides the scholar in the development and submission of the required materials:

- IRB or IACUC approval as appropriate is required **prior** to release of KL2 research funds.
- Project approval from NCATS is required for research involving human subjects and/or vertebrate animal studies **prior** to release of KL2 research funds.

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, DNP, PharmD, ND, OD, DC) or a research doctorate (PhD) and have primary faculty appointment at OHSU, PSU, OSU or UO as an Assistant Professor level or equivalent at the time of KL2 appointment. 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. Please contact Melissa Mudd (muddm@ohsu.edu) if you have a pending award and are interested in applying for the KL2.

SELECTION CRITERIA

A selection committee composed of representatives of OHSU, PSU, UO and OSU 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 translational, multidisciplinary research judging by research expertise and prior training, publications, and prior participation in research.
- Research Plan: Scientific value, potential clinical importance, and feasibility of the written multidisciplinary research plan, application of translational science.
- Training Plan: Quality, appropriateness, and composition of the multidisciplinary team of the proposed mentors, as well as plan to gain didactic and other training.
- 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 (gender, racial and ethnic minorities, and the disabled) are encouraged to apply. Special consideration will be given to individuals in disciplines traditionally under-represented in clinical research.

OCTRI RESOURCES

The educational leaders of OCTRI, including Drs. Hough and Morris, will augment input that the KL2 scholars receive from their mentors. This includes support to refine research design, need for additional mentorship, modification of career development plan, and identification of resources to support research conducted as a KL2 scholar.

KL2 scholars receive support or priority access to services through OCTRI programs:

- Regulatory Knowledge and Support team assists with KL2 OHSU IRB submission/reliance agreement, NCATS approvals and study start up. Applicants from non-OHSU institutions will need to complete their local IRB submission. *The regulatory approvals process is expected to take the first 2-3 months of the KL2 appointment to complete; KL2 scholars are expected to be the PI on their own protocol.*
- [OCTRI Informatics Program](#) to assist with applied informatics tools for bench research (bioinformatics), data management for clinical research studies, access to the Research Data Warehouse and Cohort Discovery, advanced computing, and data archiving.
- [Biostatistics and Design Program](#) for quantitative analysis of data.
- [Clinical and Translational Research Center](#) (CTRC), 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 Research Hub](#) program for collaboration with community organizations, health care practices, and researchers.

More information about OCTRI services can be found on the OCTRI website under [Research Services](#). The [Clinical Research Navigator](#) can help answer any questions about OCTRI services, research operations, study logistics, and study planning and implementation across OHSU.

APPLICATION PROCESS

1. FULL APPLICATION - [Apply](#)

Applications are due **Tuesday, July 16, 2024 by 11:59 p.m. PT**. Mentors and department chairs may submit letters of reference independently by emailing to Melissa Mudd (muddm@ohsu.edu) 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. Discuss a plan for how you will continue your career development and research if a funding gap should occur between your KL2 and next step extramural 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 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.

- Specific aims (no more than 1 page)
- Background and significance
- Prior work by the investigator (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 of human subjects consideration and 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. Budget. Provide an itemized budget for the year one allocated \$30,000 for research support and a brief justification. Please do NOT include your salary on this form. Please reference [PHS 398 template](#) for the budget details. If applicable, it is expected that your mentor's research program will supplement your research funds.

- Examples of allowable uses for KL2 funds include: lab supplies, software, minor equipment, technical personnel to supplement those provided by the mentor, and conference fees and travel.
- Examples of disallowed expenses include: books, general office supplies, lab or office equipment and student activity fees.

E. Letter in support from proposed lead mentor. Optional additional letters: Up to 2 letters in support will be accepted from secondary mentors. The letter(s) 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.
- Indicate support available 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 research support.

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

- Long-term and short-term commitment to the applicant, including support for the scholar post-KL2.
- 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 \$100,000, 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% effort protected time will be accomplished.

G. A biosketch (NIH format) of lead mentor and any other proposed mentor(s).

H. Applicant's biosketch (NIH format).

I. Applicant's proposal history (word or PDF)

Please summarize the applicant's proposal and grant submission history *as PI*, including pending and unfunded awards. List the following for each proposal:

- Title of proposal:
- Applicant's Role:
- Agency/Foundation (ex: NIH/NHLBI or AHA):
- Award Type (ex: R03):
- Funded? (yes/no/pending):

2. ORAL PRESENTATIONS

Applicants will present their proposal at a meeting of the KL2 selection committee. See key dates above for scheduling. The applicant will be given no more than 15 minutes to present the following (PowerPoint recommended):

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

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

Please direct all questions regarding the KL2 opportunity to Melissa Mudd (muddm@ohsu.edu).