University of Rochester Clinical and Translational Science Institute
KL2 Institutional Career Development Program
Request for Applications
For Projects with a Start Date of July 1, 2024

Vision: Scholars of the University of Rochester KL2 Institutional Career Development Program will become the next generation of national translational scientists, who will have the knowledge, skills and abilities to innovate and transform translational sciences from discovery to implementation and dissemination and beyond.

Mission: The UR KL2 will align with the UR Clinical and Translational Science Institute and CTSA Consortium, and implement a high quality, team-science based research career development program for early career translational scientists.

Note: The UR CTSI KL2 Institutional Career Development Program (KL2 Scholars Program) is funded by the Clinical and Translational Science Award (CTSA, a NIH-funded grant) and the University of Rochester School of Medicine and Dentistry.

Important Dates

- Monday, September 18, 2023, 5 p.m. Eastern Time - Submit Letter of Intent
- Monday, October 23, 2023, 5 p.m. Eastern Time - Submit application packet
- Friday, January 26, 2024 - Notification of recipients
- Award Period (2 years):
  - July 1, 2024 through June 30, 2025 – Year 1 of the Award
  - July 1, 2025 through June 30, 2026 – Year 2 of the Award

Important Announcement about the 2024 KL2 Award Cycle

The KL2 mechanism is being phased out by NCATS and will transition into a K12 mechanism at UR CTSI beginning on July 1, 2025, pending the CTSI's successful receipt of the K12 award being submitted in 2024. Please note that there may be additional changes to the KL2 program per NIH or NCATS guidance, to be determined at a later date. We do not anticipate significant changes for this career development award as it becomes a K12, but any changes will be based on NCATS policies and subject to NCATS guidance.

Program Description

The UR CTSI KL2 Institutional Career Development Program (KL2 Scholars Program) is a two-year program funded by the Clinical and Translational Science Award (CTSA) Program from the National Institutes of Health. The KL2 Scholars Program is designed to offer early career postdoctoral scholars advanced training in translational science research aligned with CTSA Program goals of advancing therapeutics (drugs, devices, and preventatives), clinical interventions, and behavioral modifications to improve health. The program offers flexible learning models to engage postdoctoral scholars in team

science, individual development plans, advanced research training, and career guidance to those committed to pursuing a career in clinical and translational research.

Trainees will be expected to develop and implement a research experience supervised by a mentor team. The research project should be designed as a pilot project to set the stage for an individual K-award application, or to establish a foundation for a subsequent individual R-award application. The goal of the program is to promote the successful transition of KL2 Scholars to an independent career as a clinical and translational investigator, generally by means of an individual K- or R-award. Scholars are required to commit to devoting 75% effort to the KL2 program (or 50% for candidates who practice in certain procedure-based medical specialties).

The program has devised three training specializations that capitalize on institutional strengths and priorities, including Experimental Therapeutics, Digital Health, and Health Equity-Focused Dissemination and Implementation. Prospective scholars are encouraged, but are not required, to take advantage of one of the three specializations. If applicants are interested in one of the three training specializations, they are encouraged to contact the Co-Directors of each specialization during the application process via email.

Health Equity-Focused Dissemination and Implementation

Drs. Kevin Fiscella, Reza Yousefi-Nooraie, and James McMahon
Dissemination and Implementation (D&I) is the science and practice of how evidence-based interventions and policies are effectively translated, distributed, and implemented in real world settings. Training in this specialization pathway should include education and experience in research that adapts the core elements of implementation science to promote health equity.

Experimental Therapeutics

Drs. Robert Holloway and Karen Mustian
The UR has unique strengths, infrastructure, and qualifications for programs focused on target identification and development as well as design and oversight of multi-center clinical trials. Training in this specialization pathway should encompass education and experience from different stages of therapeutic development, from discovery to implementation. A sample curriculum may include advanced topics in experimental therapeutics, such as novel study design, virtual research visits, emerging statistical methods, innovations in outcome measurement, novel recruitment approaches, and research ethics topics.

Digital Health

Drs. Jean-Phillippe Couderc and Ray Dorsey
The UR is home to a community of clinicians, computer scientists, bioinformaticians, and regulatory science experts who are modernizing methods of measuring and delivering health via digital health tools and data analysis approaches. Training proposed in this specialization pathway may include education in: remote monitoring of individuals' medical disorders, treatment adherence, integration of multimodal data (including EHR data), and developing digital measures as novel endpoints.

See also:
• University of Rochester Clinical and Translational Science Institute (UR CTSI)
• UR CTSI research education programs

Support Provided

While enrolled in the KL2 Scholars Program, scholars will receive:

- A stipend or salary to help support the proportional effort required to participate in the program. The CTSA Program will pay 75% salary support up to a maximum of $70,000 per year contingent on available funds. Therefore, the Scholar's home department may be required to supplement support according to institutional guidelines. Salary supplementation may be from extramural sources, except that no federal funds may be used for this purpose. These funds will be audited by the Office of Research Accounting and Costing Standards (ORACS) yearly.
- Typically, up to $17,000 of non-salary support per year (**as NIH funding permits, and is subject to change based on changes in annual budget**), which can be used for research, tuition, travel expenses, educational materials in support of the scholar's career development plan, or other costs related to the scholar's research project. If you are taking formal coursework, please utilize the UR tuition waiver first, and then apply KL2 funding for the difference.
- Those appointed as postdoctoral clinical or research fellows receive benefits as defined by the University of Rochester School of Medicine and Dentistry's Office of Graduate Medical Education (see their Benefits/Contract for Trainees webpage). Those appointed as faculty receive benefits as defined by the University of Rochester (see the University of Rochester Total Rewards website).
- **Please refer to the Important Announcement about the 2024 KL2 cycle at the start of this RFA.**

Other Details

The financial year for Year 1 of funding begins **July 1, 2024** and ends June 30, 2025; funding for Year 2 begins on July 1, 2025 and ends on **June 30, 2026**. KL2 program appointment start and end dates must coincide with these dates to receive NIH funding and are not flexible.   KL2 Scholars are expected to attend the annual meeting of the Association for Clinical and Translational Science (ACTS), typically held in the spring in Washington, D.C. Grant funds may be used for this purpose. Candidates selected for the KL2 Scholars Program may be eligible to apply to the NIH Loan Repayment Program; any faculty who has >50% of their time allocated for research may also be eligible, and we encourage these applications.

Program Contacts

For more information about the University of Rochester KL2 Scholars Program in Clinical and Translational research, please contact:

General inquiries:

Rachel Hillhouse
UR CTSI Education Program Assistant
Rachel_Hillhouse@urmc.rochester.edu

Alaina Maiorano
Lead Program Administrator – Research Education & Career Development, UR CTSI
Alaina_Maiorano1@urmc.rochester.edu

Financial and budgetary inquiries:

UR CTSI Finance Team
CTSI_Finance@URMC.Rochester.edu

Inquiries regarding other programmatic issues:

Thu H. Le, MD
Director, KL2 Scholar Program
Chief of Nephrology and Professor of Medicine (SMD)
585-274-0202
Thu_Le@URMC.Rochester.edu
UR CTSI KL2 Career Development Award Website

Alfred Vitale, PhD
Director of Research Education & Career Development, UR CTSI
Research Assistant Professor, Clinical and Translational Science
Alfred_Vitale@urmc.rochester.edu

Inquiries regarding degree or certificate programs offered through the Department of Public Health Sciences:

Edwin van Wijngaarden, Ph.D.
Professor and Associate Chair, Education, Department of Public Health Sciences
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Public Health Sciences Educational Programs Website

Training Specialization Contacts

Health Equity-Focused Dissemination and Implementation:

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Reza Yousefi-Nooraie, MSc, Ph.D.
Assistant Professor - Department of Public Health Sciences
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James McMahon, Ph.D.
Associate Professor – UR School of Nursing and Department of Public Health Sciences
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Experimental Therapeutics:

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Robert Holloway, MD, MPH
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Chair of Neurology, and Professor of Neurology and Public Health Sciences
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Digital Health:

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Ray Dorsey, MD, MBA
Director and Professor, Center for Health and Technology, Department of Neurology
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Ray.Dorsey@chet.rochester.edu
UR Center for Health + Technology Website

Admissions

Eligibility

To be eligible to apply to the KL2 Scholars Program, applicants must define and participate in a translational research or science project. Translational research is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public, focusing on the translational process for specific diseases. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process in order to refine the process of turning observations in the laboratory, clinic and community into interventions that improve health of individuals and communities. The focus of translational science is not on specific diseases but "what is common among them". Applicants can propose either translational research or translational science projects.

Note: The CTSA Program is funded by the National Center for Advancing Translational Sciences (NCATS). With the signing of the 21st Century Cures Act (Cures Act) into law in December 2016, the Public Health Service (PHS) Act was amended to allow NCATS to support clinical trial activities through the end of phase II for all diseases or conditions, and through the end of phase III for a rare disease or condition. Please refer to NCATS notice (NOT-TR-18-025) for more information.

Qualifications

Other qualifications for the KL2 Scholars Program include:
- A doctoral-level degree in a health discipline that can be applied to clinical or translational research. These degrees include, but are not limited to MD, DO, DMD, DDS, DPH, PharmD, as well as PhDs in a clinically relevant field, such as biostatistics, epidemiology, behavioral science, and nursing.
- US citizen or permanent resident. Individuals on temporary or student visas are not eligible.
- Must be an early-stage investigator committed to advanced training and a career in translational science research aligned with the CTSA Programs goals of advancing therapeutics (drugs, devices, and preventives), clinical interventions, and behavioral modifications to improve health.
- Scholars may have had support on a NRSA grant (F or T) or NIH small grant (R03).
- Commitment to a two-year program within the stated award period. During this time, at least 75 percent of the KL2 Scholar's full-time professional effort must be devoted to the program. The remainder of time may be devoted to developing other clinical or academic pursuits that are consistent with the objectives of developing a career as an independent clinical or translational researcher. Certain clinical specialties may have less than 75 percent effort -- but no less than 50 percent effort -- if sufficiently justified (e.g. surgical specialties requiring 50 percent direct patient care time to keep up surgical skills).

- The financial year for Year 1 of funding begins July 1, 2024 and ends June 30, 2025; funding for Year 2 begins on July 1, 2025 and ends on June 30, 2026. KL2 program appointment start and end dates must coincide with these dates to receive NIH funding – and they **cannot** be extended or changed. **Please refer to the Important Announcement about the 2024 cycle at the start of this RFA.**

Exclusions:
- At the time of application, scholars must NOT have pending an application for any other PHS mentored career development award (e.g. K07, K08, K22, K23) that duplicates any of the provisions of the KL2. A KL2 scholar candidate who is already in the process of applying for an independent mentored career development grant, a P01 grant, or R01 grant is likely too senior for the KL2 award.
- Former or current PDs/PIs on any NIH research project grant [this does not include NIH small grants (R03), exploratory Developmental (R21) or SBIR, STTR (R43, R44 grants)] or equivalent non-PHS peer reviewed grants that are over $100,000 direct costs per year, or project leaders on sub-projects of Program project (P01) or center grants (P50) are NOT eligible to participate as Scholars.

Valuing Diversity

Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with their mentor(s) to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are encouraged to apply. Applicants are also encouraged to create a diverse mentor team to provide multidisciplinary skills, expertise, and outlook. The University of Rochester is committed to fostering, cultivating, and preserving a culture of diversity, equity and inclusion. The University believes that a diverse workforce and inclusive workplace culture enhance the performance of our organization and our ability to fulfill our important mission. We believe that a diverse research workforce furthers the translational research mission and empowers organizations to ask and answer the broadest, most innovative research questions. The University is committed to fostering and supporting a culture inclusive of people regardless of their race, ethnicity, national origin, gender identity or expression, sexual orientation, socio-economic status, marital status, age, physical abilities, political affiliation, religious beliefs or any other non-merit fact, so that everyone feels included, equally valued and supported.

Application Process

Positions

Two or more positions are available annually and have a start date of July 1, 2024.

Timeline

- Please submit your intention to apply for the KL2 by filling out the [KL2 Letter of Intent (LOI) Form](#) by **5:00 p.m. Eastern Time on Monday, September 18, 2023.** If you have questions about the LOI, please contact KL2 Program Assistant, Rachel Hillhouse (rachel_hillhouse@urmc.rochester.edu) or Program Administrator, Alaina Maiorano (alaina_maiorano1@urmc.rochester.edu).
- Submit **application packet** through our online application system by **5:00 p.m. Eastern Time on Monday, October 23, 2023.** Instructions and a link for submission will be provided after the letter of intent is received.

A Note for Applicants

It is ***strongly recommended*** that prior to applying for the KL2, you sign up to present your proposed research at the interactive [CTSI Research Methods Forum](#), where you will receive feedback from its multidisciplinary team of experts that can help strengthen the quality and rigor of your proposal. The forum

is held virtually, twice per month, and is an ideal resource for junior investigators. Additional *ad hoc* sessions can be arranged if needed. Please contact kimberly_marino@urmc.rochester.edu to schedule a session. For further information about the forum, please contact Edwin_Van_Wijngaarden@urmc.rochester.edu.

How to Apply

Step 1: Identify a primary mentor and co-mentor(s). One of the most important steps in applying to the KL2 Scholars Program is to identify a multidisciplinary mentorial team. Your primary mentor should be located at the University of Rochester. You and your primary mentor should determine appropriate co-mentor(s) in other disciplines that will bring valuable expertise to your career development and research proposal. For assistance in identifying a primary mentor and one or more co-mentors, see the informational links below. You may contact the UR CTSI Research Help Desk (ResearchHelp@urmc.rochester.edu) for assistance in identifying potential mentors. See also: Research Departments and Centers at the University of Rochester.

Step 2: Notify the UR CTSI of your intent to apply by 5:00pm EST on Monday, September 18, 2023. The information allows us to better plan the review process and assist potential applicants as necessary. The submission form will ask for your name, email, doctoral degrees, your current department and position in that department, the names and specialties of your primary mentor and co-mentor(s), name of your department administrator responsible for your financials, a working title for your proposed project, and two or three sentences describing your anticipated research proposal. **Please submit your intent to apply through the KL2 Letter of Intent (LOI) Form.** If you have any questions, please contact KL2 Program Assistant, Rachel Hillhouse (rachel_hillhouse@urmc.rochester.edu) or Program Administrator, Alaina Maiorano (alaina_maiorano1@urmc.rochester.edu)**.**

Step 3: Complete the required documentation. To apply, you will need to submit the application materials listed below. Resubmissions **must** include a cover letter detailing how you addressed prior reviewer comments. Please follow NIH guidelines for grant style, content, and format contained in the NIH Application Guide.
1. **Your NIH-format biosketch** (new format sample and forms available online). Do NOT submit a CV. Prepare your personal statement to be relevant to your KL2 mentored career development proposal.
2. **NIH-format biosketches for your mentors**. Mentors should edit the personal statements on their NIH biosketches to describe their specific role in your KL2 program and career development.
3. **Research Career Development Plan (RCDP)**
   a) The candidate and the mentor are jointly responsible for the preparation of the career development plan. See Table 1 for a typical KL2 Scholar 2-year curriculum. (3-page limit, excluding references).
   b) A brief summary of your career path to date. This should include a critical self-appraisal of your training needs and description of how the mentor team will meet your needs. Please refer to NCATS Translational Science Education Resources for information regarding translational science skills and the CTSA Program's core and special interest clinical and translational research competencies.
   c) Describe a plan: (1) that shows a logical progression from prior research and training experiences to the training and research experiences that will occur during the KL2 award period; (2) that justifies the need for further career development; and (3) that utilizes the relevant research and educational resources of the institution.
   d) Descriptions of the training you are seeking and how the training by the Scholars Program will help you achieve these goals. Regarding the proposed training plan:
      i. You should address your commitment to the KL2 foundational curriculum (see Appendix);

      ii.   Select additional coursework and programs to best support your individual background, discipline, and career objectives. Scholars can choose from the UR CTSI's educational programs and coursework that span the translational research spectrum.

      iii. If you are interested in aligning your individualized training curriculum to one of the three training specializations (Experimental Therapeutics, Digital Health, and Health Equity-Focused Dissemination and Implementation), you should contact the Co-Directors for that specialization. See Table 2 for sample coursework and partnerships for each specialization. These are only samples, and each training plan should be customized to the career development needs of the applicant.

  e) Describe the professional responsibilities/activities, including other research projects, beyond the minimum required 75% effort commitment to the KL2 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator conducting clinical and translational research.

  f) Plans and timing of submission for subsequent funding, including K- or R-series mechanisms, or equivalent, as appropriate to training and research needs. A timeline is often helpful.

4. **Mentored Research Plan.** A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided (4-page limit, excluding references). Organize the research plan as indicated in the NIH Form PHS 398, following instructions for the Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods. The candidate should consult with mentor(s) regarding the development of this section. Studies that involve early stage clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects (see NIH Grants Policy Statement, section 4.1.15.6).

5. **The following 3 letters of support.**

    i. **Letter from proposed primary mentor** detailing his/her support of and commitment to the applicant and the proposed research and training plan. The letter should include the mentor's qualifications, including prior experience in the supervision, training, and successful mentoring of clinical/translational researchers. The letter should also include how often the mentor plans to meet with the candidate, and confirm that adequate space, facilities, and resources will be made available for the successful completion of the research project. The letter should describe how the proposed research fits into the mentor's research program, including a description of the role of the applicant in the research. The primary mentor letter should not exceed two pages.

    ii. **A letter of recommendation from at least one proposed co-mentor, but no more than 3 letters of recommendation in total.** The co-mentor must be in a different discipline than the primary mentor. This letter must include the co-mentor's assessment of the candidate's qualifications and potential for future success. The letter should also indicate the co-mentor's qualifications, including experience in providing similar mentorship and research expertise. This letter should not exceed one page. You may submit up to three (3) recommendation letters.

    iii. **A letter of nomination from the Chair of the candidate's Department or Director of the candidate's Center**, including explicit assurances that non-research responsibilities will be restricted to no more than 25% of the trainee's time (or 50% for certain procedure-based specialties such as surgery). **It is critical that the Department Chair or Director of the candidate's Center is aware of the scholar's responsibility for their KL2 program to ensure adequate time is protected for KL2 project research.** To avoid confusion, be sure to work with your Chair to outline the specific expectations for the 25% not-funded by the KL2 award. The letter should also comment on plans for further career development of the candidate after the period of the Scholar award and should address the candidate's motivation and likelihood to become an independent investigator.

6. A listing of your and your mentors' current and pending support, other than this award, using NIH format.

7. **A financial analysis,** signed by both your Department Chair/Center Director and your department's research administrator, documenting the financial impact of the KL2 award on the Department/Center. The analysis will calculate supplemental funds required of the Department to support the Scholar's salary, if any, based upon current and anticipated applicant salary information for the two years of the award. The applicant must contact Alaina Maiorano (Alaina_Maiorano1@URMC.Rochester.edu), UR CTSI's Research Education & Career Development Lead Administrator, who will provide a standard financial analysis template.
8. **Overview of expected spending,** using the standard NIH PHS 398 Form Page 4. Please provide, to the best of your knowledge, any purchases you anticipate making during your appointment period that will require KL2 funds. A detailed budget will let us know in advance if there are any planned purchases that are unallowable on the award. A budget justification detailing why the planned expenditures will support the success of the project needs to be included.

Step 4: You must submit the required materials listed above through our online application system no later than 5:00 p.m. Eastern Time on Monday, October 23, 2023. Supplementary material will not be accepted. You must notify the UR CTSI immediately of any revisions or updates to your current or pending support that occur between submission of your application and the date of official notification of KL2 award status. <u>Failure to notify the UR CTSI of such changes in a timely and accurate fashion may disqualify you from the KL2 program.</u>

Application Review Process and Criteria

Each application will be reviewed initially for **completeness and eligibility**.

Applications will be reviewed by the KL2 Recruitment/Selection Committee using a similar format, numerical scoring system (1-9), and template used for NIH Career Development awards. In addition to an overall impact score, reviewers will give a separate score for each of the five following criteria in the determination of scientific and technical merit: 1) Candidate, 2) Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring, 3) Research Plan, 4) Mentor(s), Co-Mentor(s), Consultants, Collaborators, and 5) Environment and Institutional Commitment to the Candidate. Faculty reviewers with a significant conflict of interest will not be allowed to review.

Notification of Recipients

Notification of recipients: By Friday, January 26, 2024.
Award start date: July 1, 2024

Requirements if Funds are Awarded

Annual and Final Progress Reports

An annual progress report is due in March of the first year during the Scholar's term of appointment. Renewal of the award in year 2 is contingent upon presentation of a satisfactory progress report. An annual progress report is also due in March of the second year during the Scholar's term of appointment. Additionally, a final research report and a final expenditure report are due within 60 days following the close of the grant term.

Publications

All publications that benefit in whole or in part from support provided by the UR CTSI must do the following:
1. Comply with the [NIH Public Access Policy](#): Assistance with the compliance process is available through the Miner Library.
2. Acknowledge UR CTSI grant funding using this language: "The project described in this publication was supported by the University of Rochester CTSA award number KL2 TR001999 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Clinical Trials

If the proposed research project involves a clinical trial, the awardee will be required to promptly inform the UR CTSI of all adverse events that are serious, unexpected and related to participation in research. Further guidance is available on the [Office for Human Research Protection website](#). In addition, most clinical trials must be registered in clinicaltrials.gov. For more information about registration requirements, see the [UR CTSI's Regulatory Support pages](#).

To satisfy expectations of NCATS, the funder of the CTSA program, award recipients conducting an NIH-defined Clinical Trial must complete the Good Clinical Practice (GCP) training module available through the Collaborative Institutional Training Initiative (CITI) before conducting human subject research. Documentation that this training has been completed by all members of the study team must be on file with the CTSI Education Program Assistant prior to the enrollment of the first research subject.

Research Involving Human Subjects or Vertebrate Animals

If the proposed research project involves human subjects or vertebrate animals, the NIH requires that the UR CTSI obtain explicit approval from the NIH before the research can begin. Accordingly, IRB or UCAR approval documentation and other materials must be submitted to the NIH at least 30 days prior to the project start date. UR CTSI personnel will work with awardees to meet these requirements.

Single IRB for Multi-Site Projects Using the Same Protocol

If the same protocol will be used to conduct your human subjects research at multiple sites, NIH requires the use of a single IRB. Office for Human Subject Protection staff will provide guidance in this process.

2 CFR 200 Procurement Principles Training

All University of Rochester Principal Investigators on the project and each person that will initiate purchases must provide documentation that they have completed the 2 CFR 200 Procurement Principles training available in MyPath.

ORCID IDs

All key personnel on the research project must obtain an ORCID ID, which provides a persistent digital identifier that the investigator owns and controls, and that distinguishes the investigator from every other researcher.

Appendix. Elements of the Foundational Curriculum

Rigorous Research Training

Coursework in Ethics and Professional Integrity (IND506): This course is only offered in the fall semester and you must enroll in IND 506 during the first year of your appointment. This course is required of all clinical and basic science postdoctoral fellows in the School of Medicine and Dentistry. The course features 10 sessions consisting of lecture/case study presentations followed by small group discussions that provide information on the various topics that the National Institutes of Health consider essential for the responsible conduct of research. Specific topics include the ethical issues underlying human experimentation and related conflicts of interest, animal experimentation, the mentor-mentee relationship, scientific misconduct and plagiarism, collaborative and team science, and publication/authorship. The course also provides an introduction to approaches for improving rigor and transparency with the goal of enhancing research reproducibility. This is a non-credit bearing course that cannot be applied to any degree program in the School.

Good Clinical Practice (GCP) Training: Scholars engaged in clinical trials will receive GCP training. Scholars will complete an online GCP training program (via the Collaborative Institutional Training Initiative) that has been approved by the UR Office for Human Subject Protection. NIH requires all funded "investigators and staff who are involved in the conduct, oversight or management of clinical trials" be trained in Good Clinical Practice. The policy further requires Investigators to take a refresher GCP training course every three years. The course is available through the CITI training platform.

Team Science Training

Team Science Course (PM 403): This course introduces Scholars to the concepts, practice, and challenges of team science and collaborative research environments. Scholars will be exposed to both team science

initiatives and the science of team science, as presented through practical examples from local research teams and researchers, with a focus on practical implications of a team science approach to biomedical research requiring large-scale data analysis.

Grant Preparation Activities

Participate and Present at the Research Methods Forum: Each Scholar will be required to regularly attend, participate in, and present at the bi-weekly UR CTSI Research Methods Forum. The Scholars will present at the Research Methods Forum to obtain feedback on the appropriateness of specific aims (both scope and clarity), strength of preliminary data, and the rigor of research methods. In addition to core Research Methods Forum faculty, additional specific faculty attendees will be invited to participate in each session, based on the discipline and content of the presenter's research. Following the presentation, members of the Forum will continue to provide KL2 Scholars with feedback and support by reviewing grant proposals and study protocols in order to improve rigor and transparency of the proposed work.

Grantsmanship course (PM 438): The Grantsmanship course will teach Scholars how to identify funding opportunities, prioritize potential grant opportunities, present a research project/program in a grant application, and navigate and complete the application process

Other Professional and Leadership Skills

2 CFR 200 Procurement Principles: It is a CTSI requirement that all KL2 Scholars take the 2 CFR 200 Procurement Principles in My Path. This module is meant for any person who has been delegated authority to purchase goods or services for a federally funded project at the University of Rochester.

Rochester Early-Stage Investigator Network (RESIN)
To leverage a greater breadth of existing resources at the University of Rochester, as well as strengthen the community of early stage faculty, a group of leaders from various departments across the medical center joined together with the existing leadership of UR K-Club, the Junior Faculty Biomedical Research Association, the UR Office of Faculty Development, and the UR CTSI Research Education branch to create the Rochester Early-Stage Investigator Network (RESIN). RESIN works across departments and centers to optimize and support training for early-stage investigators from across the translational spectrum, including past and current KL2 scholars. RESIN helps early-stage investigators develop the skills and knowledge to innovate and improve the efficacy and efficiency of translation, from discovery to implementation and dissemination within the Learning Health System and beyond. RESIN activities complement, and do not replace, individual department and center efforts to support early-stage investigators. RESIN supports the University's efforts to be a fully inclusive, equitable, anti-racist and multicultural organization by helping departments recruit and support diverse faculty. The bi-monthly workshop has included hands-on workshops and seminars, such as: Conducting Clinical and Translational Research: How the UR CTSI Can Help; Starting Your Lab: How to Hire your First Employee; How to Talk to a Biostatistician or Bioinformatician; Preparing and Presenting an Elevator Speech; Art of Writing a Good K Grant; Social Media to Maximize Research Exposure; and includes a yearly mock NIH Study-Section that occurs during the UR CTSI's annual Translational Research Day event, which also provides opportunities for networking with fellow K scholars and other early stage faculty. Other important resources and schedule of events can be found on the UR CTSI's RESIN web page.

Association for Clinical and Translational Science Annual Conference (ACTS). Scholars will be expected to attend at least one Annual Conference of the Association for Clinical and Translational Science.

Table 1. Typical Curriculum for UR KL2 Scholar

	Year 1		Year 2	
	July-December	January-June	July-December	January-June
Application and Orientation*	Sets the stage for overall program goals, timelines, and expectations			
Customized Education Plan	Chosen from UR's wide range of educational programs and coursework			
Mentored Research Project(s)	Mentored primary and collaborative research projects			
Rigor and Team Science Training	Ethics course and proposed team science experience and training			
Program Wide Meetings/Series:				
Rochester Early-Stage Investigator Network (RESIN)	Bi-monthly meetings covering translational research and career development topics.			
Research Methods Forum	Multidisciplinary meeting to present and obtain feedback on grant submissions			
Leadership Circle	Journal club reviewing Harvard Business Reviews 10 Must Reads: On Leadership			
Other Skill-Building Activities	As needed for Scholar career development (e.g., process innovation and improvement skills, diversity training, recruitment, regulatory science)			
Mentored Grant Writing^	Prepare and submit grant within 12-18 months			
Annual ACTS Meeting		x		x
Monitoring Scholar Progress	x	x	x	x

*Orientation occurs April or May prior to the start of Year 1. ^Structured internal grant review and feedback through Research Methods Forum

Table 2. Sample Coursework and Partnerships with Training Specializations

	Experimental Therapeutics	Digital Health	Health Equity-Focused Dissemination and Implementation (DI)
Co-Directors	Robert Holloway and Karen Mustian	Ray Dorsey and Jean-Phillippe Couderc	Kevin Fiscella, Jim McMahon, and Reza Yousefi-Nooraie
Sample Coursework	Experimental Therapeutics (PM488)	Machine Learning (CSC 446)	Intro to HSR and Policy (PM455)
	Design of Clinical Trials (BST465)	Artificial Intelligence (CSC 442)	Program Evaluation (PM461)
	Recruitment and Retention (PM419)	FDA Reg Process & IP (BME431)	Community-Engagement Studios
	Measurement and Evaluation (PM472)	FDA Regulatory & Commercialization Landscape (BME432)	Qualitative Health Care Research (PM458)
External Partnerships	Trial Innovation Network PhRMA Foundation Praxis Precision Medicine Emerging Research Networks	Critical Path Institute Sage Bionetworks 23andMe	University of Washington DI Research Core Ohio State University Implementation Science Core