# Clinical and Translational Science Institute
# University of Rochester Medical Center
# Mentored Career Development Program (KL2) in Clinical and Translational Research

Request for Applications



## Important Dates

- Monday, November 2, 2015, 5 p.m. Eastern Time: Notify CTSI of plans to apply
- Friday, December 4, 2015, 5 p.m. Eastern Time: Submit application packet
- Friday, March 4, 2016: Notification of recipient(s)
- July 1, 2016: Start of the award

# Important Notice

The KL2 Mentored Career Development Program is funded by the NIH Clinical and Translational Science Award (CTSA) program. The University of Rochester submitted an application for a third cycle of CTSA funding on September 25, 2015, for a grant to begin on July 1, 2016. While we are optimistic that our application will be successful, please be advised that 2016 KL2 awards are dependent upon availability of CTSA funding.

# Program Description

The Mentored Career Development Program (KL2 Scholars Program) in Clinical and Translational Research is a two-year program funded by the Clinical and Translational Science Award (CTSA) program from the National Institutes of Health (see http://www.ncats.nih.gov/research/cts/ctsa/ctsa.html). The KL2 Scholars Program is designed to support the early career development of multidisciplinary clinical and translational scientists. 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 KL2 Scholars Program provides core programmatic elements (core curriculum, mentored research project, team science training, mentor/protégé support and training) and individualized program elements (training pathways, degree and certificate programs, elective coursework, extra-curricular activities, and hands-on team science experiences). Trainees will be expected to develop and implement a research experience supervised by a primary mentor and mentorial team. The research project should be designed as a pilot project to set the stage for an individual K-award application, or in exceptional circumstances, establish a foundation for a subsequent individual R-award application.

The program has devised three training pathways that capitalize on institutional strengths. They are described below. Prospective scholars may choose, but are not required, to take advantage of one of the three, and are also free to propose their own training pathway as well.

**Enabling Technologies:** Novel technologies are poised to revolutionize clinical research conduct. For example, the need for frequent in-person visits and the resulting time and travel costs are a major burden to participation in clinical trials. Technology-enabled remote research visits (e.g. video conferencing) have had great impact on patient care in the context of telemedicine, but also have great potential for overcoming research participation hurdles like distance, disability, and the distribution of research centers. Additionally, implementation and evaluation of novel measures of disease that are either portable (e.g., smartphone applications) or wearable can provide objective, frequent, and potentially more sensitive assessments that can be conducted almost anywhere. Smartphone technology includes applications like Apple's recently released open-source ResearchKit and its first five smartphone-based clinical research studies

for asthma, breast cancer, cardiovascular disease, diabetes, and Parkinson disease, the latter of which was based in part on work done by University of Rochester researchers. Wearable technologies are increasingly diverse and include (sometimes implantable) devices that are capable of measuring outcomes that were previously undetectable (e.g., intermittent atrial fibrillation or QT prolongation) through standard methods.

**Regulatory Science:** Regulatory Science, as defined by the FDA, is "the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products". Several UR-CTSI faculty who are leading national efforts to establish core Regulatory Science curriculum standards based on recently establish core competencies which were developed via collaboration between UR, other CTSA hubs, and the FDA Centers of Excellence in Regulatory Science and Innovation. UR-KL2 Scholars who are interested in gaining training and experience in Regulatory Science will have the opportunity to capitalize on faculty expertise and experiences from within the UR (and its UR-CTSI) and through a collaborative effort with the University of Pennsylvania's Institute for Translational Medicine and Therapeutics (ITMAT).

**The Electronic Health Record as a Resource for Research:** An urgent need exists for workforce training in translational research that utilizes the electronic health record in the following ways: 1) as a primary source of research data, 2) as a source of secondary data that needs to be merged with other data sets (e.g. genomic, qualitative, etc.), or 3) as a tool for gathering additional research data at the point of clinical care. The potential demand for such training at UR is extensive, as evidenced by the >1,000 clinical-translational researchers conducting ~2,300 active studies and accessing over 8Tb of clinical EHR data at URMC. This specialization will give Scholars the tools and expertise to extract and integrate EHR data with basic science and genomics data, and a robust analytic skill set including database construction, data mining, advanced statistical methods, risk adjustment modeling, analysis of molecular and social networks, and high dimensional data visualization. The pathway builds on the UR-CTSI pioneering development of novel data extraction and integration software tools, including implementation of Informatics for Integrating Biology and the Bedside (i2b2) within the Research Electronic Data Capture (REDCap™) program.

Table 1 below illustrates the components of the program and provides examples of educational experiences within each of the three training pathways

**Table 1. UR-KL2 Career Development Objectives and Example Scholar Experiences**

| | Career Development Objectives | | | | |
|---|---|---|---|---|---|
| | **1 Foundational Curriculum** | **2 Individualized Curriculum** | **3 Mentored Research Experience** | **4 Team Science Experience** | **5 Evaluation** |
| **Core Scholar Experience** | 1. Research Ethics<br>2. GCP Training<br>3. Grant Prep.<br>4. Leadership and Network Dev.<br>5. CTSI Research Methods Forum | Coursework and extracurricular activities (e.g. conferences) chosen to meet Scholar needs | Research project that aligns with Mentor research area and engagement of external partners when applicable | Activity that provides experience in scientific team-based collaboration and aligns with Scholar research or career goals | Customized evaluation developed from Scholar's Research Career Development Plan |
| **Enabling Technologies Specialization (Example Experiences)** | | Courses:<br>• Experimental Therapeutics<br>• Medical Device Design<br>Conferences:<br>• d.health Executive Summit<br>• Dpharm Conference | Mentor/ Research/ Partner:<br>1. Biglan/Virtual research visits/ 23andMe<br>2. Dorsey/Remote measurement/ MC10 | Participation in Academic CRO-based activities or future UR Trials Innovation Unit | |
| **Regulatory Science Specialization (Example Experiences)** | | Courses:<br>• Drug Discovery<br>• Pathway to Med Innovation<br>Conferences:<br>• CTSI/ITMAT Workshops<br>• FDA Science Forum | Mentor/Research/ Partner:<br>1. Venuto/disease modeling/University at Buffalo<br>2. Dworkin/novel assessment of pain/FDA | Participation in PhRMA Foundation-sponsored activity | |
| **EHR as a Resource for Research Specialization (Example Experiences)** | | Courses:<br>• The Art of Data Structures<br>• Data Mining<br>Conferences:<br>• Clinical Research Informatics World Conference<br>• Summit on Clinical Research Informatics | Mentor/Research/ Partner:<br>1. Noyes/ outcomes research/RHIO<br>2. Dye/Patient Reported Outcomes/ Medical Faculty Group Practice | Participation in the UR's Enterprise Clinical Steering Committee or Center for Clinical Innovation | |

See also:

- University of Rochester Clinical and Translational Science Institute (CTSI) (http://www.urmc.rochester.edu/ctsi/)
- CTSI Education, Training, and Career Development (http://www.urmc.rochester.edu/ctsi/education-career/)

## 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 provide up to approximately $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 $24,000 of non-salary support per year, 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.
- 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 http://www.urmc.rochester.edu/education/graduate-medical-education/benefits-contract/). Those appointed as faculty receive benefits as defined by the University of Rochester (see https://www.rochester.edu/working/hr/benefits/index.html).

## Other Details

KL2 scholars are strongly encouraged to attend the annual meeting of the Association for Clinical and Translational Science (ACTS), typically held in the Spring in Washington, D.C. More information can be found at http://www.actscience.org/. Grant funds may be used for this purpose. Candidates selected for the KL2 Scholars Program in Clinical/Translational Research may be eligible to apply to the NIH Loan Repayment Program for clinical investigators.

## Program Contacts

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

General inquiries:

- Katie Libby
- CTSI Education Program Manager

- 585-275-0656
- Katherine_Libby@urmc.rochester.edu

Financial and budgetary inquiries:

- Thomas Fogg
- CTSI Executive Director for Operations
- 585-275-0684
- Thomas_Fogg@urmc.rochester.edu

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

- James Dolan, MD
- Associate Chair, Education, Department of Public Health Sciences
- 585-276-5161
- James_Dolan@urmc.rochester.edu
- Website: http://www.urmc.rochester.edu/public-health-sciences/educational-programs/

Inquiries regarding other programmatic issues:

- Robert Holloway, MD, MPH
- Director, KL2 Scholar Program
- Chair of Neurology, and Professor of Neurology and Public Health Sciences
- 585-273-3079
- Robert_Holloway@urmc.rochester.edu
- Website: http://www.urmc.rochester.edu/ctsi/funding/kl2-career-development-program.cfm

# Admissions

## Eligibility

To be eligible to apply to the KL2 Scholars Program, you must define and participate in a clinical or translational research project. For the purpose of this program, clinical research is defined as all aspects and kinds of clinical research including epidemiologic and natural history studies, patient-oriented research, clinical trials and outcomes research. In addition, for the purpose of this program, translational research includes three areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of research studies in humans. The second and third areas of translation concern either research aimed at developing an evidence-base to improve clinical practice (e.g., clinical trials, diagnostic test assessments, comparative effectiveness research) or at enhancing the adoption of best practices in the community. The KL2 Recruitment/Selection Committee determines whether or not the research experience proposed for your program meets the intent of the program.

Note: The NIH unit that funds the CTSA program is the National Center for Advancing Translational Sciences (NCATS). NCATS by law may only support clinical trials through Phase 2a; therefore Phase 2b clinical trials or later are not eligible for support through the KL2 program. NCATS defines a phase 2a trial as “a pilot study to evaluate the efficacy and safety of an intervention in patients with the disease or condition to be treated, diagnosed or prevented. These studies may focus on participant population characteristics, dose response, dose frequency or other characteristics related to safety or efficacy. Phase [2a] trials are not considered pivotal trials of efficacy.”

## Valuing Diversity

The University of Rochester welcomes and encourages women, members of under-represented minority groups, and individuals with disabilities to apply.

## 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 a fellow or junior faculty committed to an academic career in clinical and translational research. Preference will be given to applicants early in their training/career.

- 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 any of the provisions of the KL2 program. A KL2 scholar, once appointed, may apply for support from a PHS mentored career development award (http://grants.nih.gov/grants/guide/notice-files/NOT-RM-08-017.html).

- Commitment to a two-year program. 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).

- Identification of a multidisciplinary mentorial team with extensive clinical or translational research experience with one of the members willing to serve as your primary mentor.

- No prior receipt as Principal Investigator of R01, R21, Center or Mentored Career Development (K) grants, or project leader on sub-projects of program projects (P01) or center grants (P50) (or equivalent non-PHS peer reviewed research grant over $100,000 per year in direct costs). Scholars may have had support on a NRSA grant (F or T) or NIH small grant (R03).

# Application Process

## Positions

One or two positions are available annually and have a start date of July 1, 2016.

## Timeline

- Please email Katie Libby at katherine_libby@urmc.rochester.edu by **5 p.m. Eastern Time on Monday, November 2, 2015** if you intend to apply**.**
- Submit **application packet** by **5 p.m. Eastern Time on Friday, December 4, 2015.**

## 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 informational links below. You may contact the CTSI Research Help Desk (ResearchHelp@urmc.rochester.edu) for assistance in identifying potential mentors.

Also see:

- Research Departments and Centers at the University of Rochester (http://www.urmc.rochester.edu/research.aspx)
- URMC Research Network (https://www.urmc.rochester.edu/profiles/search/)

**Step 2: Notify the CTSI of your intent to apply by 5pm EST, Monday, November 2, 2015.** The information to be provided allows us to better plan the review process and assist potential applicants as necessary. The email should contain two or three sentences describing your areas of interest and the names and specialties of your primary mentor and co-mentor(s).

- **Send your email to Katie Libby at katherine_libby@urmc.rochester.edu.**

**Step 3: Complete the required documentation**. To apply, you will need to submit the following application materials. Resubmissions should include how you addressed prior reviewer comments in a cover letter. Please follow NIH guidelines for grant style, content, and format contained in section 2.6 of the SF424 Application Guide (available online at http://grants.nih.gov/grants/funding/424/index.htm#inst).

1. **Your NIH-format biosketch** (sample and form available online at http://grants.nih.gov/grants/funding/424/index.htm#format). Do NOT submit a CV. Prepare your personal statement so as to be relevant to your KL2 mentored career development proposal.

2. **NIH-format biosketches for your primary mentor as well as all secondary mentors**. Mentors, consultants and collaborators 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)**

The candidate and the mentor are jointly responsible for the preparation of the career development plan. A timeline is often helpful (3 page limit, excluding references):

- 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 and mentorial committee will meet your needs. Please refer to the CTSA's core and special interest clinical and translational research competencies (https://ctsacentral.org/consortium/best-practices/335-2/)
- Describe a systematic 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.
- Descriptions of the training you are seeking and how the training by the Scholars Program will help you achieve these goals. The description should follow the structure provided above in table 1; specifically, you should address your commitment to the KL2 foundational curriculum (see Appendix A for a description of the foundational curriculum); plans for your individualized curriculum; and your proposed team science experiential training. Examples of team science training experiences are provided in Appendix B.
- 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.
- Plans and timing of submission for subsequent funding, including K- or R-series mechanisms, or equivalent, as appropriate to training and research needs.

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 Form PHS 398, following instructions for the Specific Aims, Background and Significance, Progress Report/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 Federal Citations in Section VIII in NIH program announcement PA-05-143).

5. The following **3 letters of recommendation**. Do not submit additional letters of recommendation other than those requested below:

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 projects. The letter should describe how the proposed research fits into the mentor's research program, including a description of the specific role of the applicant in the research. The primary mentor letter should not exceed two pages.

ii. **A letter of recommendation from one of the proposed co-mentors of the candidate.** 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.

iii. **A letter of nomination/recommendation from the Chair of the Department or Director of the Center**, including 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). 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. This letter should not exceed one page.

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 Thomas Fogg, CTSI Executive Director for Operations, for assistance in completing the financial analysis, using a standard template supplied by the CTSI (585-275-0684 or Thomas_Fogg@urmc.rochester.edu).

**Step 4: You must submit the required materials listed above through our online application system no later than 5 p.m. Eastern Time on Friday, December 4, 2015.** We will send a link to the online system after we have received your email documenting your intention to apply. Supplementary material will not be accepted. You must notify the 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. Failure to notify the CTSI of such changes in a timely and accurate fashion may disqualify you from the KL2 program.

# Application Review Process and Criteria

Each application will be reviewed initially for completeness and eligibility.

Step 1: 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, 5) Environment and Institutional Commitment to the Candidate.

Each applicant will receive up to 3 reviews from faculty members at the University of Rochester. Faculty members with a significant conflict of interest will not be allowed to review.

Step 2: The KL2 Recruitment/Selection Committee will meet to discuss the written reviews. The Committee may pose additional questions for the applicants; if so, the applicant's will be asked to respond to the reviewer questions in writing.

Step 3: The KL2 Recruitment/Selection Committee will review the written responses to questions and assign a final score for each application.

Step 4: The KL2 Recruitment/Selection Committee will present its recommendations to the KL2 Steering Committee, which will make final award decisions.

## Annual and Final Progress Reports

An annual progress report is due in May 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. 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 CTSI must do the following:

1. Comply with the NIH Public Access Policy: Assistance with the compliance process is available through the Miner Library. Information regarding the Public Access Policy is located on the Miner Library website at http://www.urmc.rochester.edu/libraries/miner/publishing/NIHPublicAccessPolicyMinerLibrary.cfm.

2. Acknowledge CTSI grant funding using this language: "The project described in this publication was supported by the University of Rochester CTSA award number _____(TBD) 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 CTSI of all adverse events that are serious, unexpected and related to participation in research. Further guidance is available here: www.hhs.gov/ohrp/policy/advevntguid.html. In addition, most clinical trials must be registered in clinicaltrials.gov. For more information about registration requirements, see http://www.urmc.rochester.edu/ctsi/regulatory-support/clinical-trials-registration.cfm.

## Notification of Recipients

Notification of recipients: Shortly before or on March 4, 2016.
Award start date: July 1, 2016

## Appendix A. Elements of the Foundational Curriculum

Each Scholar will participate in a foundational curriculum to ensure a minimum standard of career development competencies in research ethics, Good Clinical Practice (GCP) training, grant preparation, leadership and network development.

***A. Research Ethics.*** The UR-KL2 Program is fully invested in the development of early-career faculty who are educated and committed to ethical conduct in research.

*Course:* All Scholars are required to complete and pass the course, *Ethics and Professional Integrity in Research* (IND506, 1 cr). The one-credit course provides >16 hours of lectures and small-group discussion over a 2-month time period. Any Scholar who has completed this course as part of a UR-based training program will be required to participate as a small group facilitator for the course.

*Training:* All Scholars who work with patient-oriented research, vertebrate animal models, or patient data are required to complete relevant training in human subjects protection, animal welfare, and/or HIPAA.

*Continuing Education*: Scholars will be encouraged to continue ethics-related education by attending widely-available special invited lectures, online courses, skill-building workshops, and monthly seminar series.

***B. Good Clinical Practice (GCP) Training*.** Scholars engaged in clinical trials will receive GCP training.

*Online Course:* Scholars will complete an online GCP training program (via the Collaborative Institutional Training Initiative) that has been approved by the UR Human Research Protection Program.

***C. Grant Preparation.*** We require curricular elements that prepare and guide Scholars in their preparation of an individual K- or R-award application.

*Course: Practical Skills in Grant Writing* (PM 438, 3 cr) All Scholars are required to take this spring semester course during their first year. Course content includes didactic lectures on grant-related topics, opportunities to engage in peer grant review, and presentation of grant-related tools and resources. All participants are required to write a grant and subsequently receive critical review from course faculty and classmates. This course provides Scholars with the invaluable opportunity to write and receive critique on their individual grant application (K- or R-award), which must be submitted prior to completion of the UR-KL2 program.

*Research Review Experience:* Each Scholar will be required to participate in at least one scientific review experience. Examples include a 1-year experience as a member of the UR-CTSI Clinical Research Unit's review of protocol implementation specifics (PCI-Hub Capacity Core) or providing Department-level scientific and ethical review (in a mentee capacity) of human subjects research proposals intended for IRB review (each URMC Department is required to perform internal scientific review prior to IRB submission).

***D. Leadership and Network Development.*** Effective leadership and establishment of a research network are fundamental to the development of any independent

investigator. In addition to executing their own research project, Scholars will receive training in the 'hard' and 'soft' skills necessary to become an effective leader.

*Seminar/Online Course: UR Leadership Development Program.* This program has two tracks, Management Essential and Leadership Enhanced, and allows participants to engage course content via an independent online curriculum or instructor-led lecture series (eight, 1-hour classes). The content addresses eight leadership competencies: Leading Change; Giving and Receiving Feedback; Building and Leading Teams (including Trust, Accountability and Emotional Commitment); Managing Conflict; Using Emotions Effectively; Leading and Communicating Vision; Leading Innovation; and Culture and Process Improvement.

*Seminar: Academic Career Development Series*. This monthly seminar is open to any UR early-career scholar or trainee, and covers a broad range of professional skills development, including: 1) Proposal development (specific aims, background and significance, research methods and analysis, career development plan), 2) Time management, 3) Working with students/trainees (including how to write individual development plans), 4) Mentoring, 5) CV workshop, 6) Biosketch workshop, 7) Nuts and Bolts of getting promoted, 8) Scientific communication (scientific writing and review, oral presentation, and poster presentation), 9) Well-being and Balance/Mindfulness workshop, 10) Supporting a research program, and 11) Networking. These interactive sessions between faculty and participants provide the foundational skills that are relevant to the diverse audience members. Many of the presenters are UR-KL2 Program Faculty.

*Peer Networking Group: UR Junior Faculty Biomedical Research Association*. Scholars will be automatically enrolled in this academic peer group of early stage MD and PhD faculty from basic and clinical research backgrounds. Participation promotes early career success in scientific discovery, funding, publications, mentoring through regular newsletters and email communications and in-person meetings (3x/year) that provide a forum to network, discuss challenges of early career start-up, and receive guidance from senior faculty through interactive presentations.

***E. Presentation at the CTSI Research Methods Forum.*** The CTSI Research Methods Forum is organized by the CTSI Research Methods Core, and is attended by biostatisticians, epidemiologists, members of the regulatory knowledge and support team, and experts from other CTSI cores. It provides an interactive setting for investigators to: 1) present initial research ideas for review and critique, and in turn receive recommendations from forum attendees and potential collaborators; 2) review preliminary results; 3) discuss significance of pilot data; 4) generate, in collaboration with other attendees, ideas for future studies; and 5) review grant proposals and receive constructive criticism. KL2 Scholars will present their research proposal(s) at least twice at the Forum: once at the early stages of project development, and again when the research design and desired collaborative team are more established. These meetings provide an opportunity for an unstructured discussion of goals, methods, practical limitations and issues ranging from design and participant recruitment to funding and publication strategies. The forum also provides an opportunity to identify potential collaborators at the URMC or at other institutions.

## Appendix B. Examples of Team Science Experiences

The UR-KL2 Program leadership will work with each Scholar to plan a team science experience that is both feasible and relevant to the Scholar's career development, and will facilitate the administrative implementation of the experience when necessary. The following overarching principles will be required to determine a 'qualifying' experience: 1) the Scholar obtains career-relevant experiences, gaining new knowledge and skills, 2) the Scholar ideally contributes work of value to the host Program or Center where the experience is occurring, 3) the duration of the experience has to be sufficiently long enough to gain an appreciation of the team science research effort (e.g., one year or longer), and 4) the Scholar will have to produce a written summary of the experience in their required progress reports.

To assist with conceptualization of a qualifying experience, five examples of potential experiences are provided below. Many of these examples draw upon the UR's unique depth of experience in both running global, multicenter drug and device trials ("research hub"), and functioning as a performing site in NIH-funded research networks ("research spoke"). Scholars may choose one of these specific examples or propose an alternative qualifying experience that aligns with the overarching principles above and is approved by the UR-KL2 Program Director.

- *Participation in National Research Networks and Academic Study Groups.* The UR has been a consistent contributor to multi-center research groups across a broad range of disease conditions, involving all stages of translation. These networks include the NINDS NeuroNEXT Network, NIAID AIDS Clinical Trial Group, HIV Vaccine Evaluation Group, NIA-funded Alzheimer's Disease Cooperative Studies, and NINDS funded studies conducted by the Parkinson, Huntington, and Muscle Study Groups. Scholars can elect to be an enrolling site investigator or sub-investigator of a clinical trial or observational follow-up study within one of the existing networks or serve as an ad-hoc Steering Committee member for one of the Study Groups. Scholars will gain experience in contributing to "spoke" activities (e.g., central-IRB reliance models and master contract agreements, clinical trial budgets, considerations for biorepositories, and working with clinical research coordinators and other study personnel) while appreciating the governance and broader organization of Network/Study Group activities.
- *Contributor to Operational Activities within an Academic Clinical Research Organization (CRO).* The UR has served as a central coordinating center for over 36 NIH funded clinical trials and observational studies, and over 50 industry- and foundation-funded trials, utilizing hundreds of clinical trial sites across 4 continents. Scholars can elect to participate in one of the academically-based CROs located at the UR (e.g., Center for Human Experimental Therapeutics, the Heart Research Follow-up Program, and the Cancer Control Program as a newly established hub for the NCI Community Oncology Research Program). These organizations perform a multitude of study-related activities that span study conception, planning, implementation and disseminating results. Given the overall time it takes to complete a multi-study effort, a Scholar experience will likely require engaging in an active study. Experiences include assisting with site selection and activation activities (including contracts administration), serving as a Medical/Clinical monitor of an active study, participating in ongoing implementation meetings to address recruitment/retention concerns, or co-leading efforts to develop clinical protocols, informed consent documents, DSMB reports, or manuscripts. This type of experience imparts knowledge related to "hub" activities required to accomplish multi-center efforts, including any compromises and corrective actions.

- *Participation within UR's Local Trial Innovation and Recruitment Units.* While we await the NCATS creation of Trial Innovation Centers (TICs) and Recruitment Innovations Centers (RICs), we anticipate the organization of local UR Trial Innovation and Recruitment Units. Our local Trial Innovation Unit will monitor and resolve impediments in the research approval process, including establishing protocols to monitor common metrics to improve our hub efficiency. Scholars may elect to participate in the Unit's monthly meetings to gain an appreciation of the activities needed to streamline the "activation period" to efficiently participate in Network-driven studies. The Recruitment Unit consults with researchers to recommend evidence-based approaches to clinical study recruitment, works to promote institutional policies and practices to advance research recruitment, and reaches out to the community to promote participation in research.
- *Contributor to Community Engagement Endeavors.* The URMC Center for Community Health has a unique and well-developed infrastructure for developing community-academic partnerships and providing consultation to faculty to establish community-based initiatives and research to reduce health disparities and prevent communicable and chronic disease. Scholars may elect to participate one of several community-engagement expert bodies (e.g.: Community Advisory Council, Greater Rochester Practice-Based Research Networks, Population Health Interest Group) to gain an appreciation of the needs of a broad range of stakeholders in research, approaches to special populations, and to improve on approaches to develop culturally competent, population-specific recruitment and retention strategies.
- *Electronic Health Record Clinical Research Integration into the Clinical Enterprise.* The Electronic Health Record (EHR) is the major institutional resource that forms the basis of a majority of informatics-based research. To support these efforts, the URMC and UR-CTSI have several programs and offices (Office of Innovation and Technology for Clinical Applications and the UR-CTSI's Informatics Core) that facilitate access to EHR data, liaise with external groups (e.g. other CTSA hubs, tool developers) around development of multi-institutional initiatives, and facilitate use of EHR mechanisms to access populations. Scholars can elect to participate in the monthly meetings to appreciate the needs of different stakeholders, including health care organizational priorities, technical constraints of the EHR, and the language of bioinformatics.