

CLINICAL RESEARCH SCHOLARS

Director: Edgar R. Miller, III, MD, PhD

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2020 CALL FOR APPLICATIONS KL2 MENTORED CAREER DEVELOPMENT AWARDS

Application Deadline: **JANUARY 15TH, 2020, 11:59 PM EST**
Apply online at <https://ictr.johnshopkins.edu/ClinicalResearchScholars>

The Clinical Research Scholars Program is seeking applications for the 2020 KL2 Mentored Career Development Awards. We are able to offer 2-3 new awards to begin July 1st, 2020. The KL2 award supports the development of individuals dedicated to a career in clinical investigation. Support is provided for two years, with an additional year supported by the nominating Department/Division.

Purpose

The purpose of the KL2 is to provide support for clinical and translational research training and career development of persons in relevant disciplines and professions (including but not limited to internal medicine, surgery, pediatrics, obstetrics/gynecology, nursing, pharmacy, statistics, nursing, epidemiology and behavioral sciences, psychology, and engineering) and their various specialties and sub-specialties.

Research areas may include: patient-oriented research, epidemiology and behavioral studies, and outcomes research and health services research. Epidemiologic and natural history studies, patient-oriented research, clinical trials, and outcomes research are all possible types of research supported through this award. We support a spectrum of scientific disciplines (medicine, surgery, nursing, pharmacology, statistics, psychology, and engineering) that are employed by health professionals, often in specialties and sub-specialties (internal medicine, surgery, pediatrics, obstetrics/gynecology, oncology, cardiology, nephrology, etc.) using a variety of study methodologies.

This type of research is a complex endeavor that is ideally performed by an interdisciplinary team using an integrated team approach. An interdisciplinary approach brings experts from diverse disciplines (i.e. clinician, clinical researcher, statistician, computational scientist, and pharmacologist, as well as expert faculty with in informatics, regulatory science, entrepreneurship, and commercialization) from our Schools of Medicine, Public Health, Nursing, Engineering, and Business to address collectively a common complex problem. There is a shortage of well-trained physicians and other health professionals performing clinical research in a rigorous, highly collaborative, team-oriented environment.

Fundamental elements of the award include: structured, core didactic coursework; training in the design, conduct, and analysis of clinical research in team settings (protocol development, preparation of IRB applications, clinical research/trial management, patient accrual, data collection, analysis and manuscript writing); conduct of a research project under the supervision of mentors and; engagement in related career development activities and seminars that include introduction to innovative

methodologic approaches to translational science, regular research-in-progress presentations, and grant writing.

Eligibility

In order to be eligible for consideration for the Johns Hopkins Clinical Research Scholars Program, applicants must meet **each** of the following criteria:

- Research or health-professional doctoral degree or equivalent, including but not limited to, MD, DO, DDS, PhD, PharmD, PsyD, DPH; Epidemiologists, behavioral scientists, nurses, and engineers with clinically relevant doctoral degrees are eligible as well.
- A full-time faculty appointment (Instructor, Assistant Professor, Research Associate, or equivalent, for 5 years or fewer) at the Johns Hopkins Schools of Medicine, Public Health, Engineering or Nursing by the date of receipt of the award. Postdoctoral clinical fellows with a pending faculty appointment **are** eligible to apply. The faculty appointment cannot be dependent upon receipt of the KL2 award.
 - At least **75%** protected time available for research and training for the next **three** years. NIH allows Scholars from some surgical specialties to request less than 75% protected time for research (must be at least 50%), if it can be substantiated that more than 25% clinical effort is necessary to maintain clinical skills and privileges. A request for this exception must be made and justified in the application; and approved by NCATS before appointment.
- A commitment to a career focused on clinical investigation.
- A commitment to additional training, which may include:
 - a. MHS or PhD in clinical research (e.g. Clinical Epidemiology, Clinical Investigation, or Biostatistics)
 - b. Proposal for coursework/training relevant to Scholar needs – **NOTE:** The Bloomberg School of Public Health allows 16 credits in Special Student Limited (non-degree) status, though this would include courses taken prior to the KL2 appointment.
- Identification of and support from at least one, but ideally an interdisciplinary team of Johns Hopkins active faculty mentor(s), established and successful in clinical investigation.
- United States citizenship, permanent resident, or non-citizen national status (persons born in outlying possessions of the United States, limited to American Samoa, Swain's Island, or the unincorporated United States Minor Outlying Islands) at the time the application is submitted. Individuals on temporary or student visas are not eligible. Proof of residency may be required.
- Have **NOT** served as Principal Investigator on a R01 or R29 award, subproject of P-series program project award or U-series research grant, or received any NIH K-series award (this does not include NIH Small Grants or Exploratory/Developmental grants or their equivalents).
- Must **NOT** have an active NIH K-series award pending. However, once **appointed**, KL2 Scholars are expected to apply for further grant support such as K23, K01, or K08 support.

JHCRS is committed to increasing the participation of women and individuals from ethnic or racial groups underrepresented in the biomedical and behavioral sciences – such groups include American Indian or Alaska native, Asian, Black or African-American, Hispanic or Latino, and Native Hawaiian or other Pacific Islander. Applications from women and minority candidates are encouraged. In addition, accommodations will be made to assist any individuals with disabilities so those persons who are qualified applicants can complete the program.

Source of Support

Funding for the JHCRS KL2 comes from the Johns Hopkins Institute for Clinical and Translational Research (ICTR) through a National Institutes of Health (NIH) National Center for Advancing Translational Science (NCATS) funded Clinical and Translational Science Award (CTSA).

Scholar Support

- Up to \$110,000 in annual salary support proportional to effort committed to program activities (75-90%), plus fringe benefits, for up to two years (ongoing support is contingent upon the Scholar making adequate progress in the program and completing program requirements)
- Up to \$30,000 to support the costs of their degree or training programs, research project(s) and other related activities (supplies, computers/software, biostatistics services, personnel, and other project infrastructure).
 - Tuition support is capped at \$18,000* annually (**included in \$30,000*)
 - *All tuition support provided by JHCRS and 'forgiven' by BSPH is taxable income to the IRS!*
- An additional \$2500 annually for scholarly travel in support of the objectives of the award

Award Stipulations

JHCRS is a **three** year commitment. The first two years are supported by the KL2, while the third year salary support is provided by the nominating division/department. Often year one is devoted to didactic studies. Year two is devoted to the research project, any remaining academic requirements, and submission of K or other career development award. (e.g. K23, K08, K01). Year three is a continuation of research efforts and grant writing.

- Scholars often complete at least one year of structured, didactic coursework, preferably leading to an advanced degree.
- Scholars are expected to submit a Patient-Oriented Research Career Development Award or other NIH grants by the end of the second year.
- Annual participation in the Translational Science Annual meeting is required.
- Participation in **required** program activities over the three-year period of combined support – including our monthly Research-in-Progress meetings and monthly CATALiST Seminar Series.
- Demonstration of ongoing participation in mentors' multidisciplinary clinical research team(s).
- Scholars are required to submit annual progress reports to the NIH.
- Extensions of support or leaves of absence are possible only under exceptional circumstances
- Scholars are expected to update the program on publications, grants and awards after appointment

Application Instructions and Submission Process

Completed applications include **all** components (with supporting documents) listed below. It is the applicant's responsibility to prepare and collect each component and submit them. Please visit our website to submit the completed application and supporting documents on-line. Applications missing any required component or submitted after the deadline will not be considered. **PLEASE NOTE: The entire online application must be submitted in order to trigger the automatic release of requests for nomination and recommendation/reference letter(s).**

- 1. Personal statement** (2-3 pages) detailing accomplishments to date plus career goals and plans. This statement should specifically address:
 - a. background information relevant to the applicant's interest in clinical/translational research; we encourage projects that have a clear translational component.
 - b. long-term career goals
 - c. how the KL2 award would advance these goals
 - d. need for additional training to achieve goals
 - e. interactions to date with potential mentors within the sponsoring clinical division or department including any prior or ongoing research experience and/or plans for identifying and selecting a mentor/preceptor for the program's research requirement.
- 2. Research Plan** (2-5 pages) describing ongoing or proposed clinical/translational research project and plans for future grant submission. May include:
 - a. Specific Aims - objectives of your research project, what you want to accomplish; should be driven by the hypothesis you set out to test; make sure they are highly focused
 - b. Background/Significance - how your research is innovative/is from a fresh point of view/develops or improves technology; justify with background information about the field
 - c. Preliminary Data - may consist of your or others' publications, unpublished data from your own laboratory or from others; make sure it's clear which data are yours and which others reported
 - d. Research Design/Methods - describe the design and procedures in detail; give rationale
 - e. Literature Cited (will not count toward page limit) - Refer to the literature thoroughly and thoughtfully but not to excess. The publications you cite need not be exhaustive but should include those most relevant to your proposed research.

3. Plans and justification for Proposed Advanced Training (1-2 pages). A description of the plans for advanced training must be included. Acceptance into an advanced didactic training program in clinical research (e.g. Clinical Investigation, Clinical Epidemiology or Biostatistics master's or doctoral programs at JHMI) would suffice. An alternative plan for training outside of a degree program based on individual needs is acceptable.

An application **separate** from the KL2 Scholars application (though it includes many of the same components) must be made to the School of Public Health degree program if pursuing an advanced degree. Their online application can be found at <http://www.jhsph.edu/Admissions/index.html>. Please be mindful of the deadlines for each of the programs and degrees! The Program Manager will, by written request, forward Clinical Research Scholars application materials to the School of Public Health.

Applicants already accepted into the GTPCI, Clinical Epidemiology, or Biostatistics degree program at the School of Public Health, JHCRS will require a transcript of courses taken and a listing of those planned to be taken. For those who may have completed relevant coursework outside Johns Hopkins, a detailed description of the coursework previously taken must be included.

4. Curriculum vitae including list of publications and current/prior grant support.

5. Nomination letter written by the primary mentor and the Division/Department Director (though separate letters are acceptable). The letter should address:

- a. Career development plans for the candidate and how the award would facilitate these plans
- b. Candidate's promise for a successful academic career in clinical investigation and listing of any supporting past accomplishments
- c. Mentor's/division's commitment to the candidate's career development, including what commitment and/or plans there are for the nominee should a KL2 Award NOT be made
- d. Assurance of a third year of support and dedicated research time from the division/department – a specific commitment to salary support and at least 75% effort for research to complement the two year KL2 award, including identifying the likely source of such support (During this third year, there is no salary/stipend, tuition, research or mentor funding from JHCRS)
- e. Provisions (if any) made for faculty advancement, mentoring, space and other support

The nomination letter must specifically state, “I/We will guarantee a third year of salary support for Dr. X with (indicate source of support) and protect his/her time so that at least 75% time is available for the pursuit of research, education and training activities for three years.”

IMPORTANT NOTE: NIH allows Scholars from some surgical specialties to request less than 75% protected time for research (must be at least 50%), if it can be substantiated that more than 25% clinical effort is necessary to maintain clinical skills and privileges. A request for this exception must be made and justified in the application; and approved by NCATS before appointment.

6. **Proposed mentor(s) NIH formatted biosketch** including research support. Applicants without a mentor should submit a letter explaining this and outlining potential identifiable mentors.
7. **Two letters of recommendation and reference forms** from faculty, past mentors/advisors who can assess the candidate's ability. These letters are in addition to the Nomination letter and should not be written by your primary mentor or Department/Division directors.
8. **Unofficial Transcripts** from *all* academic training,

Review and Selection Process (subject to change)

Our goal is to select candidates who, with proper career development and clinical and/or translational research training, have potential to become independently funded, successful and ethical clinical investigators. A committee of faculty from Public Health, Nursing, Engineering and Medicine, will review applications, interview candidates and select awardees. Interviews will be conducted in late February and awards will be announced in March 2020. Decisions will be based on the strength of the application materials submitted, the overall potential of the applicant and the track record of the mentor(s).

Contact Us

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Website: <https://ictr.johnshopkins.edu/ClinicalResearchScholars>

Applicants and/or nominating sponsors are encouraged to contact the JHCRS Program Directors and/or program manager to discuss eligibility requirements, obtain guidance about any special circumstances or discuss other aspects of the KL2 award and its terms:

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