

KL2 Junior Faculty Scholars Program – Frequently Asked Questions

ELIGIBILITY

1. What are the eligibility requirements for applicants?

- All candidates must be US citizens, Non-Citizen Nationals, or Permanent Residents (Proof of status will be required prior to official appointment)
- All candidates must have a full-time faculty or equivalent appointment at a GHUCCTS institution (Georgetown University, Howard University, or MedStar Health) at the time of award activation
- Must devote 75% effort to the program for a full 3 years (will consider 50% effort, with prior consultation and approval, in accord with NIH guidelines, for some surgeons or procedural subspecialists)
- Individuals who were, or currently are Principal Investigator of NIH R01, R29, P01, K01, K08, K22 K23, K99/R00 grant **ARE NOT** eligible
- 2. As an emergency medicine physician, would I qualify for the 50% protected time commitment? No, this only applies to surgeons.
- 3. The award program starts soon but I am committed to 75% clinical work already, how is that going to work?
 - You must have a firm and convincing written commitment for release of 75% of your time from your Department Chair and Division Chief effective by the date of appointment. You would need to decrease your total clinical, teaching, and administrative commitments to 25% of total effort during the entire 3year award period.
- 4. I do not have my faculty appointment yet, is it required?
 - A faculty appointment is required. All candidates must have a full time Georgetown, Howard, or MedStar faculty appointment at the time of award activation.
- **5. Ischerna/citisenship requirement2** nationals, or an individual lawfully admitted for permanent residence who possesses an Alien Registration Receipt Card (I-151 or I-551), or some other verification of legal admission as a permanent resident prior to appointment, are eligible to become K12 scholars. Non-citizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.
- 6. If a portion of KL2 salary is provided by a department, does this mean that the percent effort devoted to KL2 activities may be reduced?
 - No. At least seventy-five percent effort of a full-time position must continue to be dedicated to the KL2 activity regardless of the source(s) of salary funding. The fact that a department may fund a portion of the scholar's salary can in no case require the scholar to redirect effort toward Departmental priorities outside of those directed to the research and career development activities of the KL2.

7. Can a candidate who has submitted K23 application but has not received a score or has been informed that he or she has an unfundable score apply for the KL2 program?

Yes, but only IF the submitted NIH K23 application (or equivalent) is either not yet under review or has been withdrawn (in writing). However, it is not possible to have 2 K applications (e.g. KL2 and K23) under review simultaneously. If you have further questions, please consult with **Program Leadership**: Jason G. Umans, MD, PhD: jgu@georgetown.edu; Charles D. Howell, MD: charles.howard@howard.edu, or Kathryn Sandberg, PhD: sandberg@georgetown.edu

PRE-APPLICATION

- 8. When is the Pre-application due?
 - November 29, 2018
- 9. Will the committee provide feedback on the pre-applications
 - Yes. Applicants will receive feedback within 4 weeks after the deadline.
- 10. Are the letters of support from mentors and chair required at the time of pre-application or final application?
 - You need letters from the chair (or equivalent) and from primary mentor at time of pre-application. These can be updated in the final application.
- 11. Is there a page limit for the pre-application?
 - Below are guidelines for the Pre-Application:
 - ○NIH Biosketch –5 pages(New Format)
 - oPersonal Statement 500 words
 - oProject abstract OR Specific Aims page 500 words
 - \circ Specific disciplines or areas of expertise required among prospective reviewers 200 words
 - oLetters of support 6 pages
- 12. I see that the Pre-Application is due on November 29, 2018; can I submit it before the deadline to get feedback from the executive committee?
 - Absolutely! We would prefer that you do that. That's the deadline, but the earlier you contact us, the better so that you can modify your planned application and ensure it is responsive to the RFA.
- 13. When will I receive feedback and information about proceeding to Final Application?
 - You will receive feedback 4 weeks after the Pre-application deadline.
- 14. How will I know if I have been invited to submit a final application?
 - You will receive notification via email.

FINAL APPLICATION

15. When is the final application due?

• January 24, 2019

16. Is it requirement to meet with a Biostatistician prior to submitting my final application?

• Yes. Applicants that are invited to final application are required to meet with a GHUCCTS Biostatistician to discuss study design, sample size calculations and power analysis.

17. Where do I send the completed/Final application?

• Email complete application in **PDF file format** to Ms. Cyndi Campbell: narcissc@georgetown.edu

18. What is the review criteria?

- Standard NIH review criteria will be applied to include:
 - Demonstrated commitment to clinical and translational research and potential for a productive and independent research career with independent funding following KL2 support
 - Quality of the application (impact), likelihood of research productivity during KL2 support, and likelihood of transition to independent funding
 - Creativity and innovation of the proposed inter-/multi-/trans-disciplinary research project(s)
 - Feasibility of the major project proposed
 - Qualifications of the mentors and their commitment to inter-/multi-disciplinary research
 - Individual appropriateness and rigor of the educational/career development plan
 - Long term commitment to inter-/multi-disciplinary research and team science

The reviewers will use the NIH 9-point rating system for the impact priority score of 1 (exceptional) to 9 (poor).

- o Assigned reviewers will provide ratings for each of the review criteria described above using the 9-point scale.
 - 1 to 3 = high impact
 - 4 to 6 = moderate impact
 - 7 to 9 = low impact
 - An overall score will be assigned to each application in the range of 1-9.
- Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10-90).

19. Who reviews the applications?

• Applications are reviewed and assigned to at least 2 individual scientific reviewers with relevant expertise, a statistician, and then discussed by the executive leadership

20. If my application is unsuccessful, will I received summary sheets with reviewers' comments?

• Yes. You will have the opportunity to meet with the KL2 Executive Committee to discuss feedback on your application and assistance they can offer as you consider your next steps.

MENTORS

21. What are the eligibility requirements of the mentors?

Mentors must interact closely with the scholar, and should have research expertise and experience relevant to the proposed career development program. Mentors must be committed to continue their involvement throughout the total period of the scholar's career development under this award. Each Scholar candidate appointed in the program award must have a primary mentor, preferably from a GHUCCTS institution, who: (1) has a track record of successful and sustained federal (i.e., NIH, AHRQ, CDC, FDA, DOD, HRSA or VA) research funding, (2) has the research resources (including funding, facilities, space, collaborations, access to key populations, technologies, and reagents) to ensure productivity, and 3) has a track record of successful mentorship of trainees who have gone on to productive independent academic careers. The mentor must be committed to continue this involvement throughout the candidate's total period of development under the award. Secondary or joint mentors should be similarly committed to the scholar's career development, but provide complementary perspectives, guidance, and support. For example, joint mentors should be expert in demonstrably-differing disciplines or specialties than the primary mentor or focus their research in differing parts of the clinical-translational research continuum (T1-T-4). The applicant and mentors must explain the rationale for selection of the mentoring team and how it will function to guide the applicant to independent funding, translational research productivity, and successful academic career development.

22. Do I need to include a Biosketch for each of my mentors?

• Yes; it must be in the new format (including an appropriate narrative section)

23. Will there be funding provided to potential mentors?

No.

24. Do ALL mentors need to be from a GHUCCTS institution?

No, but must meet mentor qualifications and at least one member of mentorship team should be from a GHUCCTS institution. See KL2 Scholars Page for details: http://www.georgetownhowardctsa.org/education/kl2-scholar-program

25. Is it required to have mentors from both Georgetown and Howard universities?

- No. It is not required but it is viewed favorably. The focus, as it relate to mentor(s) is on their qualifications (funding, productivity, training record, etc.). We encourage you to look across all of the GHUCCTS institutions to identify potential mentors.
- You may also select qualified co-mentors from the NIH, FDA and non-academic institutions.

26. Could the lead mentor or co-mentor also be the department chair or division chief?

Yes. But each should have a record of funded research and successful mentoring. As well, application would have to explain how mentorship role would be distinct from supervisory role. See KL2 Scholars Page for details: http://www.georgetownhowardctsa.org/education/kl2-scholar-program

27. How do I select a mentor?

- Scholars are responsible for recruiting their own mentors. Scholars should have one primary mentor as well as two or three other mentors on their mentoring team. The KL2 program directors are available to assist with this process.
- Your mentor should be committed to helping you attain research and career development goals. For research this may include direct support of research studies, assistance in experimental design, and analysis/interpretation of research results, preparation for formal presentations, manuscripts, and grant applications. For career development this may include notifying you of scholarships/awards/programs that may be of benefit to your career development, helping you network and build professional connections in your field of study, assistance with promotion and tenure, providing support and advice for long-term goal setting.

DIDACTIC TRAINING

28. What if you already have a MPH? Is a Master's in Clinical and Translational Research be required?

• No. Your educational plans do not require any degree or certificate programs or that you take any specific coursework. You and your mentors should design a highly-individualized program, driven by your own Individual Development Plan, that will enable you to develop the skills and insights needed for your own research AND equip you with the additional competencies and skills in Clinical and Translational Research that that have been identified by NCATS as crucial to your training as a translational scientist.

29. What is the duration of the Graduate Program in Clinical and Translational Research?

Approximately 2 years (33 credit hours over 6 consecutive semesters including summers allowing for continued full time work) for the Master's degree and 1 ½ years (16 credit hours over 4 consecutive semesters including one summer allowing for continued full time work) for the Graduate Certificate. We recommend that you contact the Administrative Director for the option that best suit your needs – education@ghuccts.org

30. What is the curriculum of the Master of Science in Clinical and Translational Research (MS-CTR?

• The Master's degree core curriculum consists of 33 credit hours of training in clinical and translational research including biostatistics, ethics, design of clinical trials, epidemiology, etc. It will assure that students have attained the core skills that constitute training in clinical and translational science. Students also choose electives based on their research background and interests. A capstone project is required, but could be derived from the trainee's ongoing KL2 research. The Certificate program consists of 16 credits, including the core courses of the MS-CTR.

31. Will I have to do anything else in the KL2 program during my period of support?

Yes. All KL2 scholars attend regularly scheduled GHUCCTS Grand Rounds, as well as workshops and
conferences focused on (K and T scholar) research in progress, project and grant development, and NIHrequired sessions focused on the Responsible Conduct of Research and on Rigor and Reproducibility. As
well, all scholars are expected to attend and present at the Translational Science annual meetings, usually
held in Washington, DC during the month of April.

CONCURRENT FUNDING

32. Can a KL2 scholar accept a small grant award?

• Yes. KL2 scholars may be named PIs on a competing NIH research grant application (R01, R03, R15, R21, R34, or equivalent application from another federal agency) or a sub-project director on a competing multi-component research or center grant or cooperative agreement application (P01, P50, U01, etc. or an equivalent application from another federal agency). However, the effort requirement of the KL2 award applies. In addition, each KL2 scholar who plans to apply for an NIH K award must assure they remain eligible. Becoming a PI on a R01 would disqualify an applicant from a KL2 or other K award.

33. Can candidates applying for a GHUCCTS KL2 appointment also apply for additional mentored K awards (i.e., K08 or K23)?

• Appointed KL2 scholars (those awarded KL2 funding) may subsequently apply for K08, K01, or K23 support. If they are successful, they then move from one mechanism to the other. In conversations with NCRR program officials they have made it clear that the goal is to have KL2 awardees "graduate" as quickly as possible to individual NIH funding. Typically this would be an NIH career development award in the K series. In many instances, including from our own GHUCCTS program, KL2 awardees have transitioned to R01 or equivalent NIH support directly.

GENERAL INFORMATION

34. What is the program start date?

• Anticipated start date is **April 2019**

35. Is there a designated statistician to help with my KL2 application?

• <u>Dr. Nawar Shara</u>, (MHRI) or <u>Dr. John Kwagyan</u> (HU) will direct you to the appropriate resources. You May also visit the program page for more information: <u>Design, Biostatistics, and Populations Studies</u>

36. Are there additional resources available through the GHUCCTS to assist with my KL2 project?

- Yes. Available resources range from population and behavioral science services such as community outreach and recruitment services to molecular and cellular resources.
- Biostatisticians: https://goo.gl/y1eqyz
- Bioinformatics: https://goo.gl/hh8Sbn
- Clinical Research Unit: https://goo.gl/6g3jPp
- Core Laboratories/Shared Resources: https://goo.gl/yFMzrj
- Community Recruitment: https://goo.gl/qR9qnp

37. How many years of support does the program provided?

• The KL2 program provides up to three years of support, with two years provided by the grant and one by the sponsoring department or institution. Each year of funding is, however, contingent upon satisfactory progress, active participation in program activities, and submission of required progress reports. Every KL2 scholar is expected to be working toward submission of a meritorious and fundable individual NIH/AHRQ or equivalent individual career development award (e.g. K23, K08) in either the 1st or 2nd year of this three-year period. Alternatively, the exceptionally well-prepared KL2 scholar should plan to apply directly for R type funding by the end of the second year of KL2 support without additional career development funding.

38. How many awards are there this year?

• We anticipate appointing one scholar in April 2019

39. May I apply for 100% of salary support from the KL2 Program?

• No. The GHUCCTS KL2 will support at most 75% effort (up to \$90,000).

40. If I have a funded GHUCCTS KL2 award, would it beneficial or detrimental to apply for another K award?

• You would be advised to use the protected time, support, and mentorship provided by the KL2, in order to prepare a highly meritorious NIH/AHRQ or comparable competitive peer reviewed application, typically for an individual research career development award (e.g., K01, K08, K23) at the earliest feasible point so as to extend the period of career development support from 3 to 5 years.

41. What is the total number of years for K awards combined?

Typically, not more than 5 years. Therefore, if two years of KL2 funding is received, a subsequent
individual NIH K award would typically be for an additional three years. In exceptional instances, a longer
period of total funding may be available.

42. If I am a mid-career person and I want to move into a different area, is this the appropriate mechanism for me to do that?

• The KL2 is designed to be an internally awarded mentored career development award that parallels the NIH K series career development awards. Therefore, it is not appropriate for mid-career faculty who have already benefitted from a period of mentored research training. You may, however, wish to consider the GHUCCTS pilot awards to determine if that source of funding could assist in changing the direction of your research. Please feel free to contact the program leadership for more details: : Jason G. Umans, MD, PhD: jgu@georgetown.edu; Charles D. Howell, MD: charles.howell@howard.edu; or Kathryn Sandberg, PhD: sandberg@georgetown.edu

43. Do you have to provide evidence of productivity in the field in which you are writing your K award?

• It will significantly strengthen your application, but this is not a requirement.

44. Is the KL2 award transferrable?

No, KL2 awards are linked to the funding institution.

45. Does the KL2 program fund projects that focus on health disparities research?

Yes. GHUCCTS recognizes our special responsibility for leading research and training that addresses
disparities in health and health care of the underserved populations that characterize the region served by
our institutions, prominently including people from diverse racial, ethnic, and cultural backgrounds, older
adults and people with disabilities.

46. When will I receive notification of the award?

Anticipated award notification is April 2019

47. If I am granted the KL2 award, will there be any other required documents to complete my application?

- Yes, there are Post-Award documents that must be completed/submitted within 30 days of the award:
 - KL2 Enrollment Contract
 - NCATS HSE documentation
 - Items 1-4 are only required if applicable. No expenditures related to human subjects or animals will be permitted until the GHUCCTS is provided with a copy of the official IRB/IACUC letter of approval. Investigators are encouraged to submit IRB and/or IACUC protocols early in order to avoid significant delays in project initiation.
 - 1. IRB/IACUC Approval Memo
 - 2. IRB/IACUC Application
 - 3. Consent and/or Assent Forms Human subject studies only. Stamped approved forms are required for study Initiation and relevant funds release.
 - 4. Animal Subjects Research

48. Can I reapply to the program if I did not get in the first time?

• Yes, of course you may reapply to the program. However, reapplying does not guarantee admittance.

49. If I accept a position at another institution, may I transfer my KL2 award there?

• No, the KL2 is an institutional career development award granted to the Georgetown-Howard Universities Center for Clinical and Translational Science. Awards are non-transferrable. Scholars who leave Georgetown-Howard Universities Center for Clinical and Translational Science will have their award terminated and will not be able to continue to receive funding from the KL2 Scholars Program.

50. Whom can we contact for additional questions or information?

Scientific & Research Contacts:

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Administrative Contact

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