THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Request for Applications: KL2 Mentored Career Development Grant

Release Date: September 4, 2018

Letter of Intent EXTENDED: October 29, 2018 at: http://go.osu.edu/KL2LOI
Application Deadline: January 9, 2019 at http://go.osu.edu/KL2Application
Start Date: June 1, 2019

The OSU Center for Clinical & Translational Science (CCTS) KL2 Program supports the career development of investigators who have made a commitment to conduct either patient-oriented or translational research. The KL2 Award is available for a period of three years (contingent on satisfactory progress), with two years of CCTS funding and a third from the scholar's home college.

Junior faculty Ohio State University or Nationwide Children's Hospital on the tenure-track or clinical track with fewer than three years since their initial appointment are eligible to apply.

The award is designed to benefit a wide spectrum of clinical or translational researchers across OSU. The award provides salary support to ensure protected time for mentored research and didactic training in clinical/ translational research across a wide variety of project topics and academic areas. The overall goal of the program is to equip early career investigators to advance from mentored to independent researchers funded by an NIH RO1 award, K award, or equivalent.

KL2 Scholars will be selected based on a competitive application process in which the following will be key review considerations that determine funding:

- The transdisciplinary/translational science of the research project
- The experience of the mentorship team
- The quality of the training plan

A Study Section will make recommendations to the CCTS Executive Committee for funding **up to two KL2 scholars**. All applicants will receive reviewer comments on their applications.

Please note the following requirements:

- To be considered, all applicants must submit the required Letter of Intent form by 11:59 PM on the date noted above using the online form indicated above.
- Applicants must complete all sections of the entire application. Applications are due by 11:59 PM on the date noted above using the online form indicated above
- No late LOI or applications will be accepted.

Please direct all questions to the Program Manager, Stuart Hobbs at 614-685-5972 or stuart.hobbs@osumc.edu

Benefits of the KL2 Award

- 75% salary support and appropriate fringe benefits. (50% for surgeons) (of a salary cap of $120,000).
- Project support up to $15,000 per year.
- Access to the CCTS professional services and staff including assistance in the areas of biostatistics, subject recruitment, and human subject's research.
- Access to a training curriculum in clinical and translational research methodology and specialized training seminars.
- Individualized career development and mentorship from the trainee's own appointed scientific committee and the KL2 directors.
- Support to develop an R grant or individual K award to fund research at the conclusion of the KL2 funding.

Expectations of KL2 Awardees

- Commit 75% of your effort to this KL2 Scholar Award (50% for surgeons).
- Commit to attending the following CCTS organized KL2 Training programs:
  - ✓ An orientation to the KL2 program and CCTS.
  - ✓ Monthly K Lunch & Learn that cover a variety of topics on clinical and translational science and research (currently on the second Tuesday of each month)
  - ✓ The Business of Science – a three day training program in leadership and project management in science.
  - ✓ Training in Research in Academic Health Center Systems or Public Health Systems
  - ✓ The Annual meeting of the Association of Clinical and Translational Science (typically held in April in Washington, DC).
  - ✓ Consultation privileges with the CCTS Translational Therapeutics Think Tank.
  - ✓ Grant writing training in the Autumn or Winter of Year 2.
  - ✓ Lead Mentor will attend CCTS mentor training, if he or she has not already done so.
  - ✓ Completion of the Innovation, Entrepreneurship and Commercialization certificate program.
  - ✓ Individualized coaching to enhance verbal communication skills
- Individual development plan will be developed in collaboration with KL2 leadership and project mentoring teams, and monitored quarterly (see Appendix 1).
- Progress reports will be required twice yearly on research progress and individual development plan progress.
- Annual written report and an oral presentation to either the CCTS Program Director or Executive Committees.

Other Requirements:

- Applicants and mentors must become CCTS members by completing a CCTS membership form. https://ccts.osu.edu/form/become-a-member
- Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest.
- Any clinical trial supported by this grant will have an NCATS approved DSM plan or DSM Board, as appropriate, and the researcher will comply with that plan.
- Clinical trials beyond the end of Phase IIA cannot be supported by this grant.
- The CCTS is funded through a CTSA grant from NIH's National Center for Advancing Translational Science (NCATS). NCATS requires that they review and approve all OSU CCTS KL2 studies involving human subjects research prior to funds being released. If your application is funded and involves human subjects research, the CCTS will require additional documentation to send to NCATS. NCATS generally completes their review in 30 days or less.
- If this award provides support for one or more clinical trials, by law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website.
- No KL2 scholar or mentor will be permitted to work on any project involving live vertebrate animals or human subjects

that has not been approved by the IACUC and/or IRB, as appropriate. If any scholar undertakes a project which includes human subject research studies, these must conform to the NIH policies on the inclusion of women, minorities, and children in study populations. Funds for non-compliant projects will be withheld.

- No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects by any site engaged in such research for any period not covered by both an OHRP-approved Assurance and an IRB approval consistent with 45 CFR Part 46. See " Human Subjects Protections" Part II, Chapter 4 (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf) for specific requirements and grantee responsibilities related to the protection of human subjects.
- All scholars appointed to this award who are involved with human subjects must have completed education on the protection of human subjects and Good Clinical Practice (GCP) in accordance with NIH policy.
- Any individual involved in the design and conduct of a study not included in any certification must satisfy this requirement prior to participating in the project.
- All foreign activities must be cleared through the NIH foreign component tracking system.
- The Statement of Appointment form (PHS 2271) will be submitted for the awardee by CCTS staff each year at the time of appointment through xTrain, and the awardee will comply with any requests for action or information related to xTrain appointment in a timely manner.

KL2 Eligibility

The KL2 grant is for junior faculty at Ohio State University or Nationwide Children's Hospital on the tenure-track or clinical-track with three years or fewer since their initial appointment at the time of application.

The CCTS follows eligibility criteria for KL2 appointments as established by the National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS), funding opportunity Clinical and Translational Science Award U54. See Part 2. Section III. 3 at https://grants.nih.gov/grants/guide/pa-files/PAR-15-304.html

- Candidates must be U.S. citizens or non-citizen nationals, or an individual lawfully admitted for permanent residence who possesses a permanent resident card (a Green Card), or some other verification of legal admission as a permanent resident prior to appointment.
- Candidates must have a research or health-professional doctoral degree or its equivalent (e.g., PhD, DDS, DVM, OD, MD, DO, or PharmD).
- Candidates must have a full-time faculty appointment at the applicant institution.
- At the time of their appointments, scholars must not have pending an application for any other PHS mentored career development award (e.g. K07, K08, K22, K23) or equivalent non-PHS peer reviewed grant that duplicates any of the provisions of the K component.
- 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 are NOT eligible to participate as scholars.
- Project leaders on sub-projects of program project (P01) or center grants (P50) are NOT eligible to participate as scholars.
- Appointed scholars are encouraged to apply for individual mentored K awards (e.g. K07, K08, K22, K23) and independent awards (R01, R03, R21) or equivalent non-PHS grants; if successful, the KL2 appointment would be terminated and funding received from the new individual K, R, or non-PHS award.
- Scholars to be supported by the institutional career development program must be at the career level for which the planned program is intended. In keeping with the type of mentoring and career development being provided by the CTSA, 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.

In addition:

- Applicants must be considered a Principal Investigator by the OSU Office of Research. Eligibility information can be found at the Ohio State Office of Research website: http://research.osu.edu/researchers/policies/pistatus/
- Your College Dean or Department or Division Chair (whoever is authorized to make these commitments) must agree to the release time and salary support requirements of the KL2 by signing the page below.

KL2 Letter of Intent

To be eligible, it is required that you indicate your intention to apply via the KL2 Letter of Intent form which can be accessed at the link on page 1 of this document.

All Letters of Intent must be submitted through the online process by 11:59 PM EST on the date listed at the top of this RFA. **No late Letters of Intent will be accepted.**

The LOI form requires you to:

- Submit a project title and Abstract (250 words)
- Attach your NIH Biosketch
- Complete an eligibility checklist will clearly tell you if you are eligible to go on to apply for the KL2. You should review carefully the eligibility criteria above before applying

The LOI will be used to

1. Assess your eligibility for the KL2 award,
2. Let program staff know of your intent to apply for the KL2 Award in order that they may organize the Study Section.

You will be notified by November 5, 2018, if you should or should not proceed with the application.

If you have questions or concerns, **please contact the Program Manager, Stuart Hobbs at 614-685-5972 or stuart.hobbs@osumc.edu**

KL2 Application Checklist

Applications and supporting materials are to be completed **by 11:59 p.m. EST on the date noted at the top of this RFA. No late applications will be accepted.**

Please read these instructions carefully before going online to apply. The application must be completed and submitted online at the web address noted on page 1 of this document. (The application process is designed so that you can save your information and return to it [you will be given a code, so be prepared to save that information]).

All documents asked for in the application must be submitted online in **PDF format** with the file named using the following guideline < last_first_KL2_Application_2018 >

The Application consists of several parts. You can use the following as a checklist to help you gather, enter, and complete the application.

- ☐ Personal Information
  (Includes Employee ID Number, OSU name.#, and ERA Commons username)
- ☐ Campus Address
- ☐ Current University Employment Information
- ☐ Race, ethnicity, and additional such reporting information asked for by the NIH
- ☐ Project Title and Abstract (250 words)
- ☐ Project Description – 10 page maximum (to be uploaded to the Application)
  - ☐ Personal Statement (1 page maximum)
    - ☐ Who are you? Why have you chosen a research career?
    - ☐ Your previous research experience?

- ☐ How you believe this training program will change the trajectory of your career or enhance your movement towards your goals?
- ☐ Career Development Plan (2 pages maximum)
  - ☐ Your Five Year Goals
  - ☐ Role of your mentors
  - ☐ What are the gaps in your training this program will help fill?
  - ☐ How will you fill those gaps?
  - ☐ How will you meet the NIH requirements for training in responsible conduct of research
- ☐ Research Plan (7 pages maximum)
  - ☐ Specific Aims
  - ☐ Significance
  - ☐ Innovation
  - ☐ Approach
  - ☐ Preliminary/supportive data
- ☐ References to Scientific Literature (not included in page count. 3 pages maximum)
- ☐ IRB/IACUC: Human Subjects/Vertebrate Animals. If either one is applicable, include the regulatory approval letter. The on-line application form has a space to indicate applicability, regulatory status (pending/approved) and protocol number and approval date.

☐ NIH Formatted Biosketches (to be uploaded to the Application)
- ☐ Applicant
- ☐ Lead Mentor
- ☐ All other members of your Mentorship Team

☐ Letters of support from each member of your Mentorship Team

☐ Signature page (to be uploaded to the Application)
- ☐ Department Chair or Dean guaranteeing 75% (50% for surgeons) protected research time for the duration of the award and salary support
- ☐ Applicant

Project Description

This section cannot exceed **10** type-written, single-spaced pages. Please use Arial size 11 font. Margins should be no smaller than 0.5" on all sides.

Personal Statement (1 page)

A one-page personal statement addressing the following points:

- Who are you? Why have you chosen a research career?
- Your previous research experience?
- How you believe this training program will change the trajectory of your career or enhance your movement towards your goals

Career Development Plan (2 pages)

A two-page career development plan addressing the following points:

- Your five-year goals
- Where are the gaps in your training that this program will help fill
- How will you fill those gaps. Be as specific as possible (e.g., courses, workshops, individualized training from an expert)
- Roles of your mentors
- How you will meet the NIH requirements for instruction in the responsible conduct of research (see http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html for more information).See Appendix 2, below, for training options.

Research Plan (7 pages)

The three year research plan should include:

- Specific Aims and hypothesis of the project
- Significance of the problem and how the proposed project will improve scientific knowledge and/or change the field of study.
- Innovation – explain how the proposed project challenges current practice or creates a novel approach to the problem.
- Approach – Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project, noting in particular how it is clinical and/or translational. Discuss potential problems, alternative strategies, and include a list of milestones/benchmarks for success anticipated to achieve the aims. For materials and methods, highlight powerful non-routine approaches, summarize routine approaches, and address statistical approach. Note: no clinical trials beyond the end of Phase IIA can be funded.
- Preliminary/supportive data that help demonstrate feasibility.

References to Scientific Literature (3 pages maximum) This section is not included in the 10-page limit but should not exceed 3 pages.

Scientific Mentorship Team

Your Scientific Mentorship Team must consist of at least three members. Your team must include among its membership a Lead Mentor and two other mentors (additional mentors are optional).

Lead Mentor

It is expected that the applicant will identify a faculty member mentor in his or her area of clinical or translational research. Under guidance from your mentor, you will prepare a proposal that describes the clinical research project to be undertaken. Your mentor (or each co-mentor) is responsible for:

- Providing career development and counseling;
- Guiding and encouraging the design and execution of an original, high quality, clinical research project;
- Collaborating with the mentorship team to support the KL2 Scholar.
- Attending CCTS sponsored events including a mentor training program and an on-boarding session, as well as other meetings with program leaders and administrators as needed.

The letter of support from your lead mentor should acknowledge his or her understanding of these requirements, and describe their mentoring plan for your development. The letter should also describe the Mentors experience with mentoring, including number of mentees.

At least TWO Additional members of the mentorship team

The Mentorship Team provides additional expertise in the scientific area of research chosen for the project, complementary to the interests of the lead mentor. It is highly desirable that the other members of your Mentorship Team be drawn from another discipline so that they can provide transdisciplinary input into your project. Your mentorship team members may also include a University faculty member who is not a regular member of the graduate faculty (e.g., an adjunct professor), a University staff member, or a qualified individual outside the University who can provide expertise in your discipline.

NIH Biosketches

You must upload (as PDFs) NIH formatted biosketches of yourself, your lead mentor, and everyone else on your Mentor Team.

Biosketch forms and instructions can be found here: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html

Letters of Support

Letters of support are required from: your Lead Mentor and each member of your mentorship team.

The letters should be addressed to:

Cynthia Carnes, PharmD, PhD
Mark Wewers, MD
The Ohio State University
338 West Tenth Avenue
Columbus, OH 43210-1280

Include these letters in your application packet.

Further Information

Please direct questions to the education programs manager, Stuart.Hobbs@osumc.edu (614-685-5972).

The Co-Directors for the CCTS KL2 program are Cynthia Carnes, PharmD, PhD, and Mark Wewers, MD.

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Signatures: Protected Time and Salary Coverage

This individual is qualified for this program and will receive immediate priority for clinic coverage (if applicable), all requirements for protected time and all financial needs according to the RFA, and specifically:

1. I agree to grant this individual the required 75% (50% for surgeons) protected time beginning June 1, 2019, and continuing for up to two years (i.e. May 31, 2021)

2. I agree that the department and/or college will provide the amount of salary and benefits not covered by this award beginning with the award date, and continuing for up to two years. The award covers 75% of salary and related benefits up to a salary cap of $120,000 (i.e. 75% of $120,000 = $90,000).

3. I agree that the department and/or college will provide 50% protected time for research and training activities and cover 100% of the individual's salary and benefits during the third year of this award, along with research funding (up to $15,000), if the individual is awarded a KL2 grant and makes satisfactory progress to the third year of funding.

_____ _____
Signature Date

Printed name & title: _____

Note: The above should be signed by your College Dean or your Department or Division chair: whoever is the appropriate person to make these commitments.

Signature Page: Applicant

I certify that the statements herein are true and complete to the best of my knowledge and that I will comply with all applicable CCTS terms and conditions governing my potential appointment. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

_____ _____
Applicant's signature Date

Appendix 1: The Structured Individualized Development Plan Described

Each new KL2 scholar will complete a baseline survey to inform the development of an individual training plan. Information will be gathered to identify each scholar's needs for training and to identify alignment with available training resources. This survey will be evaluated by the co-Directors in concert with the mentoring plan submitted as part of the KL2 proposal. An individual development plan (IDP) will be developed via a collaborative process between the co-Directors, the trainee, and the lead scientific mentor. The IDP plan will outline training, coursework, conference and workshop plans as well as individualized training; this will be planned in quarterly blocks for the duration of the KL2. The mentee is responsible for scheduling mentoring activities through the Administrative Program Director; every six months, the lead mentor and KL2 co-Directors will monitor progress and provide feedback on progress to each KL2 scholar.

This process is outlined below so that it might inform the development of the career development plan included in the application.

Baseline Individual Development Plan Process: Guiding Questions

Short- and long-term research goals
Statistical and Biomedical Informatics consultation needs?
Resources needed? This may include mentoring, collaboration, etc.
What additional research skills are to be developed during the KL2? How will this be done? Timeline for completion? Includes review of mentoring plan submitted with KL2 application
Career Development Goals: topics to discuss
Entrepreneurial training goals?
Communications skills development: needs assessment
Community Outreach: interests and goals?

Sample Individual Development Plan

Required Elements	Target Completion Date	Completion Date
Workshops/Classes		
Rigor and Reproducibility in science training		
Business of Science	Held biennially in October	
Launch to Success Workshop (grantsmanship)	Winter Semester of 2nd Year	
Verbal Communications skills training		
STEAM Factory public presentation		
Community engagement activity		
Innovation, Entrepreneurship and Commercialization Certificate. (Program in development.)		
Research ethics training (may choose which venue best meets needs). (See Appendix 2)		
Implicit Bias Training		
Attendance & Presentation at ACTS meeting (at least once)	Annually, ~ 3rd week of April	
Attendance at national meeting in field (when not at ACTS)	Annual	
Support for Research Study		
Statistical Consultation		
Research data management consultation		

T4 presentation T4 is held the 2nd Wednesday of the month from 2 to 3 PM in CCTS rm 240. Contact Annie Adrian at adrian.33@osu.edu to schedule your time with T4		
Selective:		
IRB and/or IACUC meeting attendance		
CCTS Tools of the Trade programs: must attend one per year		
Lunch and Learn Programs: must attend 8 per year	Held monthly	
Comparative & Translational Medicine training	Course offered during 2019-2020 academic year	
Mentor Development Program		
Individualized training options		
May include courses, workshops or other trainings		
Optional Training 1		
Optional Training 2		
Optional Training 3		

Etc.

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Appendix 2: Options for Fulfilling Requirements in Responsible Conduct of Research

Courses:

Pharmacy 8520 - Research Ethics

Basic concepts of integrity in the process of research. The course covers all areas of responsible conduct of research including mentor/trainee roles, data management, animal use, human subjects. Often offered May term. The course fulfills NIH requirement for research ethics. Repeatable to a maximum of 20 cr hrs. This course is progress graded (S/U)

Vision Science 7960 - Ethics in Biomedical Research

Provides a general understanding of the issues surrounding the ethical conduct of science including issues related to research involving human subjects, scientific misconduct, and authorship of scientific papers. Real-life case studies will be used. 2 units.

Nursing 7781: Responsible Conduct of Research

Concepts and policies for the responsible conduct of research (RCOR), Institutional Review Boards, and dissemination of findings. 3 credits Autumn/Spring. ONLINE.

MedColl 5000 - Responsible Conduct of Research & Research Ethics

Within research, ethics is considered to be the safeguard of both the researcher and the participant. This course will examine cases which hold to demonstrate this statement. It will analyze a complex system of policies and regulations that govern human subject research and scientific Integrity. This class also satisfies the basic components of Responsible Conduct of Research (RCR) education. 2 units.

Webcast from the NIH: Ethical and Regulatory Aspects of Clinical Research:

This is a live webcast that the CCTS hosts every Fall. The sessions are typically Wednesday mornings from mid-September to November. Participants watch the webcasts and take part in discussions. By attending 6 of 7 sessions and completing evaluations and pre- and post- tests, get certification.

More information: http://www.bioethics.nih.gov/courses/

Nationwide Children's Hospital offers a Responsible Conduct of Research Training Series during the summer. The course fulfills NIH requirements. For details contact Katie.Campbell@nationwidechildrens.org.

Other Courses offered at Ohio State

Biomedical Engineering 6983 - Research Ethics

Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues. Prereq: Grad standing, or permission of instructor. 2 units.

Comparative Studies 6750.02 - Fieldwork and Ethnography of Communication

Introduction to fieldwork and ethnographic writing in the humanities - interviewing, participant observation, and research ethics. Focus on the ethnography of communication and community representations. Prereq: Grad standing, or permission of instructor. 3 units

Surgery 8814 - Responsible Conduct of Research: Human Participants and the Use of Animals in Biomedical Research

Responsible conduct of research with human participants and the use of animals in biomedical research is crucial to maintaining the public trust in both the results and the methods of biomedical research. Repeatable to a maximum of 4 cr hrs. 2 units