

## KL2 Mentored Career Development Grant

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 department.

Junior faculty (assistant professors) 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.

### Benefits of the KL2 Award

- 75% salary support and appropriate fringe benefits. (50% for surgeons) (up to a salary cap of \$120,000).
- Project support up to \$25,000 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 Phases 1 and 2 of the Innovation, Entrepreneurship and Commercialization certificate program for at least one technology product market research concept.
- ✓ 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>.

The following chart will help you determine your eligibility.

Eligibility Questions	Eligible	Ineligible
Do you have a research or health-professional doctoral degree or its equivalent (e.g., PhD, DDS, DVM, OD, MD, DO, or PharmD)	Yes: Eligible	
Are you an assistant professor at Ohio State University or Nationwide Children's Hospital on the tenure-track or clinical track	Yes: Eligible	
Are you a Research Scientist at OSU or NCH?		Ineligible
<b>Citizenship Status (choose one)</b>		
I am a US Citizen	Yes: Eligible	
I am a permanent resident who possesses a permanent resident card (a Green Card).	Yes: Eligible	
I am a non-citizen national.	Yes: Eligible	
None of the Above		Ineligible
<b>Funding</b>		
Have you ever received an NIH career development award, such as K series awards K07, K08, K22, K23 or equivalent non-PHS award, from a foundation, for example?		Ineligible if yes
Are you applying at this time or do you have pending an application for any other NIH mentored career development award, such as a K07, K08, K22, K23, or a similar award from a non-PHS source, such as a foundation?		Ineligible if yes
Have you ever received an independent (i.e., non-mentored) NIH award as Principal Investigator, such as an RO1 award? (Do not consider NIH Small Grants [ R03 ])		Ineligible if yes
Have you ever received Exploratory/ Developmental [ R21 ] grants or their equivalents)		Ineligible
Have you ever been a project leader on a sub-project of a program project (P01) or center grant (P50)? (Do not consider a prior T32 or F32 appointment.)		Ineligible if yes
Have you ever been PI on a non-PHS peer-reviewed research grant or career development grant that was over \$100,000 direct costs per year?		Ineligible if yes
<b>Career Position</b>		
Have you held your current position for three (3) years or less?	Yes: Eligible	
Have you held your current position for four (4) years or more?		Ineligible

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/award-lifecycle/how-to-be-a-p-i/>
- Your Department or Division Chair or in some cases College Dean (whoever is authorized to make these commitments) must agree to the release time and salary support requirements of the KL2 by signing on the appropriate page contained in the RFA.

### 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 will be accessible through a link in the RFA and on the CCTS website.**

All Letters of Intent must be submitted through the online process by the due date listed of the 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 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](mailto: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 the RFA. No late applications will be accepted.**

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; see these instructions for complete details)
  - 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 mentor(s)
- 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 studies
- 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)
- 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 Findings 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.

**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**

<b>Short- and long-term research goals</b>
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
<b>Career Development Goals: topics to discuss</b>
Entrepreneurial training goals?
Communications skills development: needs assessment
Community Outreach: interests and goals?

**Sample Individual Development Plan**

<b>Required Elements</b>	<b>Target Completion Date</b>	<b>Completion Date</b>
<b>Workshops/Classes</b>		
Rigor and Reproducibility in science training		
Business of Science	Held biennially in October	
Launch to Success Workshop (grantsmanship)	Winter Semester of 2 <sup>nd</sup> 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, ~ 3 <sup>rd</sup> week of April	
Attendance at national meeting in field (when not at ACTS)	Annual	
<b>Support for Research Study</b>		
Statistical Consultation		
Research data management consultation		
T4 presentation T4 is held the 2 <sup>nd</sup> 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		
<b>Selective:</b>		
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		
Mentor Development Program		
<b>Individualized training options</b>		
<b>May include courses, workshops or other trainings</b>		
Optional Training 1		
Optional Training 2		
Optional Training 3		

Etc.

## 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](mailto: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

**Appendix 3: CCTS Career Development Awards Compared**

<b>Pre-K Davis Bremer</b>	<b>vs</b>	<b>KL2</b>
<ul style="list-style-type: none"> <li>• For early career physician-scientists/ investigators committed to a career in academic medicine; who have not previously been a PI on an NIH individual or institutional K, or R01 Award or received a pilot award from the CCTS.</li> <li>• Applicants must be physicians with OSU Wexner Medical Center credentials.</li> <li>• Provides salary and fringe support for up to a 10% FTE (capped at \$15,000) and approximately \$35,000 in research expense support for one year.</li> <li>• Aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards.</li> <li>• <b>WHO SHOULD APPLY?</b> If you picture yourself using the data from your project to apply for a K award in one year, apply for the Pre-K Davis Bremer.</li> </ul>		<ul style="list-style-type: none"> <li>• For junior faculty who have not yet been a PI on a major federal or private sector research grant or who have not previously received a K award.</li> <li>• For clinical and translational researchers with a research or health-professional doctoral degree.</li> <li>• Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support).</li> <li>• Support to develop an R grant to fund research at the conclusion of the KL2 funding.</li> <li>• <b>WHO SHOULD APPLY?</b> If you picture yourself using the data from the proposed project to apply for an R grant in two to three years, apply for the KL2.</li> </ul>

**Important note: You can apply for one or the other, but not both of these awards at the same time.**

**Complete RFAs will be found at the CCTS website:**