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 college.

Junior faculty 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 NIH RO1 grants or their equivalents.

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.

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

Note: The CCTS fund two career development programs for junior faculty: the Davis Bremer Pre-K and the KL2 Awards. See Appendix 2 of this document for a comparison of the two programs.
Benefits of the KL2 Award

- 75% salary support and appropriate fringe benefits. (50% for surgeons) (up to a salary cap of $120,000).
- Research expense 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.
- 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 the CCTS Executive Committee.

Other Requirements:

- Applicants and mentors must become CCTS members by completing a CCTS membership form. https://ccts.osu.edu/member/join
- 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.
- Requests for prior approval of planned research involving human subjects must be submitted in writing to NCATS no later than 30 days before the proposed implementation of research involving human subjects. Documentation must be submitted by an Authorized Organizational Official.
- 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 on the tenure-track with fewer than three years since their initial appointment.

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/pafiles/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/pisstatus/ Residents and clinical and postdoctoral fellows are not eligible.
- 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.
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 the day of deadline. 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.
3. Confirm the support of your Division/Department chair or college dean (as appropriate) for your application

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

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_2017]

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
☐ 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. 2 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

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**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).

**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** (2 pages maximum) This section is not included in the 10-page limit but should not exceed 2 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.

**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.

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.

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

<table>
<thead>
<tr>
<th>Short- and long-term research goals</th>
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<tr>
<td>Statistical and Biomedical Informatics consultation needs?</td>
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<td>Resources needed?</td>
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<td>This may include mentoring, collaboration, etc.</td>
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<td>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</td>
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<table>
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<tr>
<th>Career Development Goals: topics to discuss</th>
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<tr>
<td>Entrepreneurial training goals?</td>
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<tr>
<td>Communications skills development: needs assessment</td>
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<td>Community Outreach: interests and goals?</td>
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</table>
Sample Individual Development Plan

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<tr>
<th>Required Elements</th>
<th>Target Completion Date</th>
<th>Completion Date</th>
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<tr>
<td>Research data management consultation</td>
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<td>Rigor and Reproducibility in science training</td>
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<td>Statistical Consultation</td>
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<td>T4 presentation</td>
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<td>Launch to Success Workshop (grantsmanship)</td>
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<td>Verbal Communications skills training</td>
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<td>STEAM Factory public presentation</td>
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<td>Community engagement activity</td>
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<td>Innovation, Entrepreneurship and Commercialization Certificate</td>
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**Selectives:**

- Research ethics training
- IRB and/or IACUC meeting attendance
- Tools of the Trade programs: must attend one per year
- Lunch and Learn Programs: must attend 8 per year
- Mentor Development Program

**Individualized training options**

May include courses, workshops or other trainings

Appendix 2: CCTS Career Development Awards Compared

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<th>Pre-K Davis Bremer</th>
<th>vs</th>
<th>KL2</th>
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<tr>
<td>• 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.</td>
<td>• 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.</td>
<td>• For clinical and translational researchers with a research or health-professional doctoral degree.</td>
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<tr>
<td>• Applicants must be physicians with OSU Wexner Medical Center credentials.</td>
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<td>• Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support).</td>
</tr>
<tr>
<td>• 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.</td>
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<td>• Support to develop an R grant to fund research at the conclusion of the KL2 funding.</td>
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<tr>
<td>• Aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards.</td>
<td></td>
<td>• WHO SHOULD APPLY? 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.</td>
</tr>
<tr>
<td>• WHO SHOULD APPLY? 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.</td>
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Further Information

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

The Director for the CCTS Research Education, Training, and Career Development programs is Dr. Joanna Groden.