Request for Applications
KL2 Mentored Career Development Grant

Release Date: September 6, 2016
Letter of Intent Due: September 23, 2016
Application Deadline: November 1, 2016
Start Date: May 1, 2017

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. The start date for the KL2 award is May 1, 2017.

Preference will be given to junior faculty members with fewer than three years since their appointment, but junior faculty with three or more years since their appointment and research scientists with a research track record 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 research across a wide variety of project topics and academic areas.

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 three KL2 scholars. The awarded scholars will be notified in approximately January, 2017. The position will commence May 1, 2017. 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, September 23, 2016 (found online at: http://go.osu.edu/LOI2016KL2)
- Applicants must complete all sections of the entire application. Incomplete applications will not be accepted. The online application can be found here: http://go.osu.edu/2016KL2
- No late applications or letters will be accepted. Applications are due at 11:59 PM on November 1, 2016.

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 1 of this document for a comparison of the two programs.

KL2 Award Information Brown Bag
When: 09/14/16 Noon to 1 PM
Where: CCTS, Prior Hall, Ste. 260, room 236
Bring your lunch and learn about the KL2 programs
Topics include eligibility, benefits, and tips on writing a successful application.
To register:
https://redcap.bmi.osumc.edu/redcap/surveys/?s=Mltnd4Cuyn
Benefits of the KL2 Award

- 75% salary support and appropriate fringe benefits. (50% for surgeons).
- 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 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.
  ✓ The Annual meeting of the Association of Clinical and Translational Science (typically held in April in Washington, DC).
  ✓ At least one consultation with the CCTS Translational Therapeutics Think Tank.
  ✓ R 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.
- Brief progress reports will be required three times a year as well as a brief annual written report and an oral presentation to the CCTS Executive Committee.
- 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. (Note: Clinical trials beyond the end of Phase IIA cannot be supported by this grant).
- 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.
- 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.
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 appointment at the applicant institution.

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/ Residents and clinical and postdoctoral fellows are not eligible.

You are NOT eligible to participate as a KL2 scholar if you are a former or current principal investigator on any NIH research project grant grants or their equivalents. Exception: you are still eligible if you have had an NIH Small Grant (R03) or Exploratory/ Developmental (R21) grant.

You are NOT eligible if you are a former or current PI on any non-PHS peer-reviewed research or career development grants that are over $100,000 direct costs per year.

You are NOT eligible if you are a current or former project leader on sub-projects of program project (P01) or center grants (P50). A prior T32 or F32 appointment is acceptable.

Applicants for KL2 appointments may not simultaneously submit or have pending an application for any other PHS mentored career development award (e.g., K07, K08, K22, K23) that duplicates any of the provisions of the KL2 program.

The commitment form for the third year of funding must be signed by your college dean.

To be eligible, it is required that you indicate your intention to apply via the KL2 Letter of Intent form found here: http://go.osu.edu/LOI2016KL2

The purpose of the Letter of Intent is twofold:

1. To let program staff know of your intent to apply for the KL2 Award in order that they may organize the Study Section.
2. So applicants can fill-out the eligibility checklist to know that they are eligible.

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 process of completing the 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 found at the top of this page before applying.

Staff will use the information you submit about your project to organize the KL2 Study section. The information about your project that you submit in the Letter of Intent will not undergo scientific review. Do not expect further contact from project staff after submitting the Letter of Intent. If project staff do have questions or concerns they will contact you.

If you have questions or concerns, please contact the Program Manager, Stuart Hobbs at 614-685-5972 or stuart.hobbs@osumc.edu
Applications and supporting materials are to be completed by November 1, 2016 by 11:59 p.m. EST. Please read these instructions carefully before going online to apply. The application must be completed and submitted online at: http://go.osu.edu/2016KL2
(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_11-1-2016]

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
- NIH Formatted Biosketches (to be uploaded to the Application)
  - Applicant
  - Lead Mentor
  - All other members of your Mentorship Team
- Three letters of support from your:
  - Lead mentor
☐ Another member of your mentorship team
☐ Department Chair guaranteeing 75% (50% for surgeons) protected research time for the duration of the award

☐ Signature page (to be uploaded to the Application)
  ☐ Lead mentor
  ☐ Department Chair or Dean
  ☐ 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](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.

**IRB / IACUC** 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.
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:

- Guiding and encouraging the design and execution of an original, high quality, clinical research project;
- Supervising the preparation of a final report; and
- Providing career development and counseling

The lead mentor will be expected to attend CCTS sponsored events including a mentor training program and an on-boarding session.

**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**

Three letters of support are required, one each from: (1) your Lead Mentor, (2) one additional member of your mentorship team, and (3) your department chair, affirming protected research time.

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.
Signature: Lead Mentor

As the Lead Mentor, I take responsibility in:

- Providing career development and counseling;
- Guiding and encouraging the design and execution of an original, high quality, clinical research project;
- Supervising the preparation of a final report; and
- Collaborating with the mentorship team to support the KL2 Scholar.

I understand that myself or another member of the mentorship team will be required to attend CCTS sponsored events including a mentor training and on boarding session.

________________________________________________
Signature of Lead Mentor ____________________________ Date

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 May 1, 2017, and continuing for up to three years.

2. I agree that the department and/or college will cost share the amount of salary and benefits not covered by this award beginning May 1, 2017, and continuing for up to two years. The award covers 75% of salary and related benefits up to a salary cap of $185,100.

________________________________________________
Signature ________________________________________ Date

Printed name & title: __________________________________________________________

3. I agree that the department and/or college will cover 100% of the individual’s salary and benefits from May 1, 2019 to April 30, 2020, if the individual is awarded a KL2 grant and makes satisfactory progress to the third year of funding.

________________________________________________
Signature ________________________________________ Date

Printed name & title: __________________________________________________________
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: 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>
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<td>• Applicants must be physicians with OSU Wexner Medical Center credentials.</td>
<td>• For clinical and translational researchers with a research or health-professional doctoral degree.</td>
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<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>
<td>• Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support).</td>
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<td>• Aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards.</td>
<td>• Support to develop an R grant to fund research at the conclusion of the KL2 funding.</td>
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<tr>
<td>• <strong>WHO SHOULD APPLY?</strong> 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>
<td>• <strong>WHO SHOULD APPLY?</strong> 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>
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### Important note: You can apply for one or the other, but not both of these awards at the same time.

### Complete RFAs and instructions can be found at the CCTS website:

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<td><a href="https://ccts.osu.edu/funding-opportunities/current-ccts-grant-opportunities">https://ccts.osu.edu/funding-opportunities/current-ccts-grant-opportunities</a></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.