THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Overview Information

Funding Opportunity Title	**KL2 Mentored Career Development Grant**
Funding Opportunity Purpose	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/department. Junior faculty Ohio State University or Nationwide Children's Hospital on the tenure-track or clinical track who are in the fifth year or less of their initial appointment are eligible to apply. The Ohio State CCTS seeks proposals that address scientific questions consistent with the Center's mission at any "stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public" as described in NIH NCATS' Translational Science Spectrum. An RFA is released annually, typically in late August or early September.

Table of Contents

Section I. Funding Opportunity Description

Purpose

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 R01 award, individual 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 and quality of the research project
- The qualification of the applicant
- 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 in the RFA using the online form indicated.
- Applicants must complete all sections of the entire application. Applications are due by 11:59 PM on the date noted in the RFA using the online form indicated.
- No late LOI or applications will be accepted.
- Prior approval of all research subject to review by IRB or IACUC is required by National Institutes of Health National Center for Advancing Translational Science who funds the CCTS. Full applications identified by comprehensive review as meritorious for funding will be subject to NIH prior approval prior to release of funds. Documentation for this federal review will be collected from applicants and submitted after acceptance of the award if selected for funding. If the NIH/NCATS declines such approval, the CCTS will not be able to support the project. See Section V, below.

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

Note: The CCTS also sponsors the Path to K Award for junior faculty in OSU Health Science Colleges. See Appendix 3 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) (the 75% multiplier is applied up to a salary cap of $120,000).
- Research funds of up to $25,000 per year for three years from the CCTS.
- Biostatistics support for all three years of your KL2 free from charge up to a maximum of 40 hours per year from Center for Biostatics of the Department of Biomedical Informatics of the College of Medicine.
- 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 fourth 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).
  - ✓ Consultation privileges with the CCTS Translational Therapeutics Think Tank.
  - ✓ Grant writing training in the Spring Semester of Year 2.
  - ✓ Lead Mentor will attend CCTS mentor training, if he or she has not already done so.
  - ✓ Completion of the Innovation & Entrepreneurship workshop 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 twice yearly (see Appendix 1).
- Brief progress reports will be required three times per year.
- An Annual written report and an oral presentation to either the CCTS Program Director or Executive Committees is required.

Section II. Eligibility Information

Eligible Applicants

The KL2 grant is for junior faculty at Ohio State University or Nationwide Children's Hospital on the tenure-track or clinical-track with five 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

- Citizenship Status: Applicants must be citizens or non-citizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence and have in their possession an Alien Registration Receipt Card (I-151 or I-551) or other legal verification of admission for permanent residence. Non-citizen nationals are persons born in lands that are not States but are under U.S. sovereignty, jurisdiction, or administration (e.g., American Samoa). Individuals on temporary or student visas are not eligible for support, per NIH regulations.
- 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.
- Candidates must have been appointed to their current position after June 1, 2017.
- 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.

Other Eligibility Information

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.

Section III. Application and Submission Information

This grant program involves a two-phased application process: a Letter of Intent to Apply (LOI) and a Full Application.

This funding announcement will serve as the instructions and guidelines for both the LOI and the Full Application submissions.

Phase One: Letter of Intent

To be eligible, it is required that you indicate your intention to apply via the KL2 Letter of Intent

through an online REDCap form, which can be found at the text and hyperlinked web address.

All Letters of Intent must be submitted through the online process by 11:59 PM EST on the date listed at the top 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 within a short time 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**

Phase Two: Regulatory Consultation

Prior approval of all research subject to review by IRB or IACUC is required by National Institutes of Health National Center for Advancing Translational Science who funds the CCTS. Full applications identified by comprehensive review as meritorious for funding will be subject to NIH prior approval prior to release of funds (see Section V, below, for more information).

Documentation for this federal review will be collected from applicants and submitted after acceptance of the award if selected for funding. Because of the complexities of the Prior Approval process, all KL2 applicants must schedule a regulatory consult with the CCTS Regulatory Manager, Robert Rengel, to discuss what documentation might be required for their project. Contact him at Robert.rengal@osumc.edu or 614- 614-366-7367 to schedule an appointment.

Phase Three: Full Application

This funding announcement will serve as the instructions and guidelines for Full Application submissions

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

Please read the instructions carefully before going online to apply. The application must be completed and submitted online at the web address noted on the RFA. 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 < lastname_firstname_KL2_Application_2021 >

A consultation with a biostatistician for the impending proposal is strongly recommended. You can request a virtual consultation at https://medicine.osu.edu/departments/biostatistics/service-request-form.

Investigators are strongly encouraged to visit the CCTS website to search for and make use of other CCTS resources relevant to your project.

KL2 Application Checklist

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.#, ERA Commons username, ORCID number; see orcid.org)
- ☐ 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. No more than 3 pages preferred)
  - ☐ 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 (not submitted, pending, or approved) and protocol number and approval date.
- ☐ Human subjects research (up to 3 pages). If your project requires IRB approval, it is considered human subject research for purposes of this grant. Therefore, as required by federal regulations (45 CFR 46) and NIH policy, applications that propose to involve human subjects must address:
  - ☐ Risks to Human Subjects.
  - ☐ Adequacy of Protection Against Risks
  - ☐ Potential Benefits of the Proposed Research to Human Subjects and Others
  - ☐ Importance of the Knowledge to be Gained
  - ☐ 5. Data and Safety Monitoring Plan/Board. *If the proposed research includes a clinical trial, describe an appropriate Data and Safety Monitoring Plan*
- ☐ Live Vertebrate Animal research (up to 3 pages). If the proposed work involves live vertebrate animals, federal policy requires applicants to address the criteria noted below. This includes work involving animals obtained or euthanized for tissue harvest and generation of custom antibodies.
  - ☐ Description of Procedures (Vertebrate Animals Section)
  - ☐ Justifications (Vertebrate Animals Section)
  - ☐ Minimization of Pain and Distress (Vertebrate Animals Section)
  - ☐ Method of Euthanasia

- ☐ Authentication of Key Biological and/or Chemical Resources (up to 3 pages)
- ☐ 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

KL2 Application Components: Personal Statement

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

KL2 Application Components: Career Development Plan

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.

KL2 Application Components: Research Plan

This section can be up to 7 pages.

The three-year research plan should include:

- Specific Aims and hypothesis of the project
- Significance of the problem. State how the proposed project will improve scientific knowledge and/or change the field of study; what will be the (short- or long- term) impact of the research on human health; what will be the long-term impact of the proposed research on health inequities.
- 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 (Up to ~3 pages). This section is not included in the 10-page limit but please try not exceeding 3 pages.

KL2 Application Components: Human Subjects Research

Up to 3 pages. If your project requires IRB approval, it is considered human subject research for purposes of this grant. Therefore, as required by federal regulations (45 CFR 46) and NIH policy, applications that propose to involve human subjects must address:

Risks to Human Subjects.
Describe Human Subjects Involvement, Characteristics, and Design, Sources of Materials, and Potential Risk, including:

- description and justification for the proposed involvement of human subjects
- characteristics of subject population (number, age range, and health status)
- inclusion/exclusion criteria
- rationale for involvement of vulnerable populations (e.g. fetuses, pregnant women, children, prisoners, institutionalized individuals, or others)
- role of collaborating sites where research will be performed
- description and justification of research procedures (including dosage, frequency, etc. of intervention)
- description of what research material, data, and information will be collected
- access to personally identifiable information collected and retained
- management and protection of materials and information
- all potential risks to subjects (physical, psychological, financial, legal, or other) including likelihood and seriousness
- any alternative treatments or procedures

Adequacy of Protection Against Risks
Describe Recruitment and Informed Consent and Protections Against Risk, including:

- how subjects will be recruited
- description of informed consent, parental permission and assent
- waiver for any elements of consent
- how risks described previously, including privacy and confidentiality, will be minimized
- additional protections for vulnerable populations
- ensuring necessary medical/professional intervention for adverse events

Potential Benefits of the Proposed Research to Human Subjects and Others
Describe how potential risks to subjects appear reasonable in relation to anticipated benefits

Importance of the Knowledge to be Gained
Describe how potential risks to subjects appear reasonable in relation to the importance of the knowledge that may result from the study?

Data and Safety Monitoring Plan/Board
If the proposed research includes a clinical trial, describe an appropriate Data and Safety Monitoring Plan that includes:

- A description of a monitoring plan, who will be responsible for monitoring and the process by which Adverse Events (AEs) and Unanticipated Problems (UP) will be reported to all relevant regulatory bodies.
- A Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials

KL2 Application Components: Live Vertebrate Animal Research

Up to 3 pages. If the proposed work involves live vertebrate animals, federal policy requires applicants to address the criteria noted below. This includes work involving animals obtained or euthanized for tissue

harvest and generation of custom antibodies.

Description of Procedures (Vertebrate Animals Section)
Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

Justifications (Vertebrate Animals Section)
Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, *in vitro*).

Minimization of Pain and Distress (Vertebrate Animals Section)
Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.

Method of Euthanasia
State whether animals will be euthanized or not. If yes, state whether or not the method to be used is consistent with American Veterinary Medical Association (AVMA) guidelines. If not, provide a justification for methods of euthanasia that are not consistent with the AVMA Guidelines for the Euthanasia of Animals.

KL2 Application Components: Authentication of Key Biological and/or Chemical Resources

If applicable, the authentication plan should state how you will authenticate key resources, including the frequency, as needed for your research. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies -- Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Do not include authentication data in your plan.

KL2 Application Components: Scientific Mentorship Team

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

Lead Mentor
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.

Biostatistician. Your mentorship team must include one biostatistician.

At least One Additional member 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 member of your Mentorship Team be drawn from another discipline so that he or she 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.

KL2 Application Components: 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: https://grants.nih.gov/grants/forms/biosketch.htm

Letter(s) of Support

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

Include these letters in your application PDF.

The Letters should acknowledge awareness and support of the project and address the role and qualifications of the mentor for the project.

Address the letters to:

Cynthia Carnes, PharmD, PhD
Loren Wold, PhD
The Ohio State University
338 West Tenth Avenue
Columbus, OH 43210

Section IV. Application Review Information

Each application will be read by three reviewers. Applications will receive an Impact Score (NIH 1-9 scale). Individual components will also be scored 1-9.

The overall impact will reflect an evaluation of the trainee, the mentoring team, the training plan, and the proposed research. All are equally weighted and the study section will assess the overall fit of the components together.

Each application will also receive biostatistical review that will not be formally scored but will be reported to the study section. Rigorous biostatistics are an important part of scientific research.

Section V. NIH / NCATS Prior Approval

Prior approval of all research subject to review by IRB or IACUC is required by the National Institutes of Health National Center for Advancing Translational Science who funds the CCTS. Full applications identified by comprehensive review as meritorious for funding will be subject to NIH prior approval prior to release of funds.

Definitions:

Human Subjects Research: Any research that requires the submission of a Protocol to any Ohio State University or other Institutional Review Board is defined as human subjects research for the purposes NIH Prior Approval and of this RFA.

Vertebrate Animals Research: Any research that requires the submission of a Protocol to any Ohio State University or other Institutional Animal Care and Use Committee is defined as research involving vertebrate animals for the purposes of NIH Prior Approval this RFA.

Documentation for this federal review will be collected from applicants and submitted after acceptance of the award if selected for funding. Information provided in the human subjects research and/or vertebrate animals research sections will be used to put together prior approval documentation. Depending on your research, other information will be required. CCTS staff will reach out to applicants selected for funding as soon as a signed letter of offer is received to work with potential KL2 scholars to collect all of the necessary documentation. Once submitted to the NIH, the Prior Approval process takes months to complete. Therefore, the sooner the packet is submitted, the more likely it is that NIH approval will have been received by the announced start date of the KL2.

Because of the complexities of the Prior Approval process, all KL2 applicants must schedule a regulatory consult with the CCTS Regulatory Manager, Robert Rengel, to discuss what documentation might be required for their project. Contact him at Robert.rengal@osumc.edu or 614- 614-366-7367 to schedule an appointment.

A protocol approved by the appropriate review board (IRB, IACUC) is required before a Prior Approval submission to NCATS can be made. Therefore, the sooner your project has the appropriate regulatory approval at OSU, the sooner it can be submitted to NIH for Prior Approval. **Regulatory approval before submission of the KL2 application is highly recommended.**

If your project is subject to Prior Approval, part of the documentation required is that all study team members have obtained CITI training or equivalent training in human research protections as well as GCP training. If the project involves the use of animals, all study team members must obtain the relevant animal use training. Applicants should not delay in confirming that all research team members have completed and are up to date in their required training. Incomplete records will delay the submission of the Prior Approval application. See the Office of Responsible Research Practices website for study team training requirements. https://orrp.osu.edu/

If the NIH/NCATS declines Prior Approval, the CCTS will not be able to support the project.

Section VI. Integrating Special Populations

Applicants are encouraged to integrate special populations into their projects. The term “Special Populations” encompasses a multitude of groups and communities that are commonly underrepresented in clinical and translational research, and the CCTS is actively working to correct this problem. These groups include, but are not limited to, the following:

- Fetuses, neonates, and children
- Pregnant or nursing women
- Older adults
- Individuals with physical disabilities
- Individuals with communication or sensory impairments (hearing, vision)
- Racial, ethnic, or cultural minorities
- Non-English speaking individuals
- Underinsured or socioeconomically disadvantaged patients
- Gender or sexual minorities (LGBTQ+)
- Individuals with intellectual disabilities
- Isolated urban or rural communities

Socioeconomic or demographic factors may contribute to the systematic underrepresentation of special populations, regardless of whether these groups are explicitly targeted for research participation. Historical cases of research misconduct have also ingrained a deep-rooted mistrust of the medical establishment in certain communities. Investigators often encounter additional challenges when recruiting or retaining special populations for research, such as how to effectively obtain informed consent for individuals with intellectual disabilities or how to ensure success for a study requiring multiple clinic visits for individuals with limited physical mobility. All of these factors contribute to the underrepresentation in research of specific populations.

Therefore, though this is not a scored category, applicants are encouraged to design research projects that

address the needs of special populations; devise recruitment and retention plans that will optimize the participation of one or more special population; or pursue other strategies that integrate underrepresented groups into clinical and translational research.

Section VII. Award Administration Information

Award Notices

Meritorious applications will receive formal notice in the form of a Letter of Offer provided to the applicant. A completed and signed CCTS Award Acceptance Letter is required before the start date.

Award Requirements

- Applicants and mentors must become CCTS members by completing a CCTS membership form. https://ccts.osu.edu/form/become-a-member
- The NIH requires individuals supported by the KL2 to have ORCID IDs (Open Researcher and Contributor Identifiers) beginning in FY 2020. You may acquire your ORCID here: https://orcid.org/
- 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.
- 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.
- 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.
- This award is issued in accordance with, and is subject to, the conditions set forth in PAR-18-464 "Institutional Clinical and Translational Science Award (U54)," which are hereby incorporated by reference as special terms and conditions of this award. This RFA may be accessed at: < https://grants.nih.gov/grants/guide/pa-files/PAR-18-464.html >
- This award is issued in accordance with, and is subject to, the conditions set forth in the NIH grants policy statement as of the date of this letter and subsequent updates. By accepting an award, you agree to comply with the requirements in the NIH Grants Policy Statement except where the notice of award states otherwise. See: < https://grants.nih.gov/policy/nihgps/index.htm# >

Reporting

You will provide brief interim progress reports three times per year and an annual progress report at the end of the year in which you will report on the progress of meeting the project milestones you listed in your application. The annual report will also include a brief presentation about your experience as a KL2 scholar to the CCTS Executive Committee.

Trainees, Mentors, and KL2 Program Directors will meet every six months to review progress on the scholars Training Plan.

Citation Requirements: Awardees are required, by National Institutes of Health (NIH) grants policy to include a specific acknowledgment of grant support on all products (publications, patents, presentations, posters) resulting from this award. The specifics for this grant are: CTSA KL2 Award number **KL2TR002734.** See https://ccts.osu.edu/content/acknowledging-ccts for sample text.

Compliance with the NIH Public Access Policy: Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central, upon acceptance for publication, of an electronic version of a final peer-reviewed manuscript resulting from research supported in whole or

in part by the NIH. The staff of Prior Health Science Library can help investigators navigate the Public Access Policy processes.

Section VIII. Agency Contacts

Grant Management Contact

If you have any questions regarding this RFA, please contact:

Stuart D. Hobbs, PhD, MBA
Program Director
Research Education, Training, & Career Development
Center for Clinical & Translational Science
Ste. 260 Prior Hall, 376 W. 10th Avenue, Columbus, OH 43210
614-685-5972 Office
stuart.hobbs@osumc.edu ccts.osu.edu

CCTS KL2 Program Co-Directors

Cynthia Carnes, PharmD, PhD
KL 2 Program Director
Associate Dean for Graduate Studies and Research
College of Pharmacy
Carnes.4@osu.edu

Loren Wold, PhD, FAHA, FAPS
Assistant Dean for Biological Health Research, College of Nursing
Director of Strategic Projects, Office of the Chief Scientific Officer, Wexner Medical Center and Health Science Colleges
Professor, Depart of Physiology & Cell Biology
Wold.5@osu.edu

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 Fall.	
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 Workshop		
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		

on zoom. 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 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.

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. Dr. Cynthia Carnes, instructor. 1 credit

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. Often offered Fall Term. Dr. Karla Zadnik, instructor. 2 credits.

Nursing 7781 - Responsible Conduct of Research

Concepts and policies for the responsible conduct of research (RCOR), Institutional Review Boards, and dissemination of findings. Offered Online, Spring. Dr. Amy Mackos and Dr. Karen Williams, instructors. 3 credits

HTHRHSC 7883 - Responsible Conduct of Research

Seminar encompassing a variety of professional skills in Health and Rehabilitation Sciences Research including the process of writing, publishing, and reviewing journal manuscripts; human & animal subjects in research & responsible conduct. 1 credit.

BioPhrm 7510 – Professional & Ethical Issues in Biomedical Sciences

A discussion course based on case scenarios dealing with ethical issues facing biomedical researchers, such as publishing practices, confidentiality, mentoring. Typically offered in Spring Semester. Dr. Frederick Villamena, instructor. 2 credits.

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. Offered Autumn term. Dr. Alan Litsky, instructor. 2 credits.

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. Offered Spring semester. Dr. Tatiana Oberyszyn, instructor. 2 credits.

Other Training Programs

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

This is a live webcast that the CCTS hosts most autumns. 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, participants receive certification. More information: https://www.bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml
Contact Karen Carter of the CCTS at KarenK.Carter@osumc.edu for local hosting information.

Conversations about Research Ethics (CARE) Training Program

The Center for Ethics and Human Values (CEHV) offers a semester-long, multidisciplinary, and discussion-based RCR program called the CARE Training Program. It involves 8 hour-long sessions led by CEHV ethicists. Each session uses a "flipped classroom" model, providing participants with resources prior to each discussion. Details here: https://cehv.osu.edu/care-training-program

Responsible Conduct of Research Training at Nationwide Children's Hospital

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.

Appendix 3: CCTS Career Development Grants Compared

Path to K Grant	vs	KL2
• For early career physician-scientists and other health science investigators 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. • Provides salary and fringe support for up to a 10% FTE (capped at $15,000) and approximately • ~$30,000 in research expense support for one year. • Aims to place junior scientists on the path to be competitive for NIH K Career Development Awards. • **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 Path to K Grant.		• 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. • For clinical and translational researchers with a research or health-professional doctoral degree. • Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support). • Up to $25,000 in research expense support. • Support to develop an R grant to fund research at the conclusion of the KL2 funding. • **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.

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

More information can be found at the CCTS website:

Path to K Grant	KL2 Grant
https://ccts.osu.edu/content/davis-bremer-path-k-program	https://ccts.osu.edu/content/kl2