THE OHIO STATE UNIVERSITY
CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

Overview Information

Funding Opportunity Title	**K12 Mentored Career Development Grant** **Request for Applications**
Funding Opportunity Purpose	The Ohio State University Clinical and Translational Science Institute (CTSI) calls for applicants for the K12 Mentored Career Development Grant. The K12 program is designed to develop a diverse cadre of well-trained early-stage faculty investigators through individualized training to engage fully, succeed, and lead in translational research and science. The training programs and educational infrastructure will foster a pipeline of early career clinician scientists with training that promotes scientific curiosity and discovery. We will sustain and enhance a culture in which translational scientists can collaborate to accomplish trans-disciplinary research that results in improved clinical outcomes. The K12 program is open to any assistant professor engaged in clinical or translational research or science, who has less than three years of service in that role at the time of appointment. The K12 Award is available for a period of three years (contingent on satisfactory progress), with two years of CTSI funding and a third from the scholar's home college/department. The Ohio State CTSI seeks proposals that address scientific questions consistent with our mission to fund research across the Translational Spectrum from the biological basis of health and disease to interventions that improve the health of individuals and the public.

Key Dates*

Posted Date	January 2, 2025
Letter of Intent Due Date	February 5, 2025, midnight at http://go.osu.edu/K12LOI
Full Application Due Date	March 30, 2025, midnight at https://redcap.link/pvfhrk17
Regulatory Consultation	By March 15, 2025. Contact April.Green2@osumc.edu
Study Section	April 2025
Notice of Award Date	May 2025
Start Date	July 1, 2025

*Some dates may vary because of unanticipated circumstances

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K12 Information Session

►January 15, 2025

►Noon to 1 PM

► Zoom

Register here: https://redcap.link/iogq7rwk

A recording will be distributed to those who register.

Section I. Funding Opportunity Description

Purpose

The K12 grant is designed to benefit a wide spectrum of clinical or translational researchers and scientists across Ohio State. The grant provides salary support to ensure protected time for mentored research and didactic training in clinical/ translational research. 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, an individual K award, or equivalent.

The K12 grant funds the following areas of research on the Translational Science spectrum:

> **T1: Preclinical Research**. Preclinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.
>
> **T2: Clinical Research**. Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.
>
> **T3: Clinical Implementation**. Clinical implementation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.
>
> **T4: Public Health**. Public health includes studying health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.
>
> (See NIH NCATS' Translational Science Spectrum for more information.)

K12 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 review panel will make recommendations to the K12 External Advisory Committee, who will approve funding up to two K12 scholars. All applicants will receive reviewer comments on their applications.

Please note the following requirements:

- To be considered, all applicants must submit the required Letter of Intent form by 11:59 PM on the date noted above using the online form indicated above.
- Applicants must complete all sections of the entire application. Applications are due by 11:59 PM on the date noted above using the online form indicated above.
- No late LOI or applications will be accepted.
- Prior approval of all research subject to review by the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) is required by the National Institutes of

Health National Center for Advancing Translational Science who funds the CTSI. Full applications identified by review as meritorious for funding will be subject to NIH prior approval prior to the release of funds. Documentation for this federal review will be collected from applicants and submitted after acceptance of the grant. If the NIH/NCATS declines such approval, the CTSI will not be able to support the project. See Section V, below.

Please direct all questions to Program Manager Stuart.Hobbs@osumc.edu or 614-685-5972.

Note: The CTSI also sponsors the Path to K Award for junior faculty in the health sciences. See Appendix 3 of this document for a comparison of the two programs.

Benefits of the K12 Award

- 75% salary support and appropriate fringe benefits (50% for surgeons) (the 75% multiplier is applied up to a salary cap of $160,000).
- **Research funds $15,000 per year for three years from the CTSI** for the following types of research-related expenses: (a) research expenses, such as supplies, equipment, and technical personnel; (b) tuition and fees related to required career development courses and activities; (c) travel to scientific meetings or training that the institution determines to be necessary for the individual's career development experience; and (d) statistical services including personnel and computer time.
- Access to the CTSI 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 K12 directors.
- Support to develop an R grant or individual K award to fund research at the conclusion of the K12 funding.

Expectations of K12 Awardees

- Commit 75% of your effort to this K12 Scholar Award (50% for surgeons).
- Commit to attending the following CTSI organized K12 Training programs:
  - ✓ An orientation to the K12 program and CTSI.
  - ✓ Monthly K Lunch and 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).
  - ✓ Grant writing workshop participation in the Spring Semester of Year 2.
  - ✓ Lead Mentor will attend CTSI mentor training, if he or she has not already done so.
  - ✓ Individualized coaching to enhance verbal communication skills
- Individual development plan will be developed in collaboration with K12 leadership and project mentoring teams and monitored every six months (see Appendix 1).
- Brief progress reports will be required three times per year.
- An Annual written report and an oral presentation to K12 External Advisory Board.

Section II. Eligibility Information

Eligible Applicants

The K12 grant is for full-time, early career faculty at Ohio State University or Nationwide Children's Hospital on the tenure-track or clinical-track who have less than three years on appointment at the time of award.

The CTSI follows eligibility criteria for K12 appointments as established by the National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS), funding opportunity Mentored Research Career Development Program Award in Clinical and Translational Science Awards (CTSA) Program, FOA PAR-21-336. See Part 2. Section III. 3 at https://grants.nih.gov/grants/guide/pa-files/PAR-21-336.html#_Section_III._Eligibility

- 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, PharmD, etc.).
- At the time of their appointments, scholars must not have a 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 K12 appointment would be terminated and funding received from the new individual K, R, or non-PHS award.
- Candidates should be early career faculty who can take full advantage of and benefit from the described state-of-the-art research-focused career development program in clinical and translational science. Consistent with the type of mentoring and career development being provided by the CTSA Program, a K12 scholar candidate who is already in the process of applying for an independent mentored career development grant, Program Project Grants/Center Grants or equivalent grant is likely too senior for the K12 award.

Other Eligibility Information

Applicants must have Principal Investigator status from the Ohio State ERIK/Office of Research. Eligibility information can be found at: https://research.osu.edu/building-your-research-program/becoming-principal-investigator/pi-status-and-research-scientist

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 K12 by signing the application.

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 K12 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 this RFA. **No late Letters of Intent will be accepted.**

The LOI form requires you to:

- Submit a project title and Abstract (250 words)
- Attach your NIH Biosketch
- Complete an eligibility checklist will clearly tell you if you are eligible to go on to apply for the K12. You should review carefully the eligibility criteria above before applying

The LOI will be used to

1. Assess your eligibility for the K12 award
2. Let program staff know of your intent to apply for the K12 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**

Phase Two: Regulatory Consultation

The National Institutes of Health National Center for Advancing Translational Science (NIH-NCATS) requires prior approval for research funded through the CTSI K12 if it involves human subjects or vertebrate animals. In addition, all K12 research studies must obtain appropriate institutional and regulatory approvals at Ohio State. The prior approval, institutional, and regulatory processes are complex and contain many components. To help navigate through these processes, the CTSI provides expert consultations to K12 applicants.

All K12 applicants must schedule a regulatory consult with the CTSI Regulatory Manager, April Green, to discuss the documentation required for their project. Note that the NIH definition of human subjects or vertebrate animals research may be different from your definition or that of Ohio State, hence the need for consultation. This consultation must be completed by 5 PM Eastern time on the date noted at the top of this RFA. To schedule this consultation, contact april.green2@osumc.edu Applicants are encouraged to schedule this consultation early in the application process.

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). The study related information and documentation for this federal review will be collected by the CTSI Regulatory Knowledge and Support team from applicants and submitted after acceptance of the award if selected for funding.

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 this RFA. No late applications will be accepted.**

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

All documents asked for in the application must be submitted online in **PDF format** with the file named using the following guideline < lastname_firstname_K12_Application_2025 >

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

K12 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, Ohio State name.#, ERA Commons username, ORCID number; see orcid.org)
- ☐ Campus Address
- ☐ Current University Employment Information
- ☐ Race, ethnicity, and additional 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 (one 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 (two 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 (seven pages maximum)
    - ☐ Specific Aims (one page maximum)
    - ☐ 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 in your application PDF packet. 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. 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
- ☐ Data and Safety Monitoring Plan/Board. *If the proposed research includes a clinical trial, describe an appropriate Data and Safety Monitoring Plan*

☐ Vertebrate Animal research. 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

☐ NIH Formatted Biosketches (to be uploaded to the Application)

- ☐ Applicant
- ☐ Lead Mentor
- ☐ All other members of your Mentorship Team describing their individual roles.

☐ 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, as well as the requirement for departmental financial support for the third year.
- ☐ Applicant

K12 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

K12 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 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html for more information).See Appendix 2, below, for training options.

K12 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 can be included where appropriate.

References to Scientific Literature. This section is not included in the 10-page limit but please try not to exceed 3 pages.

K12 Application Components: Human Subjects Research

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

K12 Application Components: Vertebrate Animal Research

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.

K12 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.

K12 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 K12 Scholar;
- Attending CTSI 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.

K12 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
K Luan Phan, MD
Clinical and Translational Science Institute
376 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.

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 CTSI. Full applications identified by comprehensive review as meritorious for funding will be subject to NIH prior approval

> 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.

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. 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. CTSI staff will reach out to applicants selected for funding as soon as a signed letter of offer is received to work with potential K12 scholars to collect all of the necessary documentation. Once submitted to the NIH, the Prior Approval process takes approximately 1 to 2 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 K12.

Because of the complexities of the Prior Approval process, all K12 applicants must schedule a regulatory consult with the CTSI Regulatory Manager, April Green, to discuss what documentation might be required for their project. Contact her at April.green2@osumc.edu to schedule an appointment, preferably before July 12.

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 Ohio State, the sooner it can be submitted to NIH for Prior Approval. **Regulatory approval before submission of the K12 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 CTSI 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 CTSI 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 CTSI Award Acceptance Letter is required before the start date.

Award Requirements

- Applicants and mentors must become CTSI members by completing a CTSI membership form. https://CTSI.osu.edu/form/become-a-member
- The NIH requires individuals supported by the K12 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 CTSI 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-21-293 "Institutional Clinical and Translational Science Award (UM1), 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-21-293.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 will 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

K12 program directors will work with scholars and their mentors to develop and Individual Development Plan (see Appendix 1, below, for more detail). Every three months, scholars will be asked through a REDCap survey to update the IDP. Every 6 months you will be asked to provide brief progress report on training and research. There will also be meetings every 6 months with the program directors, scholar and lead mentor to review the scholar's progress. The brief annual report will also include a 5-minute presentation about the scholar's experience on the K12 grant to the K12 External Advisory Board, who approved annual reappointment based on steady progress.

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 and sample text will be provided to grantees.

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
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CTSI K12 Program Co-Directors

K. Luan Phan, MD
K12 Contact-PI
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Chief of Psychiatry Services for Health System
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Cynthia Carnes, PharmD, PhD
K12 Co-PI
Senior Associate Vice President for Research Operations
Professor, College of Pharmacy
Carnes.4@osu.edu

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 July 1, 2025, and continuing for up to two years.

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

3. I agree that the department and/or college will provide 50% protected time for research and training activities and cover 100% of the individual's salary and benefits during the third year of this award, if the individual is awarded a K12 grant and makes satisfactory progress to the third year of funding.

_____ _____

Signature Date

Printed Name and Title: _____

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

Signature Page: Applicant

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

_____ _____

Applicant's signature Date

Appendix 1: The Structured Individualized Development Plan Described

Each new K12 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 K12 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 K12. The mentee is responsible for scheduling mentoring activities through the Administrative Program Director; every six months, the lead mentor and K12 co-Directors will monitor progress and provide feedback on progress to each K12 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 K12? How will this be done? Timeline for completion? Includes review of mentoring plan submitted with K12 application
Career Development Goals: topics to discuss
Entrepreneurial training goals?
Communications skills development needs assessment
Community Outreach: interests and goals?
Optional: Need for formal courses or a certificate program?

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		
Public presentation/engagement		
Community engagement activity		
Implicit Bias Training		
Mentor Development Program		
Workshop: roles and responsibilities of research team members		
Workshop: Strategic Planning and Strategic Doing		

Attendance and 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		
Selective (required to select from each row)		
IRB and/or IACUC meeting attendance		
Innovation, Entrepreneurship and Commercialization training (complete one option)		
CTSI Tools of the Trade programs: must attend one per year		
Responsible Conduct of Research training (may choose which venue best meets needs). (See Appendix 2)		
Lunch and Learn Programs: must attend 8 per year	Held monthly	
Supervision, management and leadership: select at least one program per year.		
Individualized training options		
May include courses, workshops or other trainings		
Optional Training 1		
Optional Training 2		
Optional Training 3		

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

All K12 scholars must receive instruction in the Responsible Conduct of Research, per "FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research," NOT-OD-22-055. The NIH policy outlines requirements for the format of instruction, frequency and timing and subject matter. These should be reviewed here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

In response, the Office of Research at Ohio State produced the "Institutional Responsible Conduct of Research Training Plan" that can be found at https://research.osu.edu/sites/default/files/2024-01/ORC_Institutional-Responsible-Conduct-of-Research-Training-Plan_508.pdf
Among other topics, Ohio State training plan outlines university training requirements for faculty on various funding sources and those on training grants. The K12 requires at least eight contact hours of instruction. The following fulfill both the content and contact requirements of the NIH for this training:

Graduate School 8000: Responsible Conduct of Research (Course ID 37106)

This course was specifically designed to meet NIH requirements in RCR training. The course provides a practical overview of the rules, regulations and professional practices that define the responsible conduct of research. Covers all the topics required by the National Institutes of Health. The course features weekly facilitated discussions from experts across campus. 1 Credit. Offered Spring term. Registration through BuckeyeLink.

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. Offered the first four weeks of summer term. The course fulfills NIH requirement for research ethics. Dr. Cynthia Carnes, instructor. 1 credit

Responsible Conduct of Research Training at Nationwide Children's Hospital

Nationwide Children's Hospital offers a Responsible Conduct of Research Training Series at various times during the year. The course fulfills NIH requirements. For details, contact Michelle.Abraham@nationwidechildrens.org

The Ohio State Institutional Plan includes a list of several other courses whose syllabi indicate they would meet NIH requirements for subject area, format and duration. However, these courses have not been formally reviewed or audited for their fulfillment of NIH requirements, and ethics courses alone typically are not sufficient to meet RCR .

Options for ongoing training.

On their own, the following to not meet the NIH or Ohio State RCR training requirements but provide excellent opportunities to continue your training. For example, the NIH program noted below provides a forum for clinical researchers to go more deeply into ethical issues that they might confront.

NIH Fall Ethical and Regulatory Aspects of Clinical Research Annual Forum

This is a seven-week annual presentation (typically offered September to November) by the NIH Bioethics program regarding various ethical issues of conducting human subject research. Presentations are via NIH VideoCast live and recordings may be accessed about 48 hours after the presentation via their Archive portal. Participants may request either a Certificate of Completion or Nursing CEUs by pre-registering Online and attending a set number of programs. You can find more information at the program website: https://www.cc.nih.gov/bioethics/courses/ethical-regulatory-aspects

Conversations about Research Ethics (CARE) Training Program

The Center for Ethics and Human Values (CEHV) offers a semester-long, multidisciplinary and

discussion-based program on research ethics called the CARE Training Program. It involves 8 hour-long sessions led by CEHV ethicists. The program does not fulfill all the NIH requirements but is an excellent refresher on research ethics topics. Details here: https://cehv.osu.edu/care-training-program

Appendix 3: CTSI Career Development Awards Compared

Path to K Grant	vs	K12 Grant
• 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 CTSI. • For clinical and translational researchers with a research or health-professional doctoral degree in one of the seven Ohio State health science colleges. • Provides salary and fringe support for up to a 10% FTE (capped at $15,000) • Approximately $14,000 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 from any Ohio State college. • Provides 75% salary support and research funding for three years (two years CTSI support; one year home college support). (Capped at $120K) • Up to $15,000 annually in research expense support. • Support to develop an R grant or individual K grant to fund research at the conclusion of the K12 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 K12.

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 CTSI website:

Path to K Grant	K12 Grant
https://ctsi.osu.edu/career-development/early-career-faculty/path-k	https://ctsi.osu.edu/career-development/early-career-faculty/k12-early-career-training-grant