THE OHIO STATE UNIVERSITY
CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

Overview Information

Funding Opportunity Title

CTSI Predoctoral T32 Mentored Research Training Program

Request for Applications

Key Dates*

Posted Date	**January 9, 2025**
Letter of Intent Due Date	**February 18, 2025**, midnight at https://go.osu.edu/predoc_t32_loi
Application Due Date	**April 1, 2025**, midnight at https://go.osu.edu/t32application
Study Section	**Late April 2025**
Notice of Award Date	**June 1, 2025, or as close as possible**
Earliest Start Date	**August 16, 2025**

*some dates may vary because of unanticipated circumstances

Funding Opportunity Purpose

Predoctoral T32 Information Session

- Wednesday, January 22, 2025
- Noon to 1 PM
- Registration and Zoom link: https://go.osu.edu/t32infoccts

The Clinical and Translational Science Institute (CTSI) is calling for applications to the CTSI predoctoral T32 mentored research training program.

The goal of this predoctoral training program is to leverage the large, collaborative and multidisciplinary research environment at Ohio State to increase the reach of clinical and translational science (CTS) education and training across The Ohio State University campus and to recruit and develop a diverse cohort of trainees to become the next generation of clinical and translational scientist leaders.

The T32 grant provides full-time research training support for predoctoral trainees pursuing mentored clinical and translational research or clinical and translational science who are enrolled in any Ohio State graduate degree program and are post candidacy. Examples of potential CTS projects include research focused on advancing therapeutics, developing new clinical interventions, promoting health equity or investigating/fostering behavior modifications to improve health.

Predoctoral trainees in clinical/translational related graduate degree programs (such as in the colleges of medicine, public health, engineering, nursing, veterinary medicine and others; and interdisciplinary programs such as neuroscience and nutrition) and health-professional doctorate trainees who are enrolled in a Master's or Doctoral program (such as MPH, MMS or MD/PhD program) are also eligible to apply.

The overall goal of the T32 program is to increase the number of well-trained biomedical researchers who can lead the design and oversight of future clinical and translational investigations critical to transforming the translational process so that new treatments and cures for disease can

be delivered to patients faster and efficiently to all affected populations.

Applicants who are underrepresented in health-related sciences research (see: https://extramural-diversity.nih.gov/diversity-matters/underrepresented-groups accessed December 2024) are encouraged to apply, as diversity in the biomedical research workforce is critical to the success of clinical and translational science. The Ohio State CTSI T32 training program is part of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program, the goal of which is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the nation's biomedical, behavioral and clinical research needs. It is funded through a grant from the National Center for Clinical and Translational Science (NCATS).

Table of Contents

Section I. Funding Opportunity Description

Purpose

For this cycle, three predoctoral awards will be made.

Please read this RFA carefully for complete eligibility requirements related to the applicant and type of research proposed.

Benefits of the T32 Program

- Stipend support for one year will be awarded at the NIH allowed annual maximum.
- Coverage of tuition and fees
- Access to the CTSI professional services and staff including biostatistics, research participant recruitment and retention services and regulatory support.
- Access to a training curriculum in clinical and translational research methodology and specialized training seminars.

Expectations of T32 Trainees

- Trainees must be able to commit full-time effort in the program at the time of appointment.
- Individual Development Plan (IDP): Working with the T32 PDs and the trainee mentors, the T32 trainee converts the training plan from their application into an on-line IDP. Administered as a REDCap survey, the Trainee Monitoring Assessment Tool includes the IDP and organizes training, coursework,

conference and workshop plans as well as individualized training of the T32 trainee to achieve career development goals along with target completion dates. Every six months, the PDs hold an IDP meeting with the trainee and lead mentor to monitor progress and provide feedback on trainee progress.
- Completion of required training elements.
- Participate in 8 CTSI Lunch and Learn seminars, 3 CTSI Tools of the Trade Workshops, 2 CTSI T32 Career Dinners per year.
- Research Productivity expectations are a minimum of one first authored publication and two co-authored publications, one national scientific presentation per year, experience submitting or contributing to the submission of an external grant at least once during their graduate training.
- Progress reports will be required three times per year--twice in conjunction with the IDP meeting.
- An annual written report and an oral presentation to the CTSI Executive Committee and members of the Internal Advisory Committee are required.
- All trainees must acknowledge the CTSI T32 support in all publications and presentations.
- All trainees must adhere to the NIH Public Policy Access Policy.
- All trainees complete the CITI Good Clinical Practice training, all Ohio State Office of Responsible Research Practice (ORRP) requirements and trainings, at least one course in Responsible Conduct of Research (RCR) and additional RCR related seminars and workshops.
- All trainees are expected to submit abstracts for poster or oral presentations and attend the annual Ohio State CTSI Scientific Conference and the Association for Clinical and Translational Science annual meeting.

- All trainees will take PUBHEPI 6412 - Basic Principles in Clinical and Translational Science (Autumn Semester) and PUBHEPI 6413: Conducting and Communicating Research in Clinical and Translational Science (Spring Semester).
- Trainees will complete the requirements for the Graduate Biomedical, Clinical and Translational Science Interdisciplinary Specialization (BIOMCLT-IS) (see Appendix 3 for more information).
- All courses taken through the graduate school, with the exception of courses taken under the audit option, count toward minimum hours requirement for doctoral students. Trainees are responsible for ensuring they are enrolled in the proper number of hours for Fall, Spring and Summer semesters. Failure to meet any of these conditions may result in the immediate cancellation of the Graduate School Tuition and Fee Award. Students are responsible for the payment of any “special” fees such as the COTA fee, recreation fee, student activity fee, learning technology fee, etc.
- T32 Trainees must remain in good academic standing, which requires a minimum quarterly cumulative grade point average of 3.00 while making reasonable progress toward the graduate degree.
- All trainees are expected to attend at least once the Translational Science Conference sponsored by the Association for Clinical and Translational Science, which is typically held in April Washington, D.C. They will have the opportunity to submit abstracts for poster and oral presentations.
- All trainees will follow relevant NIH Rules and Regulations as stated in the NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.htm) and the Ruth L. Kirschstein National Research Service Award (NRSA) Predoctoral Research Training Grant for the Clinical and Translational Science Awards (CTSA) Program (https://grants.nih.gov/grants/guide/pa-files/PAR-21-337.html)

Section II. Eligibility Information

Eligible Applicants

Before you apply, please note the following information.

Eligibility criteria for T32 applicants (established by our funding source, the National Institutes of Health) are

as follows:

1. **Citizenship Status:** At the time of appointment to the training program, individuals selected to participate in the training program must be citizens or non-citizen nationals of the United States or have been lawfully admitted to the United States for permanent residence by the time of award. Noncitizen nationals are individuals, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. See https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.2.2_eligibility.htm#Citizens for complete information.
2. **Degree Requirements**: Trainees must be enrolled in a program leading to a PhD or an equivalent research health professional doctoral degree program.
3. **Effort**: Trainees must be able to commit full-time effort in the program at the time of appointment.
4. Individuals currently supported by other Federal funds are not eligible for trainee support from the T32 program at the same time.
5. Applicants must be either (a) post-candidacy (applicants will be asked to supply the date of the candidacy exam); or (b) have a candidacy exam scheduled before the announced start date (applicants will be asked to provide the date of the scheduled exam). All others should wait for a later RFA to apply for the T32.
6. Doctoral students conducting research in NCH labs are eligible to apply, but to receive the T32 they must be appointed as Graduate Fellows at the Ohio State University and receive their stipend and tuition and fee waiver through Ohio State University.
7. No predoctoral trainee may receive more than 5 years of aggregate Kirschstein-NRSA support, including any combination of support from Kirschstein-NRSA institutional research training grants and individual fellowships. Therefore, if you have 4 years on an F or T32 you would be eligible for only one year on the CTSI T32.

Eligible Research

The Predoctoral T32 Funding Opportunity Announcement (FOA) from the NIH does not allow appointed Trainees to lead an independent clinical trial. Trainees may obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

The applicant can be part of the clinical trial team and can use the data generated during the clinical trial research experience in his/her proposed research project. NIH expects the mentor to assume overall responsibility of the trial including registering and reporting in clinicaltrials.gov and obtaining IRB approval.

Refer to “Appendix 1. Definitions: Clinical and Translational Research” of this RFA for more information on this topic, including a link to an NIH webpage with a decision tree that you can use to determine if your proposed research meets the NIH definition of a clinical trial, which may be different from your definition.

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 T32 Letter of Intent form found at the web address noted at the top of this RFA.

The purpose of the Letter of Intent is:

1. To let program staff know of your intent to apply for the T32 in order that they may organize the Study Section.
2. So applicants can fill-out the eligibility checklist to know that they are eligible.

The Letter of Intent takes the form of a REDCap survey. You are able to save your work and return later. REDCap will send you an email with a return link.

All Letters of Intent must be submitted through the online process by 11:59 PM EST on the date noted above. **No late Letters of Intent will be accepted.**

The process of completing the eligibility checklist will clearly tell you if you are eligible to go on to apply for the T32. You should review carefully the eligibility criteria found in Section II of this document before applying.

Staff will use the information you submit about your project to organize the T32 Study section. The information about your project that you submit in the Letter of Intent will not undergo scientific review. **Do not expect further contact from project staff after submitting the Letter of Intent. If project staff do have questions or concerns, they will contact you.**

Phase Two: Full Application

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

Please read these instructions carefully before going online to apply. The application must be completed and submitted online at **the web address noted above.** The application process is designed so that you can save your information and return to it (You will be able to bookmark the survey page to return to the survey, or you can provide an email address to which the survey link will be emailed).

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.**

Materials must be submitted online in **PDF format** with the file named using the following guideline:

< lastname_firstname_T32_Application_2025 >

Use Arial with font no smaller than size 11. Use single-space text. Margins should be at least ½ inch on all sides.

Please make sure you have completed all sections of the entire application. Incomplete applications will not be accepted.

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 CTSI website to search for and make use of other CTSI resources relevant to your project.

Grant Application Checklist

The Application consists of several parts. Please use this form as a checklist when preparing your application. The application must be completed online, with additional materials uploaded in PDF format the application.

The following information will be provided in an on-line form at the web address noted above.

- ☐ Personal Information
  (Includes Employee ID Number; Ohio State name.#; ORCID Id [see orcid.org], ERA commons name)
  - ☐ Campus Address
  - ☐ Current University Employment Information
  - ☐ Gender, ethnicity and additional such reporting information required by the NIH
- ☐ Applicant Eligibility checklist (see page 5-6 of this packet for more information)
- ☐ Research Eligibility checklist (see p. 6 and Appendix 1 for more information)

The following information must be provided in a single PDF document uploaded to the application form.

- ☐ Cover Page
  - ☐ Name
  - ☐ Graduate Program(s)
  - ☐ Proposed Research Project Title
  - ☐ Research Project Abstract (250 words)
  - ☐ Mentoring Team
- ☐ Mentoring and career development plan (up to 2 pages)
  - ☐ Applicant's Background
  - ☐ Career Development/Training Activities (see p. 6 and Appendix 2 for more information)
  - ☐ Mentoring (see pp. 7-8 for more information)
- ☐ Proposed Research Plan (up to 4 pages) (see pp. 6-7 and Appendix 1 for more information)
  - ☐ Title
  - ☐ Statement of significance of the research problem
  - ☐ Specific Aims of the Project
  - ☐ Research Methods
  - ☐ Diversity, Equity, Inclusion and Accessibility (DEIA) aspects of their research and how their research is expected to impact health equity if applicable
  - ☐ References (not included in the page limit)
- ☐ Signature page
  - ☐ Applicant
  - ☐ Primary Mentor
  - ☐ Graduate Program Chair
- ☐ Letters of support from your Primary mentor and the other members of your mentorship team.
- ☐ NIH Biosketches
  - ☐ Applicant
  - ☐ Mentoring Team: Primary Mentor and two other mentors (and any additional optional mentors you have)
- ☐ Current Advising Report (which should include GRE, MCAT or equivalent test results)

Application Components: Personal Statement, Career Development and Mentoring Plans

This section cannot exceed two type-written, single-spaced pages.

Applicant's Background: The CTSI T32 application requires trainees to describe their educational background, motivation for a research career, clinical and translational research focus and how the CTSI T32 training experience would benefit their research and their career development.

Career Development/Training Activities during the Award Period: Describe here the new, enhanced research skills and knowledge you will acquire as a result of the proposed award. The governing body of the CTSI has defined Core Competencies in clinical and translational science, and they are listed in Appendix 2, below. Draw from the list those areas in which you need development and describe how you will gain skills, knowledge and experience in Clinical and Translational Science through the T32 program. Here you may include lists of courses, workshops, meetings, etc.

You may also describe how you will use the award to gain specific technical skills, again through courses, workshops, mentoring, etc., as appropriate.

Training in Responsible Conduct of Research. Describe in this section how you will meet the NIH requirements for instruction in the responsible conduct of research. Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral and faculty levels. Instruction must be undertaken at least once during each career stage and at a frequency of no less than once every four years. T32 applicants must indicate in their training plan when in their graduate career they have had NIH compliant training in RCR. If it has been more than four years since they have had such training, the T32 training plan must include a plan to obtain instruction in the responsible conduct of research. The plan must address the five instructional components, format, subject matter, faculty participation, duration of instruction and frequency of instruction, as outlined and explained by the NIH at https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html. See Appendix 4, below, for training options.

Mentoring: This is the section in which to describe how the mentors fit with your training goals. If the training and research plan include clinical trial research experience for the Trainee, address how the mentor(s) who will supervise the Trainee have the expertise, experience, resources and ability to provide appropriate guidance and help the Trainee to meet the timelines.

Application Components: Research Plan

The Research Plan should not exceed 4 pages.

The proposed research must fit the following definition of clinical research and be situated somewhere on the translational research spectrum from T1 to T4. See **Appendix 1** for more information.

Clinical Research: Research with human subjects that is:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Clinical research includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials or (d) development of new technologies. Or:

2) Epidemiological and behavioral studies. Or:

3) Outcomes research and health services research.

Translational Research. The translational science spectrum represents each 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. For more detailed information, see Appendix 1.

T0 Basic Science. Refers to basic scientific discovery (Not funded by this award).
T1 Discovery or Foundational Research seeks to move basic discovery into a candidate health application.
T2 Health Application to Assess Efficacy: assesses the value of application for health practice leading to the development of evidence-based guidelines.
T3 Health Practice (Science of Dissemination and Implementation): attempts to move evidence-based guidelines into health practice, through delivery, dissemination and diffusion research. Research examples include health services research related to dissemination, communication and implementation; and clinical outcomes research. Phase 4 Clinical Trials are also part of T3, but are not funded by this award.
T4 Evaluation of Health Impact on Real World Populations: seeks to evaluate the "real world" health outcomes of population health practice. Research examples include: population level outcome studies; studies of the social determinants of health. [1]

The research plan should be organized as follows:

- Title of the proposed 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.
- Specific Aims of the Project. An outline that lists the individual experimental issues that are to be addressed. Each should be framed in terms of a hypothesis.
- A brief description of the Methods to be employed. A (somewhat) detailed description of the experimental system to be examined, the materials available, the procedures to be employed, expertise available in the sponsor lab and the rationale for the design of the project. From this section, the reader should be able to determine how the data to be gathered will help solve the problem identified. The reviewers should also be able to assess the feasibility of the proposal both in terms of experimental design and time frame for completion.
- Describe how your research aims to improve the health of people and reduce health disparities in minoritized, underrepresented and disadvantaged groups, advancing the societal goal of health equity. For example, if human subjects are involved in the research, a plan for recruiting a cohort that mirrors the effected population should be included. Or the applicant might discuss how the effects of the health problem being researched disproportionally affect different population groups and describe how the ultimate clinical application of the research could lead to more equitable health outcomes.
- References are **not** included in the page limit.

Application Components: Scientific Mentorship Team

Applicants will put together a three-person mentoring team.

Primary Mentor. It is expected that the applicant will identify a mentor in their area of clinical or translational research who is likely to be a member of the faculty in the applicant's unit. Under the guidance of the mentor, the applicant will further develop their proposal that describes the clinical research project to be undertaken.

The primary mentor is expected at a minimum to:

- Provide guidance for design and execution of an original, high-quality research project
- Meet with the trainee regularly
- Provide career development and counseling
- Complete Implicit Bias Training

[1] Adapted from "T-Phases of Translational Health Research" at https://www.iths.org/investigators/definitions/translational-research/ , and Harvard Catalyst at http://catalyst.harvard.edu/pathfinder/ accessed July 2021.

- Participate in formal CTSI Mentor training (and complete mentor competency assessment surveys)
- Practice inclusive and culturally responsive mentorship
- Have sufficient funding to support at least two years of trainee research
- Attend Orientation, IDP meetings (twice a year) and at least two trainings/events per year organized for T32 trainees and mentor

The Primary Mentor's Letter of Support should acknowledge their understanding of these requirements; describe their mentoring plan for your development, including reference to the mentoring and training plan in your application; and describe their training experience (including number of mentees).

The Primary Mentor will need to sign the signature page.

Additional members of the mentorship team (at least 2 additional):

The mentorship team provides additional expertise in the scientific area of research chosen for the project. In order for the team to be complementary to the interests of the primary mentor, the three-person team should have the following characteristics:

1. One mentor must be from a different department than the applicant. The choice of this mentor should reflect a skill-building purpose that is discussed in the career development and mentoring plans.
2. The mentoring team must include at least one clinician and one who is either a lab-based or a population-focused researcher.

Mentoring teams that cross health science colleges are encouraged, but not required.

Your mentorship team may 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.

Application Components: NIH Biosketches

NIH Biosketches. The biosketches of the Applicant, the Primary Mentor and the other two (or more) members of the mentoring team should be uploaded to the application. Use the "Personal Statement" section to describe why your experience and qualifications make you particularly well-suited for your role (either as T32 trainee or mentor) in the program. Within this section you may, if it is relevant to your situation, briefly describe factors such as family care responsibilities, illness, disability and active-duty military service that may have affected your scientific advancement or productivity.

You can find a "Biographical Sketch Sample," with instructions and a blank formatted "Biographical Sketch" form here: https://grants.nih.gov/grants/forms/biosketch.htm

Application Components: Letters 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:

Ginny L. Bumgardner, MD, PhD
Clinical and Translational Science Institute
376 W. 10th Ave., Suite 260
Ohio State University
Columbus, OH 43210

Other Application Components

Current Advising Report. The predoctoral application should include a current Advising Report. To access your advising report, log on to BuckeyeLink. Go to the "Student Center" section. Under "Academics" you will see the link "Generate Advising Report." Click on this link and a current Advising Report will be generated that you can save as a PDF.

Typically, the advising report includes your professional entrance examination scores (GRE or MCAT, or equivalent as relevant to your situation) in the left column. If it does not for some reason, please include documentation of your relevant score(s).

Section IV. Application Review Information

A Study Section will make recommendations to the CTSI Executive Committee for funding. 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.

Trainee selection criteria are based on a holistic review process in which the candidate's attributes, experiences and educational metrics and accomplishments to date are assessed. The candidate's academic and scholarly accomplishments, service contributions to the community, potential contribution to the diversity of the T32 trainee cohort and research career aspirations are assessed. The quality of the mentorship team and the training plan are important evaluation criteria. The potential CTR/CTS research project impact on innovation and advances in health and the rigor of the research approach contribute to the evaluation. Finally, the potential of the T32 training program to significantly impact the candidate's career trajectory is assessed.

All applicants will receive reviewer comments on their applications.

Section V. 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 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 VI. Other Information

- The NIH requires individuals supported by the T32 to have ORCID IDs (Open Researcher and Contributor Identifiers). You may acquire your free ORCID here: https://orcid.org/
- Appointed Predoctoral T32 Trainees are not allowed to simultaneously hold another appointment or position. Trainees must be appointed as a full-time fellow and must maintain that appointment during the entire award period. The student may not be required to perform any service for the fellowship stipend beyond that normally required for coursework and/or research activities and may not hold any other type of employment or appointment.
- Graduate Fellows receive stipends related to their academic programs. They do not render services for pay and therefore are not considered employees. According to the Federal Tax Reform Act of 1986, fellowship stipends are considered taxable income. However, because fellowships are considered awards, the university may not withhold income tax from the monthly stipend. Students will not receive a W-2 Form. Students may be required to file federal and state estimated quarterly income tax forms. Information and forms on quarterly filing can be obtained from a tax advisor or at Internal Revenue Service (IRS). Information about fellowships and taxes can be found at the IRS website. Students may also be required to pay the Columbus city tax (City of Columbus tax website). Questions regarding taxes on fellowships should be directed to the Office of the Controller, Payroll Services Tax Information, 614-292-2311, or < controller.osu.edu/pay/pay-home.shtm >
- Research in foreign countries is not allowed by this award.

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

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 T32 scholar to the CTSI Executive Committee and members of the Internal Advisory Committee.

Trainees, Mentors and T32 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. See Cite the Grant | Clinical and Translational Science Institute 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. Program Contacts

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

Grant Management Contact

Stuart D. Hobbs, PhD, MBA
Program Director
Education and Training
Clinical and Translational Science Institute
Ste. 260 Prior Hall, 376 W. 10th Avenue, Columbus, OH 43210
614-685-5972 Office
stuart.hobbs@osumc.edu CTSI.osu.edu

Program Directors

Ginny L. Bumgardner, MD, PhD
Associate Dean for Physician Scientist Education and Training and Professor of Surgery, College of Medicine
Director, Pre-doctoral T32 Program, Ohio State University Clinical and Translational Science Institute
Ginny.Bumgardner@osumc.edu

Sakima Smith, MD, MPH
Associate Professor, College of Medicine; Department of Internal Medicine.
Assistant Director, Pre-doctoral T32 Program, Ohio State University Clinical and Translational Science Institute
sakima.smith@osumc.edu

These signatures must be acquired in the order presented below.

Signature: 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

Signature: Primary Mentor

As Primary Mentor, I take responsibility in:

- Guiding and encouraging the design and execution of an original, high quality, clinical or translational research project.
- Providing financial support and other resources for trainee conduct of mentored research
- Providing career development and counseling.
- Attending CTSI Mentor training.
- Meeting with trainee regularly (at least monthly).
- Attending occasional meetings/trainings for T32 trainees and mentors organized by the CTSI.

_____ _____

Signature of Primary Mentor Date

Signature: Department or Graduate Program Chair

This individual is qualified for this program. The Program or Department/Division Chair has read and agrees to the guidelines of the T32 Program.

_____ _____

Signature of Graduate Program/Department/Division Chair Date

Appendix 1. Definitions: Clinical and Translational Research

Before you apply, please note the following information.

CLINICAL RESEARCH AND CLINICAL TRIALS

Per regulations, Ruth L. Kirschstein T32 awards fund clinical research, per the following definitions.

Clinical Research[2]: Research with human subjects that is:

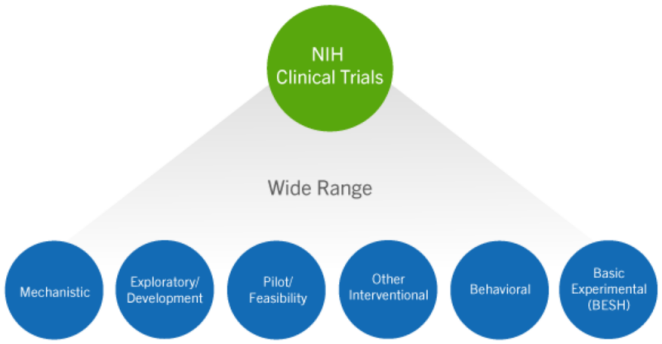
1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials or (d) development of new technologies.

2) Epidemiological and behavioral studies.

3) Outcomes research and health services research.

Clinical Trial[3]**:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

The NIH does not allow Trainees appointed to this T32 to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial on which the PI is a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.



Use the following four questions to determine the difference between a clinical study and a clinical trial. Your definition of a clinical trial may differ from that of the NIH, so it is important to make that determination.

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

[2] http://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm accessed December 2023.
[3] https://grants.nih.gov/ct-decision/index.htm accessed December 2023.

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention
- Only one aim or sub-aim of your study meets the clinical trial definition

Studies intended solely to refine measures are not considered clinical trials. Studies that involve secondary research with biological specimens or health information are not clinical trials.

Use the NIH decision tree at this webpage https://grants.nih.gov/ct-decision/index.htm to determine if your proposed research meets the NIH definition of a clinical trial. This webpage also contains case studies and FAQs to help you and your mentoring team understand the NIH definition of a clinical trial.

THE SPECTRUM OF TRANSLATIONAL HEALTH RESEARCH

Per regulations, Ruth L. Kirschstein T32 awards fund translational research that occupies a particular space on the Clinical and Translational research spectrum: T1 to T4

The application has a section where you will place your research on the spectrum and provide a two to 4 sentence justification for that placement.

Below are definitions and more information.

Translation: the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public—ranging from therapeutics and diagnostics to medical procedures and behavioral medicine.[4]

For didactic purposes, translational research has often been described in phases of translation, or "T-phases."[5]

T0 Basic Research
Basic research involves scientific exploration that can reveal fundamental mechanisms of biology, disease or behavior. Every stage of the translational research spectrum builds upon and informs basic research. (Not funded by the T32 grant)

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.

[4] Gilliland, C.T., et al., 2019. https://doi.org/10.1021/acsptsci.9b00022 accessed December 2023.
[5] https://ncats.nih.gov/translation/spectrum accessed December 2023.

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.

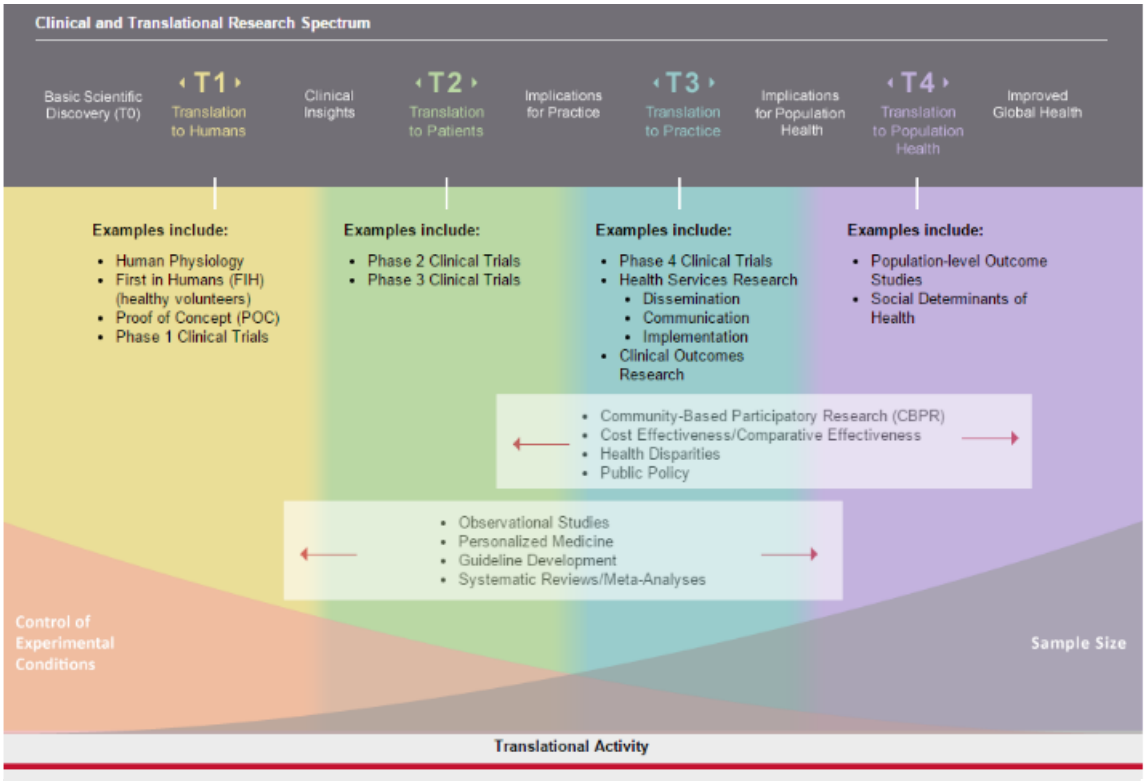
T3 Clinical Implementation

The clinical implementation stage of translation 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

In this stage of translation, researchers study 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.

THE SPECTRUM OF TRANSLATIONAL HEALTH RESEARCH (T0 TO T4)



Source: http://catalyst.harvard.edu/pathfinder/ accessed December 2023

Translational Science

Translational science is distinct from translational research. The National Center for Advancing Translational Science defines it this way:

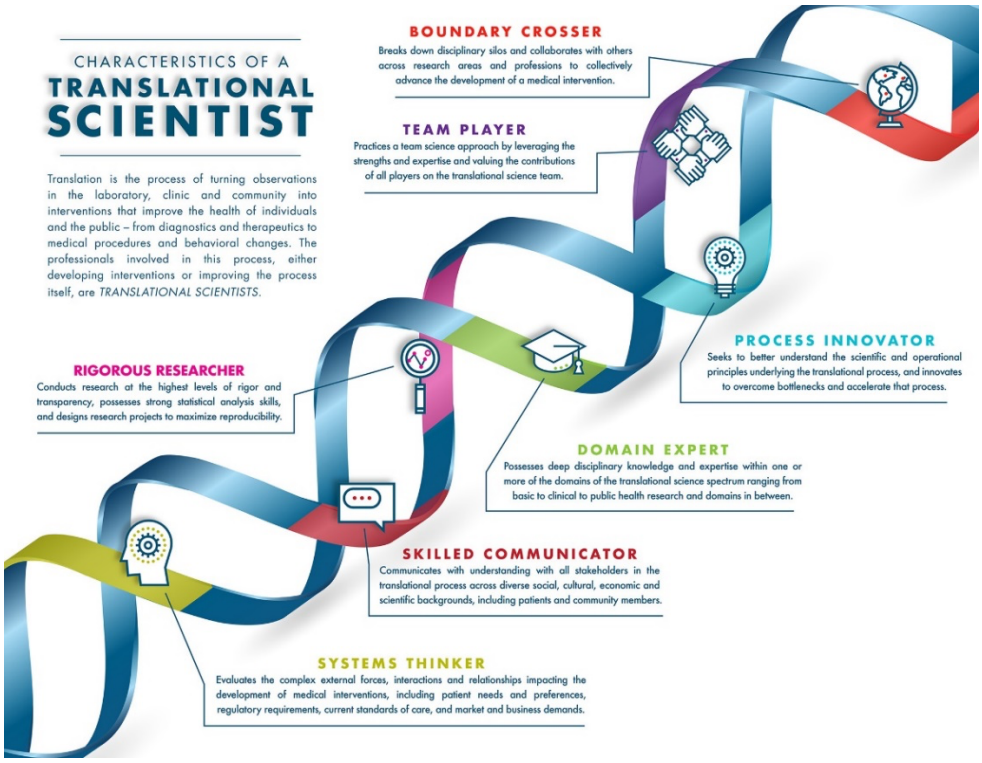
> Translational science is the field that generates scientific and operational innovations that overcome longstanding challenges along the translational research pipeline. These include scientific, operational, financial and administrative innovations that transform the way that research is done, making it faster,

more efficient and more impactful.[6]

NCATS has further defined eight translational science principles to help investigators develop strategies for successful translational research.

- Focus on pursuing scientific goals that address unmet scientific, patient or population health needs.
- Develop innovations that address persistent challenges to advancing translational progress that are found across multiple research initiatives or projects, or span research on multiple diseases or conditions.
- Leverage creativity and innovation in research design, conduct and facilitating factors, with the goal of increasing the impact of the research.
- Engage team members with expertise across disciplines, fields and professions to produce research that advances translation along the translational research continuum.
- Implement evidence-informed practices and scientific and operational innovations to accelerate the pace of translational research.
- Leverage collaborations across agencies and sectors and engage patients and communities in research to advance translational progress.
- Develop ambitious research questions and address them with rigorous and robust methods toward generating reproducible findings that contribute to advancing translation.
- Leverage diversity, equity, inclusion and accessibility to produce research outcomes that are relevant to the full diversity of the population. [7]

Appendix 2: Core Competencies for Clinical and Translational Investigator Training



Source: ACS Pharmacol. Transl. Sci. 2019, 2, 3, 213-216. https://doi.org/10.1021/acsptsci.9b00022

[6] "About Translational Science," https://ncats.nih.gov/about/about-translational-science accessed December 2023.
[7] "About Translational Science Principles," https://ncats.nih.gov/about/about-translational-science/principles accessed December 2023.

The task of CTSA education programs is to prepare the next generation of investigators to conduct clinical and translational research that will address the health care challenges faced in the United States. Creating a recognizable discipline centered on clinical and translational science will help build this workforce. To help establish the discipline, the CTSA Education and Career Development Key Function Committee has drafted national standards for core competencies in clinical and translational science.

The thematic competencies identify common, basic elements that should shape the training experiences of junior investigators by defining skills, attitudes and behaviors that can be shared across multidisciplinary teams of clinician-scientists. The overall goal is to create a competency-based education for training clinician-scientists that will define the discipline of clinical and translational science.

Research Methods

- Identify major clinical/public health problems and relevant translational research questions
- Identify, interpret and critique literature and assess the state of knowledge regarding a problem
- Know how to design a study protocol for clinical and translational research
- Understand study methods, design and implementation
- Use appropriate laboratory, clinical and population research methods
- Understand the principles of the conduct of responsible research

Analysis, Statistics and Informatics

- Be able to use appropriate statistical methods and conduct relevant analysis
- Be competent in appropriate bioinformatics

Community and Communications

- Understand the principles of community engagement in clinical and translational research
- Navigate competently among diverse populations and cultures
- Be able to communicate scientific findings to your peers and to disseminate scientific knowledge to those outside your field, including other scientists, university administrators, policy makers and the public

Leadership and Team Science

- Participate in cross-disciplinary training and mentoring
- Demonstrate leadership and professionalism
- Engage in translational teamwork

(More information: https://clic-ctsa.org/sites/default/files/CTSA_Core_Competencies_final_2011.pdf and https://clic-ctsa.org/education/competencies (accessed December 2023).

Appendix 3: Graduate Interdisciplinary Specialization in Biomedical Clinical and Translational Science

The goal of the Graduate Interdisciplinary Specialization in Biomedical Clinical and Translational Science

(BIOMCLT-IS) is to prepare graduate and professional students to be actively engaged in the field of clinical and translational science through academic training and research.

As defined by the Ohio State University Graduate School, a graduate interdisciplinary specialization (GIS) involves two or more graduate programs outside the student's home program. Completion of a GIS is noted on the student's transcript.

The core course in this program focuses on the basic components of clinical and translational science, while the electives allow students to pursue topics across the other health sciences colleges for an interdisciplinary experience.

Curriculum Requirements

- All students enrolled in the GISBCTS must take PUBHEPI 6412 Conducting and Communicating Research in Clinical and Translational Science. This is a 2-credit hour course offered each Autumn semester by the College of Public Health. It is recommended, but not required, that this course be taken first.
- Most of the participating colleges have internal procedures that are required to enroll in their courses, such as contacting the instructor. For most of these courses you will need to talk to the instructor before enrolling.
- Students must take at least one course from each of the Core Competency Clusters. The Competency Clusters are based on the National Center for Research Resources (NCRR) Core Competencies for Clinical and Translational Research. There are a total of 14 competencies that have been grouped together to form four clusters.

Specialization Guidelines

- The GISBCTS require a minimum of 10 and no more than 20 semester credit hours of graduate level coursework taken from at least 5 different courses.
- A graduate interdisciplinary specialization involves two or more graduate programs outside the student's home program.
- Nine credit hours must be taken outside of the student's home program in at least three courses. Thus, if you are a BSGP student, you must select at least three courses from the GISBCTS course menu that come from outside that curriculum. These courses can come from other programs in the College of Medicine or from other colleges.
- Credit hours can include work already required as part of the student's degree program.
- If there is a course that fits the competencies but is not listed here, it is possible to substitute it for a listed course. Contact the GISBCTS program administrator for more information.
- Apply for the Specialization through Ohio State Graduate School at this address:

  https://gradsch.osu.edu/future-students/find-your-program/graduate-minors-interdisciplinary-specializations-and-graduate accessed December 2023.

Questions? Contact the GISBCTS program administrator at Stuart.Hobbs@osumc.edu or 614-685-5972

BIOMCLT-IS COURSE OPTIONS

All students take the core course: PUBHEPI 6412: Basic Principles in Clinical and Translational Science (2 credits). Then students take at least one course from each of the four Core Competencies

Research Methods	Analysis, Statistics and Informatics	Community and Communication	Leadership and Training
BSGP 8050: Research Techniques and Resources (4 credits)	PUBHBIO 6210 - Applied Biostatistics I (3 credits) DL	BSGP 7070: Fundamentals of Grant Writing I (4 credits)	EEOB 5510: Interdisciplinary Team Science (3 credits)
MCR 7782: Clinical Research Design and Methods. (3 credits) DL	PUBHBIO 6211 - Applied Biostatistics II (3 credits) DL	BSGP 7080: Fundamentals of Grant Writing II (2 credits)	HTHRHSC 7300: Management and Leadership in Health Sciences (3 credits)
PUBHEPI 7412: Principles and Procedures for Human Clinical Trials (3 credits)	PSYCH 6810: Statistical Methods in Psychology I (4 credits)	Nursing 6110: Health Literacy (2 credits)	HTHRHSC 7350: Issues and Policy in Health Sciences (3 credits)
PUBHHBP 7534: Research Methods in Health Behavior and Health Promotion (3 credits)	PSYCH 6811: Statistical Methods in Psychology II (4 credits)	PUBHHBP 7520: Community Health Assessment (2 credits)	MCR 7404: Project Management for Healthcare and Clinical Research (3 credits) DL
HTHRHSC 7574: Mixed Methods Approaches for Policy-Related Research (3 credits)	STAT 5301: Intermediate Data Analysis I (4 credits)	PUBHHBP 6535: Community Engagement and Collaborative Community Problem-Solving (3 credits) DL	PHR 5560: Success and Leadership in Pharmacy (1.5 credits)
SOCWORK 8406: Mixed Methods Research in Social and Health Sciences (3 credits) DE	STAT 5302: Intermediate Data Analysis II (3 credits)	PUBHEPI 6413: Conducting and Communicating Research in Clinical and Translational Science (2 credits)	PUBHHBP 6558: Policy as a Prevention Strategy (2 credits)
PUBHBIO 7215: Design and Analysis of Clinical Trials (2 credits) DL	VETCLIN 8783: Experimental Design and Data Analysis in Veterinary and Comparative Medicine I (1 credit)	VETCLIN 8781 Research Methods and Grantsmanship (1 credit)	PUBHHMP 7617: Health Services Leadership and Organizational Change (3 credits)
PUBHHBP 7522: Program Planning and Implementation (3 credits)	VETCLIN 8784: Experimental Design and Data Analysis in Veterinary and Comparative Medicine II (1 credit)	VISSCI 7940: Oral Presentation of Scientific Research (1-3 credits)	PUBAFRS 6000: Public Policy Formulation and Implementation (4 credits) DL
PUBHHMP 8671: Health Care Outcomes Measurement (2 credits)	PUBHBIO 5280: Introduction to Genomic Data Analysis (3 credits)	VISSCI 7970: Grantsmanship (2 credits)	PUBAFRS 7572: Policy Simulation and Modeling (3 credits)
HTHRHSC 7883: Responsible Conduct of Research (3 credits)	BMI 5710: Introduction to Biomedical Informatics (3 credits) DL		
PHR 8520: Research Ethics (1 credit)	BMI 5750: Methods in Biomedical Informatics (3 credits) DL		
VISSCI 7960: Ethics in Bio-medical Research (2 credits)	**Research Methods, cont.**		
	GRADSCH 8000: Responsible Conduct of Research (1 credit)		
NURSING 7781: Responsible Conduct of Research. (3 credits) DL	BMI 8150: Rigorous and Reproducible Design and Data Analysis (3 credits) Can be used either for Methods or Analysis		

Appendix 4: Fulfilling Requirements in Responsible Conduct of Research

All trainees, fellows, participants and scholars receiving support through any NIH training grant, career development award (individual or institutional), research education grant or dissertation research grant must receive instruction in the RCR, 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 accessed December 2023.

Courses Offered at Ohio State to Fulfill Those Requirements

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.

The following courses have not been formally reviewed or audited for their fulfillment of NIH requirements but based on a review by the Office of Research, course syllabi indicate they would meet NIH requirements for subject area, format and duration. Note that ethics courses alone typically are not sufficient to meet RCR requirements.[8]

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

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.

Animal Science 7789 - Nutrition Research Ethics

Exploring critical aspects in conducting research, including ethical considerations, authorship, conflicts of interests and intellectual property rights. Cross-listed in HumnNtr 7789. 1 credit. Offered in person Autumn term.

Biomedical Engineering 6983 - Research Ethics

Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues. 2 credits. Offered in person most semesters.

Biopharmacy 5510 - Responsible Conduct in Biomedical Research

The broad intent of this course is to highlight the importance of responsible conduct in biomedical research and to explore how critical ethical thinking can be used to analyze personal decision-making,

[8] The Ohio State "Institutional Responsible Conduct of Research Training Plan" can be found at https://research.osu.edu/research-responsibilities-and-compliance/responsible-conduct-research accessed December 2023.

public regulation and the law concerning advanced biomedical sciences/technologies and their clinical applications. 1-2 credits. Offered Summer.

Biopharmacy 7510 - Professional and 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. 2 credits. Offered Spring Semester.

The Office of Research review also suggests that these courses meet NIH requirements for subject area, format and duration:

BIOPHYS 7600 - First-Year Student Orientation

MCDBIO 7600 - First-Year Student Orientation

MICRBIO 7600 - First Year Student Orientation

MOLGEN 7600 - First-Year Student Orientation

OSBP 7600 - First-Year Student Orientation

Other Training Programs

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://bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml

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

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

Appendix 5: Individual Development Plan

Working with the T32 Program Directors and your mentor, the T32 trainee will convert their training plan into an Individual Development Plan. Administered as a REDCap survey, the IDP plan will organize training, coursework, conference and workshop plans as well as individualized training of the T32 trainee along with target completion dates. Every six months, the lead mentor and T32 co-directors will monitor progress and provide feedback on progress to each T32 trainee.

This plan is outlined below so that it might inform the development of the career development plan included in the application.

Sample IDP for predoctoral Trainee

Training	**Target Completion Date**	**Completion Date**
Required Training Elements: Classes		
PUBHEPI 6412: Basic Principles in Clinical and Translational Science	Offered Fall Semester	
PUBHEPI 6413: Conducting and Communicating Research in Clinical and Translational Science	Offered Spring Semester	
Graduate Interdisciplinary Specialization Courses		
Course: Research Methods Track		
Course: Analysis, Statistics and Informatics Track		
Course: Community and Communication Track		
Course: Leadership and Team Science Track		
Research Ethics (RCR) Training		
Meeting Attendance		
Attendance and poster at CTSI Annual meeting.		
Attendance and poster at ACTS meeting	In Spring	
Workshops		
Tools of the Trade–attend 3 per year		
Lunch and Learn Programs—attend 8 per year		
Career Dinner Series		
Individualized Training Options		
Training 1		
Training 2, etc.		