The OSU Center for Clinical and Translational Science (CCTS) is seeking applicants for the TL1 Mentored Clinical Research Training Program. The TL1 award supports trainees seeking a practical introduction to clinical and translational research. The TL1 award provides full-time research training support for predoctoral candidates and combined health-professional doctorate-master’s candidates and to postdoctoral fellows seeking additional training in clinical research.

The overall goal of the TL1 program is to increase the number of well-trained clinician-scientists who can lead the design and oversight of future clinical investigations critical to transforming the translational process so that new treatments and cures for disease can be delivered to patients faster.

For this award cycle, applications are being accepted for:

One predoctoral awardee conducting clinical and translational research

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

The start date for the TL1 award is August 16, 2017. The one year appointment can be renewed once, for a total possible appointment of two years.

The OSU CCTS TL1 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).

All TL1 awardees will receive:

- Stipend support awarded at the NIH allowed annual maximum;
- Up to $4,000 to defray the cost of the research program and travel to national meetings;
- Access to the CCTS professional services and staff including biostatistics, subject recruitment, and human subjects approval; and
- Access to a training curriculum in clinical and translational research methodology and specialized training seminars.

Predoctoral awardees will also receive tuition support.

Please read all parts of this application carefully before applying.

The application consists of the following:

- Cover Page (1 page)
- Career Development Plan (up to 2 pages)
- Proposed Research Plan (up to 4 pages)
- Letter of support from proposedLead Mentor
- Advising report or PhD transcript
- NIH Biosketches from applicant and mentoring team

If you have any additional questions about this opportunity, please contact Stuart Hobbs at 614-685-5972 or via e-mail at stuart.hobbs@osumc.edu

All application materials must be submitted 11:59 PM on March 27 on line at http://go.osu.edu/TL1Application2017
Before you apply, please note the following information.

Eligibility criteria for TL1 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 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 NRSA support.

2. **Predoctoral Trainees:** Pre-doctoral trainees must have received a baccalaureate degree by the beginning date of their NRSA trainee appointment and must be training at a post-baccalaureate level and enrolled in a program leading to (1) a PhD in a clinical research-related doctoral degree program, or (2) a combined doctoral level professional degree plus a clinical research-related advanced degree, such as a MD, DDS, DO, DNP, PharmD AND MS or MPH, or (3) MD, DDS, DO, DNP, PharmD AND PhD.

Students who are officially enrolled in a qualifying health-professional doctoral program and wish to postpone their professional studies for one year to gain research experience may be appointed to the TL1 research training grant for that period, provided that NRSA eligibility requirements are met. NRSA support is not provided for study leading to a MD, DO, DDS, DNP, PharmD or other similar professional clinical degrees, or a master's degree that is not pursued in a combined program with a professional level doctorate. Individuals currently supported by other Federal funds are not eligible for trainee support from the TL1 program at the same time.

PhD 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 May 7, 2017 (applicants will be asked to provide the date of the scheduled exam). All others should wait for the 2018 RFA to apply for the TL1.

3. **Effort:** Trainees must be able to commit full-time effort in the program at the time of appointment.

4. **Training Support:** No individual trainee may receive more than 5 years of aggregate NRSA support at the pre-doctoral level, including any combination of support from institutional training and individual fellowship awards.

If you have any questions about eligibility, call Stuart Hobbs at 614-685-5972 or via e-mail at stuart.hobbs@osumc.edu

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**TL1 Information Session**

Want to learn more? Bring your lunch and your questions to this information session.

February 3
Noon to 1 PM
Center for Clinical & Translational Science
Prior Hall, Ste. 260, room 240

Register here: [http://go.osu.edu/TL1InfoSession](http://go.osu.edu/TL1InfoSession)
WebEx option!
**Educational Requirements**

**Note:** These requirements should be reflected in your Career Development plan, as appropriate.

- All trainees will take PUBHEPI 6412 - Basic Principles in Clinical and Translational Science and PUBHEPI 6413: Conducting & Communicating Research in Clinical & Translational Science.
- All pre-doctoral trainees are required to enroll the Graduate Interdisciplinary Specialization in Biomedical Clinical and Translational Science (GISBCTS) see: [https://ccts.osu.edu/education-and-training-programs/degree-programs/graduate-interdisciplinary-specialization-in-biomedical-clinical-and-translational-science](https://ccts.osu.edu/education-and-training-programs/degree-programs/graduate-interdisciplinary-specialization-in-biomedical-clinical-and-translational-science) (Exceptions: students enrolled in the MPH in Clinical Translational Science; students in the Biomedical Sciences Graduate Program with a clinical or translational emphasis.)
- Trainees are required to participate in the TL1 Lunch & Learn Program, which currently meets most months on the second Monday of the Month at Noon at the CCTS (times and dates may change in consultation with trainees to find the time most conducive to trainee schedules).
- All trainees are expected to attend the Translational Science Conference sponsored by the Association for Clinical and Translational Science, which will be held in Washington, D.C., in April, 2018. They will have the opportunity to submit abstracts for poster and oral presentations.
- Trainees will have the opportunity to take part in career development activities organized by the CCTS, such as assessments, externships, and internships so that they fully understand the options for biomedical careers in academia, industry, foundations, government, etc.
- 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. Predoctoral 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.
- Predoctoral TL1 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 will complete the CITI Good Clinical Practice training if they have not already done so, as well as other trainings required by NCATS and the NIH.

**TL1 Application Instructions**

Please read these instructions carefully before going online to apply. The application must be completed and submitted online at <http://go.osu.edu/TL1Application2017>.

(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]).

Materials must be submitted online in PDF format.

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

The letter of support should be addressed to Dr. Lawrence Kirschner and incorporated into the one PDF application.

Please make sure you have completed all sections of the entire application. Incomplete applications will not be accepted. No late applications will be accepted.

Please direct all questions to the Program Manager, Stuart Hobbs at 614-685-5972 or stuart.hobbs@osumc.edu
TL1 Application Checklist

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 http://go.osu.edu/TL1Application2017

- Personal Information
  - (Includes Employee/Student ID Number, OSU name. #)
- Campus Address
- Current University Employment Information
- Gender, ethnicity, and additional such reporting information required by the NIH
- Applicant Eligibility checklist (see page 2 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 at http://j.mp/1aCCtHi

- Cover Page
  - Name
  - Graduate Program(s)
  - Proposed Research Project Title
  - Research Project Abstract (250 words)
  - Mentoring Team
- A career development plan (up to 2 pages)
  - Applicant's Background
  - Career Development/Training Activities (see pp. 5-6 and Appendix 2 for more information)
- Proposed Research Plan (up to 4 pages) (see p. 6 and Appendix 1 for more information)
  - Title
  - Statement of the research problem
  - Specific Aims of the Project
  - Research Methods
  - References (not included in the page limit)
- Signature page
  - Applicant
  - Primary Mentor

- A letter of support from your Primary mentor
  The Letter of Support should be included with the other application materials addressed to

  Lawrence Kirschner, MD
  Center for Clinical & Translational Science
  376 W. 10th Ave., Suite 260
  Ohio State University
  Columbus, OH 43210

- NIH Biosketches
  - Applicant
  - Mentoring Team: Primary Mentor & two other mentors

- Current Advising Report (which should include GRE, MCAT or equivalent test results)
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 guidance from the mentor, the applicant will further develop their proposal that describes the clinical research project to be undertaken. Your mentor is responsible for:

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

Your mentor should meet with you regularly at least monthly and attend occasional meetings/trainings for TL1 trainees and mentors organized by the CCTS.

The Primary Mentor will need to sign the signature page and provide a letter of support.

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 lab-based 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.

Career Development Plan (2 page maximum)

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

**Applicant’s Background:** Use this section to provide any additional information not described in the NIH "Biographical Sketch," such as research and/or clinical training experience.

**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 CCTS 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 TL1 program. Here you may include lists of courses, workshops, meetings, etc., as well as mentoring.

You may also describe how you will use the award to gain specific technical skills, again through courses, workshops, mentoring, etc., as appropriate.
This is the section in which to describe how the mentors fit with your training goals.

It is important that you consider and discuss what you would do differently if you receive this award compared to your training without the award.

Research Plan (4 page maximum)

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. 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.

The research plan should be organized as follows:

- **Title** of the proposed project.
- **Statement of the research problem.** This should be an introductory section that places the problem in context in the field. A number of key references should be cited to provide scholarly background. From this section, the readers should be able to determine why it is of interest to examine the proposed problem; in short: what is its significance.
- **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. From this section, the reviewers should be able to assess the feasibility of the proposal in terms of experimental design.
- **The research plan should include key milestones by which reviewers will be able to assess the feasibility of the proposal in terms of time frame for completion and by which the progress of funded projects can be evaluated**
- **References** are not included in the three-page limit.
Supporting Materials

**NIH Biosketches.** The biosketches of the Applicant, the Primary Mentor and the other two 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 TL1 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: [http://grants.nih.gov/grants/funding/424/index.htm#format](http://grants.nih.gov/grants/funding/424/index.htm#format)

NOTE: The Biosketch format changed in 2015, so applicants are well advised to look closely at the new format and make sure their mentor uses the new format.

**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).

Additional information

- A Study Section will make recommendations to the CCTS Executive Committee for funding up to 2 TL1 trainees: one predoctoral and one postdoctoral. Reviewers will evaluate the applications by reviewing: the Trainee, the Training Plan, the Mentors, and the Research.
- All applicants will receive reviewer comments on their applications.
- Brief progress reports will be required at three month intervals.
- Appointed TL1 Trainees are not allowed to simultaneously hold another appointment or position. Trainees must be appointed as a full-time fellow in the PeopleSoft system 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. Ohio State does not withhold taxes from fellowship stipends of domestic students because fellowships are considered awards, not pay for service. The government, though, does consider stipends taxable income. Students should keep track of their annual stipend amount and may be required to pay federal, state, and Columbus city taxes. The Graduate School encourages fellows to consult a tax professional. You may also direct tax questions to the Ohio State Tax Office at 614-292-2311. Graduate Fellows are not eligible to pay into the state retirement system, OPERS, nor will they accrue vacation, or service credits for the length of the award period. Monthly stipends for fellowships are subject to federal, state and local taxes.
Signature Page

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 CCTS terms and conditions governing my potential appointment. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

_________________________________  __________________
Applicant’s signature                     Date

Signature: Primary Mentor

As Primary Mentor, I take responsibility in:

• Guiding and encouraging the design and execution of an original, high quality, clinical research project.
• Supervising the preparation of a final report.
• Providing career development and counseling
• Taking part in CCTS sponsored Mentor Training

I will meet regularly with the trainee and attend occasional meetings/trainings for TL1 trainees and mentors organized by the CCTS.

_________________________________  __________________
Signature of Primary Mentor               Date
Appendix 1. Research Eligibility Requirements

Before you apply, please note the following information.

CLINICAL RESEARCH AND CLINICAL TRIALS

Per regulations, Ruth L. Kirschstein TL1 awards fund clinical research, per the following definitions.

Clinical Research\(^1\): 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\(^2\): 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.

Types of Clinical Trials:

- **Diagnostic trials** determine better tests or procedures for diagnosing a particular disease or condition.
- **Natural history studies** provide valuable information about how disease and health progress.
- **Prevention trials** look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning.
- **Quality of life trials (or supportive care trials)** explore and measure ways to improve the comfort and quality of life of people with a chronic illness.
- **Screening trials** test the best way to detect certain diseases or health conditions.
- **Treatment trials** test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Phases of Clinical Trials: Clinical trials are conducted in “phases.” The trials at each phase have a different purpose and help researchers answer different questions. The OSU TL1 program is funded by the NIH’s National Center for Advancing Translational Science (NCATS). The authorization for NCATS limits specific support for clinical trials only through the end of Phase IIA\(^3\). Therefore, if your research project is a clinical trial, it should fit one of the following descriptions:

- **Phase I trials**— Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).
- **Phase II trials**— Study the biomedical or behavioral intervention in a larger, but still limited, group of people (up to several hundred) to determine efficacy and further evaluate safety.

Phase II trials are further divided:\(^4\)

- **Phase Ila**: Pilot clinical trials to evaluate efficacy (and safety) in selected populations of patients with the disease or condition to be treated, diagnosed, or prevented. Objectives may focus on dose-response, type of patient, frequency of dosing, or numerous other characteristics of safety and efficacy.
- **Phase IIb (Not funded by this award)**: Well controlled trials to evaluate efficacy (and safety) in patients with the disease or condition to be treated, diagnosed, or prevented. These clinical trials usually represent the most rigorous demonstration of a medicine’s efficacy. Sometimes referred to as pivotal trials.

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NCATS provides the additional following distinction: “Phase IIA trials provide data for exposure-response in patients, while Phase IIB trials [not funded by this award] provide data for dose-ranging in patients.”

http://ncats.nih.gov/clinical

**Phase III trials— Not funded by this award.** Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

**Phase IV trials— Not funded by this award.** Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

THE SPECTRUM OF TRANSLATIONAL HEALTH RESEARCH

Per regulations, Ruth L. Kirschstein TL1 awards fund translational research that occupies a particular space on the Clinical & Translational research spectrum: T1 to T4 (excluding clinical trials from Phase IIB to Phase IV).

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.

Translational research involves moving knowledge gained from the basic sciences to its application in clinical and community settings. This concept is often summarized by the phrases “bench-to-bedside” and “bedside-to-community” research. As the concept of translational health research has evolved with practice and time, it is clear that translational research encompasses a bidirectional continuum. For didactic purposes, translational research has often been described in phases of translation, or “T-phases.”

**T0** refers to basic scientific discovery (Not funded by this award). T0 is characterized by the identification of opportunities and approaches to health problems.

**T1** seeks to move basic discovery into a candidate health application. Research examples include: human physiology, first in humans (healthy volunteers), proof of concept, Phase 1 Clinical Trials.

**T2** assesses the value of application for health practice leading to the development of evidence-based guidelines. Research examples include: Phase 2 and Phase 3 Clinical Trials. Clinical trials IIB and following are not funded by this award.

**T3** 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** 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.

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THE SPECTRUM OF TRANSLATIONAL HEALTH RESEARCH (T0 TO T4)

Appendix 2: Core Competencies for Clinical and Translational Investigator Training

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 & 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 & Training**

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

(More information: https://ctsacentral.org/wp-content/documents/CTSA%20Core%20Competencies_%20final%202011.pdf)