THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE

Mentored Research Training Program (TL1)

The OSU Center for Clinical and Translational Science (CCTS) TL1 award supports trainees seeking a practical introduction to clinical and translational research. The TL1 award provides full-time research training support for:

- **Predoctoral** trainees in clinical/translational related graduate degree programs and health-professional doctorate trainees who are enrolled in a Master's or Doctoral program (such MPH or MD/PhD program).

- **Postdoctoral** trainees with clinical/translational related PhDs or trainees with professional doctorates plus a research related degree or trainees with professional doctorates enrolled in or planning to enroll in a research related master's degree program (for example, MPH or MMS).

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. 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).

Applicants may submit a research and career development plan that covers two years or one year. The second year renewal is contingent the trainee making satisfactory progress during the first year.

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.

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

Applicant Eligibility Requirements

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 a PhD in a clinical research-related doctoral degree program, or

a combined doctoral level professional degree plus a clinical research-related advanced degree, such as a MD, DDS, DO, DNP, or PharmD +MS or MPH or MD, DDS, DO, DNP, or PharmD + 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.

Predoctoral 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 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 TL1.

3. **Post-doctoral Trainees**. Postdoctoral trainees must have received, as of the beginning date of the NRSA appointment, a PhD, MD, DDS, or comparable doctoral degree from an accredited domestic or foreign institution. Eligible doctoral degrees include, but are not limited to the following: DMD, DC, DO, DVM, OD, DPM, ScD, EngD, AuD, DPT, DPH, DNSc, PharmD, ND (Doctor of Naturopathy), DSW, PsyD as well as a doctoral degree in nursing research or practice.

   Postdoctoral appointees can be paid up to $50,316 per year. Any stipend due them above that amount will have to be covered by the applicant's department or college, and an acknowledgement of this support from the Department Chair should be included. For NIH established postdoc stipend levels see https://grants.nih.gov/grants/guide/notice-files/not-od-17-003.html

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

5. **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

TL1 Letter of Intent

To be eligible, it is required that you indicate your intention to apply via the TL1 Letter of Intent form.

The purpose of the Letter of Intent is:

1. To let program staff know of your intent to apply for the TL1 in order that they may organize the Study Section.
2. So applicants can fill-out the eligibility checklist to know that they are eligible.

All Letters of Intent must be submitted through the online process by 11:59 PM EST on the date 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 TL1. You should review carefully the eligibility criteria found at the top of this page before applying.

Staff will use the information you submit about your project to organize the TL1 Study section. The information about your project that you submit in the Letter of Intent will not undergo scientific review.

Educational Requirements

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

- All trainees (pre- and post- doctoral) will take PUBHEPI 6412 - Basic Principles in Clinical and Translational Science and PUBHEPI 6413: Conducting & Communicating Research in Clinical & Translational Science.
- **Pre-Doctoral Trainees**
  - All pre-doctoral trainees who are not enrolled in an approved Clinical and Translational academic programs (such as MPH in Clinical Translational Science, the Biomedical Sciences Graduate Program with a clinical or translational emphasis, or the Graduate Interdisciplinary Specialization in Biomedical Clinical and Translational Science [GISBCTS],) will be required to enroll in the GISBCTS.
  - 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.
- **Postdoctoral Trainees**
  - Trainees with clinical degrees only should be or will enroll in a clinical/translational research related master's degree program, such as the Master of Public Health <https://cph.osu.edu/prospective-students/mph > Master of Medical Science <https://medicine.osu.edu/research_ed/medical_fellows/pages/index.aspx> ; Master of Applied Clinical & Preclincial Research <https://online.osu.edu/program/macpr >; Master's Degree in Biomedical informatics <https://medicine.osu.edu/bmi/education/Prospective_Students/MS-and-MPH-Degrees/Pages/index.aspx>
- All trainees are expected to attend 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 complete the CITI Good Clinical Practice training if they have not already done so.

TL1 Application Instructions

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

(The application process is designed so that you can save your information and return to it [you will be given a code, so be prepared to save that information]).

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.

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

TL1 Application Checklist

This form can be used 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, 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
- ☐ Mentoring and career development plan (up to 2 pages)
  - ☐ Applicant's Background
  - ☐ Career Development/Training Activities/Mentoring (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
  - ☐ Department Chair
- ☐ A letter of support from your Primary mentor
  The Letter of Support should be **included with the other application materials** addressed to

  Joanna Groden, PhD
  Lawrence Kirschner, MD, PhD
  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
- ☐ Predocs: Current Advising Report (which should include GRE, MCAT or equivalent test results)
- ☐ Postdocs: transcript from doctoral granting institution

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. Your mentor is responsible for:

- Guiding and encouraging the design and execution of an original, high quality, clinical research project.
- Providing career development and counseling.
- Attending CCTS Mentor training.
- Meeting with you regularly (at least monthly).
- Attending occasional meetings/trainings for TL1 trainees and mentors organized by the CCTS.

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.

Mentoring and Career Development Plan

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

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.

Mentoring: 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

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. Or:

2) Epidemiological and behavioral studies. Or:

3) Outcomes research and health services research.

The research plan should be organized as follows:

- <u>Title</u> of the proposed project.
- <u>Statement of the research problem</u>. 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.
- <u>Specific Aims of the Project</u>. An outline that lists the individual experimental issues that are to be addressed. Each should be framed in terms of an hypothesis.
- A brief des**c**ription of the <u>Methods</u> 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 feasibility of the proposal both in terms of experimental design and time frame for completion.
- <u>References</u> are **not** included in the page limit.

Supporting Materials

<u>NIH Biosketches.</u> 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
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.

<u>Current Advising Report</u>. 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).

<u>Transcript from Doctoral Granting Institution</u>. Postdoctoral applicants should provide a transcript to document their doctoral degree.

Additional information

- A Study Section will make recommendations to the CCTS Executive Committee for funding 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.
- 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 and Postdoctoral Fellows receive stipends related to their academic programs. They do not render services for pay, and therefore are not considered employees and 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. Depending on a fellow's residency status, their taxes may or may not be withheld from their stipend. 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 > More information can also be found on the Postdoc pages of the College of Medicine website: http://medicine.osu.edu/research_ed/postdoc/current_postdocs/benefits_compensation/pages/index.aspx#understanding
- **Postdoctoral Appointees and NIH Payback Agreement**. For individuals receiving postdoctoral support under individual fellowships or institutional research training grants, a payback obligation is incurred for the first 12 months of Kirschstein-NRSA support. However, the 13th and subsequent months of postdoctoral NRSA supported research training serves to pay back this obligation month by month. A Payback Agreement (PHS 6031) is required but only for the initial 12-month postdoctoral support period. Awarded postdoctoral trainees will be asked to fill out and submit an NIH Payback Agreement. For more information see: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.4_payback_requirements.htm?Highlight=payback%20requirements
  The payback form can be found here: https://grants.nih.gov/grants/funding/416/phs6031.pdf

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 IIa: 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.

---

[1] http://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm accessed February 2016.
[2] http://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm accessed February 2016.
[3] http://ncats.nih.gov/files/PHS-act.pdf accessed February 2016.
[4] http://www.virginia.edu/vpr/irb/HSR_docs/CLINICAL_TRIALS_Phases.pdf accessed February 2016.

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[5]

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[6]

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.
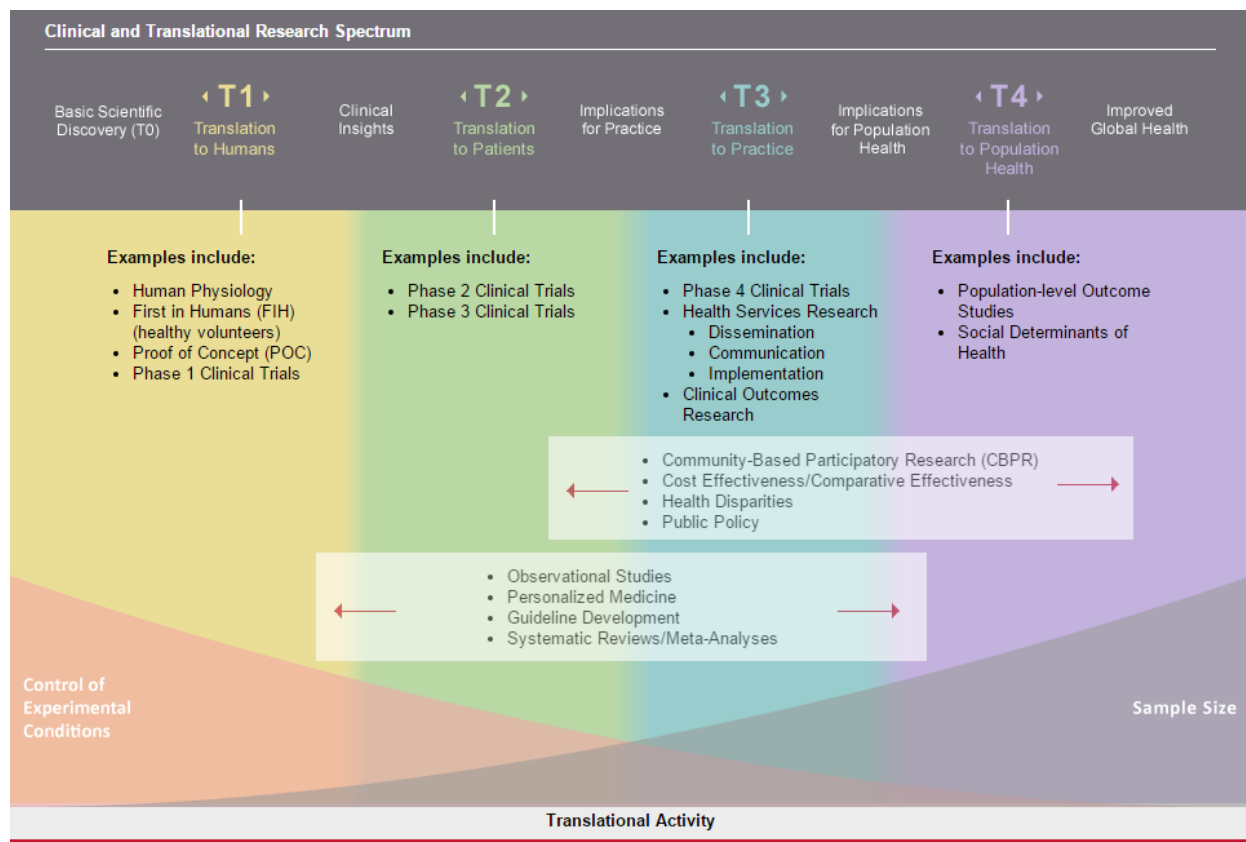
Below are definitions and more information.

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 pysiology, 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. Clincial 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 dessemination, 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 determinatns of health.

---

[5] http://ncats.nih.gov/clinical accessed February 2016.

[6] 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 June 2015.

THE SPECTRUM OF TRANSLATIONAL HEALTH RESEARCH (T0 TO T4)

Clinical and Translational Research Spectrum

| Basic Scientific Discovery (T0) | ‹ T1 › Translation to Humans | Clinical Insights | ‹ T2 › Translation to Patients | Implications for Practice | ‹ T3 › Translation to Practice | Implications for Population Health | ‹ T4 › Translation to Population Health | Improved Global Health |

Examples include:

- Human Physiology
- First in Humans (FIH) (healthy volunteers)
- Proof of Concept (POC)
- Phase 1 Clinical Trials

Examples include:

- Phase 2 Clinical Trials
- Phase 3 Clinical Trials

Examples include:

- Phase 4 Clinical Trials
- Health Services Research
  - Dissemination
  - Communication
  - Implementation
- Clinical Outcomes Research

Examples include:

- Population-level Outcome Studies
- Social Determinants of Health

- Community-Based Participatory Research (CBPR)
- Cost Effectiveness/Comparative Effectiveness
- Health Disparities
- Public Policy

- Observational Studies
- Personalized Medicine
- Guideline Development
- Systematic Reviews/Meta-Analyses

Control of Experimental Conditions

Sample Size

Translational Activity

Source: http://catalyst.harvard.edu/pathfinder/ accessed June 2015

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 divers 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://www.ctsacentral.org/documents/CTSA%20Core%20Competencies_%20final%202011.pdf)

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

The goal of the Graduate Interdisciplinary Specialization in Biomedical Clinical and Translational Science (GISBCTS) 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 OSU Graduate School at this address: https://gradsch.osu.edu/pursuing-your-degree/career-development/degree-options/applying-graduate-minors-and

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

GISBCTS 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 & Communication	Leadership & Training
BSGP 8050: Research Techniques & Resources (4 credits)	PUBHBIO 6280: Practical Biostatistics for Biomedical Laboratory Researchers (3 credits)	HTHRHSC 7888: Health and Rehabilitation Science Grand Rounds Intro (1 credit)	NURSING 7404: Leadership in Healthcare & Clinical Research Project Management ONLINE (3 credits)
NURSING 8780: Research Methods I (3 credits)	PUBHBIO 6210: Design & Analysis of Studies in the Health Sciences I (online available) (3 credits)	BSGP 7070: Fundamentals of Grant Writing I (4 credits)	NRSPRCT 8400: Leadership Throughout Organizations & Systems (3 credits)
NURSING 7781: Responsible Conduct of Research. ONLINE (3 credits)	PUBHBIO 6211: Design & Analysis of Studies in the Health Sciences II (3 credits)	BSGP 7080: Fundamentals of Grant Writing II (2 credits)	NRSPRCT 8401: Strategic Macrosystem Management for the Doctor of Nursing Practice (3 credits)
NURSING/PHARMACY 7782 Research Design and Methods for Clinical and Preclinical Research. ONLINE (3 credits)	PUBHBIO 7245: Biostatistical Collaboration (2 credits)	Nursing 6110: Health Literacy (2 credits)	HTHRHSC 7300: Management & Leadership in Health Sciences (3 credits)
NRSPRCT 8780: Clinical Effectiveness & Translation in Clinical Science (3 credits)	PSYCH 6810: Statistical Methods in Psychology I (4 credits)	PUBHHBP 7520: Community Health Assessment (2 credits)	HTHRHSC 7350: Issues & Policy in Health Sciences (3 credits)
PUBHEPI 7412: Principles & Procedures for Human Clinical Trials (3 credits)	PSYCH 6811: Statistical Methods in Psychology II (4 credits)	PUBHHBP 7544: Fundamental Determinants of Population Health & Implications for Public Health (3 credits)	PHR 5560: Success & Leadership in Pharmacy (1.5 credits)
PUBHHBP 7532: Program Evaluation in Public Health (3 credits)	STAT 5301: Intermediate Data Analysis I (4 credits)	PUBHHBP 7558: Social Ecological Strategies in Prevention (2 credits)	PUBHHMP 7617: Health Services Leadership & Organizational Change (3 credits)
PUBHHBP 7534: Research Methods in Health Behavior & Health Promotion (3 credits)	STAT 5302: Intermediate Data Analysis II (3 credits)	PUBHEPI 6413:Conducting & Communicating Research in Clinical & Translational Science (2 credits)	PUBAFRS 6000: Public Policy Formulation & Implementation (4 credits)
PUBHHBP 7522: Program Planning & Implementation (3 credits)	VETCLIN 8783: Experimental Design & Data Analysis in Veterinary & Comparative Medicine I (1 credit)	VISSCI 7940: Oral Presentation of Scientific Research (1-3 credits)	
PUBHHMP 8671: Health Care Outcomes Measurement (2 credits)	VETCLIN 8784: Experimental Design & Data Analysis in Veterinary & Comparative Medicine II (1 credit)	VISSCI 7970: Grantsmanship (2 credits)	
PUBHHMP 7678: Approaches to Health Services Research (3 credits)		VETCLIN 8781 Research Methods and Grantsmanship (1 credit)	
VISSCI 7960: Ethics in Biomedical Research (2 credits)			
PHR 8520: Research Ethics (1 credit)			

Course Descriptions

Core Course:

College of Public Health – Epidemiology

PUBHEPI 6412: Basic Principles in Clinical and Translational Science
Identification of clinical and translational research issues, assessment of the literature, ethically responsible research, cross-disciplinary training and mentoring. 2 units.

Other Courses to Select From:

College of Medicine

School of Health and Rehabilitation Sciences

HTHRHSC 7300: Management & Leadership in Health Sciences
Application of management and leadership principles for the development of administration of allied health departments in the health care system. 3 units

HTHRHSC 7350: Issues and Policy in Health Sciences
Allied health professionals must increasingly face many complex issues that affect healthcare. It is crucial that graduate students be able to critically examine a broad range of issues and understand various positions and their implications. 3 units

HTHRHSC 7888: Health and Rehabilitation Science Grand Rounds Intro
Students develop skills in analyzing, discussing and synthesizing health and rehabilitation research. Students present their own research and critically appraise faculty research. Discussion and demonstration of leadership will occur. 1 unit.

Biomedical Science Graduate Program

BSGP 7070: Fundamentals of Grant Writing I
Introduce students to the basic principles of grant writing. 4 units.

BSGP 7080: Fundamentals of Grant Writing II
Introduce students to principles of grant writing. Students will also write their own grants in the style of NIH submissions. Students will also learn about the grant review process. 2 units

BSGP 8050: Research Techniques and Resources
Survey of research techniques used to solve problems in modern cell and molecular biology, immunology, biochemistry, microbiology, microscopy, laboratory safety, and related available resources. 4 units.

College of Nursing: Nursing Practice

NRSPRCT 8400: Leadership Throughout Organizations & Systems
Socialization to leadership and excellence in multiple dimensions of the Doctor of Nursing Practice role. 3 units

NRSPRCT 8401: Strategic Macrosystem Management for the Doctor of Nursing Practice
Integration of theoretical, leadership and communication principles into strategic management strategies for evidence based, innovative macro system health care optimization for selected populations.3 units

NRSPRCT 8780: Clinical Effectiveness and Translation in Clinical Science
Theoretical underpinnings of nursing knowledge and critical appraisal of clinical relevant research related to clinical effectiveness and translational science concepts. 3 units.

College of Nursing

NURSING 6110: Health Literacy
Examination and analysis of issues of low health literacy, including populations at risk, research, measurement tools, writing in plain language; health communication techniques; and organizational approaches. 2 units.

Nursing 7404: Leadership in Healthcare and Clinical Research Project Management
Principles of project management, strategic planning, and leadership in healthcare, clinical research and regulatory settings. 3 credits. Summer. ONLINE

Nursing 7781: Responsible Conduct of Research
Concepts and policies for the responsible conduct of research (RCOR), Institutional Review Boards, and dissemination of findings. 3 credits Autumn/Spring. ONLINE, face-to-face as needed

Nursing/Pharmacy 7782 Research Design and Methods for Clinical and Preclinical Research
Study of research design and methods used in clinical and preclinical research. Measurement issues, bias and confounding, statistical considerations, evaluation of published clinical and preclinical research designs, and protocol and proposal development. 3 credits. Autumn/Spring. ONLINE

NURSING 8780: Research Methods I
Survey of quantitative design and measurement approaches relevant to nursing and health. Emphasis is placed on experimental designs and measurement in nursing and health research. 3 units.

College of Pharmacy

PHR 5560: Success & Leadership in Pharmacy
Explore the meaning of success and leadership, attributes of successful leaders and what can be done to be a successful leader. 1.5 units

PHR 8520 – Research Ethics
Basic concepts of integrity in the process of research. The course fulfills NIH requirement for research ethics. 1 unit.

Pharmacy/Nursing 7782 Research Design and Methods for Clinical and Preclinical Research
Study of research design and methods used in clinical and preclinical research. Measurement issues, bias and confounding, statistical considerations, evaluation of published clinical and preclinical research designs, and protocol and proposal development. 3 credits. Autumn/Spring. ONLINE

College of Public Health – Biostatistics

PUBHBIO 6210: Design and Analysis of Studies in the Health Sciences I
Theory and application of basic statistical concepts for design of studies in health sciences, integrated with statistical software applications. In class & online sections available. 3 units.

PUBHBIO 6211: Design and Analysis of Studies in the Health Sciences II
A second course in applied biostatistical methods with an emphasis on regression methods commonly used in the health sciences. The focus is on linear regression and ANOVA. Integrated with the use of computer statistical packages. 3 units.

PUBHBIO 6280: Practical Biostatistics for Biomedical Laboratory Researchers
Introduction to statistical principles and methods appropriate for experimental laboratory data with applications in biomedical sciences. 3 units

PUBHBIO 7245: Biostatistical Collaboration
Basic biomedical research methodologies; collaborate with biomedical researchers to design experiments and plan analyses; protocol preparation; professional skills development; statistical report preparation. 2 units.

College of Public Health – Epidemiology

PUBHEPI 6412: Basic Principles in Clinical and Translational Science
Identification of clinical and translational research issues, assessment of the literature, ethically responsible research, cross-disciplinary training and mentoring. 2 units.

PUBHEPI 6413: Conducting and Communicating Research in Clinical and Translational Science
Design and writing of protocol, study methods and implementation, community engagement, informatics, translational teamwork. Scientific communication skills and dissemination of clinical and translational science. 2 units.

PUBHEPI 7412: Principles and Procedures for Human Clinical Trials
Principles and procedures for clinical professionals in the design, conduct and analysis of human clinical trials. 3 units.

College of Public Health – Health Behavior and Health Promotion

PUBHHBP 7520: Community Health Assessment
Models of community health assessment; skills in identifying, analyzing and integrating information concerning community resources and needs. 2 units.

PUBHHBP 7522: Program Planning and Implementation
Planning and implementation of programs to address public health issues in defined populations; development of a health promotion program for a specific community partner. 3 units

PUBHHBP 7532: Program Evaluation in Public Health
Examination of evaluation models for public health programs; exploration of philosophical and scientific issues in evaluation; and skill building in both qualitative and quantitative evaluation methods. 3 units.

PUBHHBP 7534: Research Methods in Health Behavior and Health Promotion
Social science research methods emphasizing methods used to assess the dimensions of health-relevant behaviors and community-based prevention research. 3 units.

PUBHHBP 7544: Fundamental Determinants of Population Health and Implications for Public Health
Presents the ideas that population health is determined by factors outside of health care and individual behavior occurs within a social context. 3 units.

PUBHHBP 7558: Social-Ecological Strategies in Prevention
Community health promotion strategies using policy, systems, and environmental change perspectives. 2 units

College of Public Health – Health Services Management and Policy

PUBHHMP 7617: Health Services Leadership and Organizational Change.
Overview of leadership and organizational change theories, as well as the application of those theories to case studies in health sector organizations. 3 units

PUBHHMP 7678: Approaches to Health Services Research
Overview of the field of health services research and the role of health services research in improving health care delivery. 3 units.

PUBHHMP 8671: Health Care Outcomes Measurement
Evaluation of specific techniques for measuring outcomes in clinical and health services research studies. 2 units.

John Glenn School of Public Affairs

PUBAFRS 6000: Public Policy Formulation and Implementation
Overview of the public policy process and the historical and contemporary context in which policy making and implementation are carried out in the United States at the federal, state and local levels. 4 units.

Psychology

PSYCH 6810: Statistical Methods in Psychology I
Basic concepts of descriptive and inferential statistics; includes estimation, hypothesis testing, non-parametric techniques, and analysis of variance. 4 units.

PSYCH 6811: Statistical Methods in Psychology II
Simple linear regression and correlation, multiple linear regression, interactions; introduction to other related methods such as nonlinear regression and random effects models. 4 units.

Statistics

STAT 5301: Intermediate Data Analysis I
The first course in a two-semester non-calculus sequence in data analysis covering descriptive statistics, design of experiments, probability, statistical inference, one-sample t, goodness of fit, two sample problem, and one-way ANOVA. 4 units.

STAT 5302: Intermediate Data Analysis II
The second course in a two-semester sequence in data analysis covering simple linear regression (inference, model diagnostics), multiple regression models, variable selection, model selection, two-way ANOVA, mixed effects model. 3 units.

College of Veterinary Medicine

VETCLIN 8781: Research Methods and Grantsmanship
Introduction to grantsmanship, including the development of a research question, use of appropriate statistical methods, and the preparation of a research proposal that will be reviewed by the class. 1 unit.

VETCLIN 8783: Experimental Design & Data Analysis in Veterinary & Comparative Medicine I
Principles and practice of study designs and data analyses commonly used in veterinary and comparative medical research. 1 unit.

VETCLIN 8784: Experimental Design & Data Analysis in Veterinary & Comparative Medicine II
Introduction to the principles and practice of study designs and data analyses commonly used in veterinary and comparative medical research. 1 unit.

Vision Science

VISSCI 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. 2 units.

VISSCI 7970: Grantsmanship
The structure of the National Institutes of Health, the principles of good grantsmanship, and description of the grant review process. Emphasis focused on Mentored Clinical Scientist Development Award (K23) and Research Project Grant (R01). 2 units.

VISSCI 7940: Oral Presentation of Scientific Research
Student gives a talk based on his/her research or scholarship and improves his/her speaking skills. 1-3 units