

# **TL1 Mentored Career Development Grant**

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# TL1 Faculty Directors

## TL1 Director



**Ginny Bumgardner, MD, PhD**  
Professor & Associate Dean,  
College of Medicine  
Director, Medical Student Research  
Director, Department of Surgery  
Research Training Program

## TL1 Co-Director



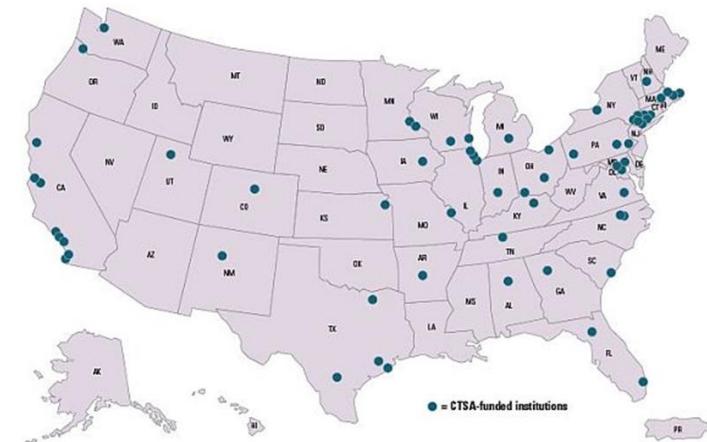
**Lawrence Kirschner, MD, PhD**  
Professor, College of Medicine  
Director, MSTP Program

# Outline

- The Center for Clinical & Translational Science
- The TL1 Grant & Clinical & Translational Science
- Eligibility
- Benefits of the TL1
- Applying for the TL1
- The TL1 Study Section

# Who Are We?

- Center for Clinical and Translational Science
- One of ~60 centers in the US
- Funded by the Clinical & Translational Science Award (CTSA) program
- Part of the National Center for Advancing Translational Science (NCATS)



1,000s of  
diseases

Treatments  
for ~ 500

Toll: \$2 million  
Time to Cross: 18 years  
(or never)

## CROSSING THE VALLEY OF DEATH

A chasm has opened up between biomedical researchers and the patients who need their discoveries. **Declan Butler** asks how the ground shifted and whether the US National Institutes of Health can bridge the gap.

*Nature*. 453. June 12, 2008  
NCATS

# NCATS to CCTS

## Translation

*Multi-step process of turning observations in the lab, clinic, and community, into interventions that improve peoples' lives in the form of...*

Diagnostics



Therapeutics



Medical Procedures



Devices



Behavioral Changes



Source: NCATS

# TL1

- Institutional NIH Career Development Award funded by CTSA program of NCATS
- For investigators who have made a commitment to conduct either patient-oriented or translational research
- Targeted to predoctoral and postdoctoral researchers
- Goal: Prepare for successful clinical / translational research career

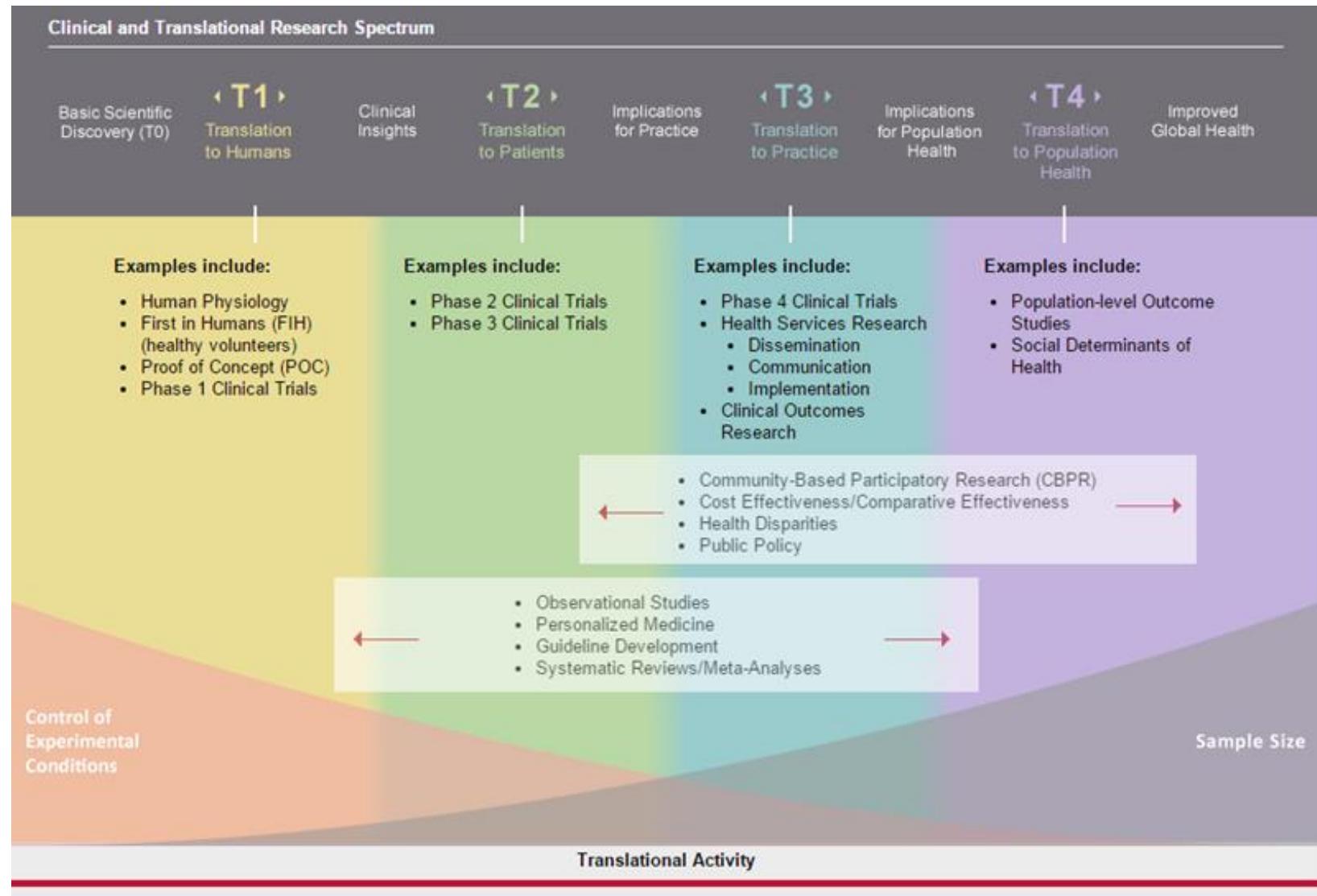
# Clinical Research

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 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

Source: <http://grants.nih.gov/grants/glossary.htm#ClinicalResearch>

# Translational Research



Sources:  
Definition: <https://ncats.nih.gov/translation/spectrum>  
Image: <http://catalyst.harvard.edu/pathfinder/>

# TL1 Award: Eligibility

Candidates must be

- U.S. citizens or non-citizen nationals,
- or an individual lawfully admitted for permanent residence who possesses a permanent resident card, or some other verification of legal admission as a permanent resident prior to appointment.

# TL1 Award: Predoc Eligibility

Must be 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:  
MS or PhD

# TL1 Award: Predoc Eligibility

Must be either (a) post-candidacy

OR

(b) have a candidacy exam scheduled before  
August 15, 2021

Applicants will be asked to supply date of  
candidacy exam

# TL1 Award: Postdoc Eligibility

- Must have received, as of the beginning date of the NRSA appointment, a PhD, MD, DDS, DVM, or comparable doctoral degree from an accredited domestic or foreign institution.

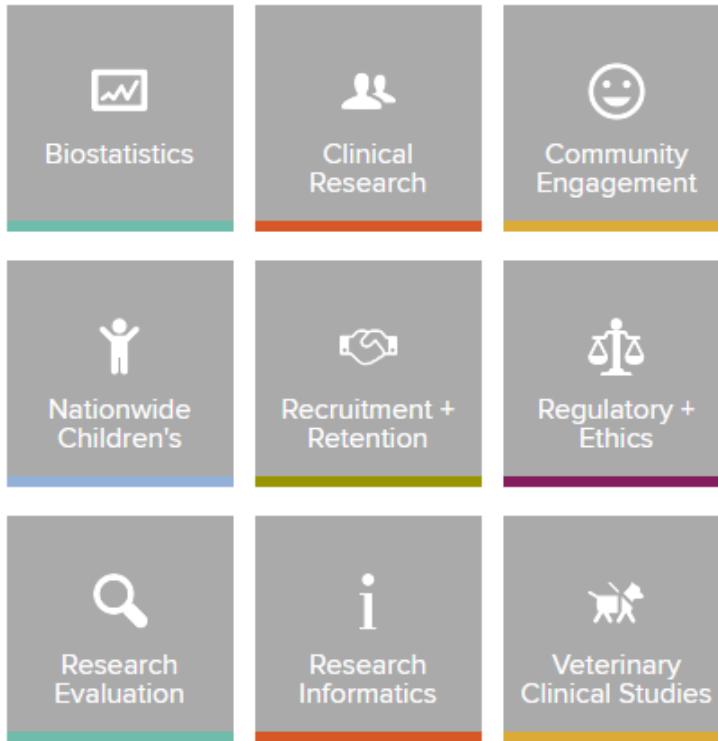
# TL1 Award: Benefits

- Stipend support awarded at the NIH allowed annual maximum;
- Research expense support
  - Predocs: Research: \$2,000 ; Travel: 300
  - Postdocs: Research: \$4,000 ; Travel \$1,400
- Tuition and fees paid by graduate school (predoc)

# TL1 Grant

- TL1 is for up to two years
  - Training and research plans should reflect that time line
  - Trainee progress is monitored by program faculty
  - Executive Committee of CCTS appoints trainees to TL1 and re-appoints to 2<sup>nd</sup> year after hearing brief presentation
- Can apply for one year TL1

# CCTS Research Services



<https://ccts.osu.edu/content/research-consultation>

# Join the CCTS!

ccts.osu.edu



ABOUT US NEWS AND EVENTS

Research  
Consultation

Funding  
Opportunities

Training and  
Career Development

Research  
Toolkit

Participate in  
Research

Become a  
Member



## BECOME A MEMBER

Sign up to become a CCTS Member

## RESEARCH CONSULTATION

Discover a variety of services provided by CCTS that benefit clinical studies

## RESEARCH TOOLKIT

Access a collection of resources for researchers and research coordinators

## VOUCHER PROGRAM

Learn how to apply for a voucher supporting OSU and NCH Investigators



## FUNDING OPPORTUNITIES

Developing cross-disciplinary research teams, technologies and methodologies.



## PARTICIPATE IN RESEARCH

Research study volunteers are essential in shaping the future of medicine.

## News

2018 Career Training Programs  
Mentored Research Training Programs now accepting applications

Celebrating Dr. Michael Para  
CCTS Recruitment Program Director  
celebrates 30 year anniversary of study

[VIEW ALL STORIES](#)

## Events

May 29  
FDA Conference: IND/IDE Overview and Audit

<https://ccts.osu.edu/node/402>



4:01 PM  
5/24/2018

# Center for Biostatistics Services

Request consultation using Project Request Form on Center homepage

<https://medicine.osu.edu/departments/biostatistics/service-request-form>

Formerly offered walk-in biostatistics consultation at the CCTS.

# TL1 Benefits: Training Curriculum

- Monthly Lunch & Learn that cover a variety of topics on clinical and translational science and research (currently on the first Tuesday of each month)
- Foundations Course Sequence:
  - PUBHEPI 6412: Basic Principles in Clinical & Translational Science (offered in the Fall Semester)
  - PUBHEPI 6413: Conducting & Communicating Research in Clinical and Translational Science (offered in the Spring Semester).
- The Annual meeting of the Association of Clinical and Translational Science (typically held in April in Washington, DC)
- Your Individualized career development and mentorship plan

# Training Curriculum: Graduate Interdisciplinary Specialization in Biomedical Clinical & Translational Science

- The GISBCTS require a minimum of 10 and no more than 20 semester credit hours of graduate level coursework taken with nine credit hours taken outside of the student's home program in at least three courses.
- Five courses Required: CCTS core course (PUBHEPI 6412) plus a course from each of four skills areas. Courses already taken as part of your PhD can count to the GIS

<https://ccts.osu.edu/content/gis-biomedical-clinical-and-translational-science?highlight=gis>

# Training Curriculum : Postdocs

- All TL1 Trainees take the core course sequence: pre and postdocs
- Postdoctoral awardees with research degree are not required to have further courses
- Postdocs with MD or other professional degree are required to be in research degree program, such as MMS or MPH

# TL1 Letter of Intent

- Due: early October

The purpose of the Letter of Intent is:

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

# TL1 Letter of Intent

- Asks You to identify the clinical and translational aspects of your research.

Variable: resrch\_describ

Which of the following best describes your research?

\* must provide value

Patient-oriented research. Research conducted with human subjects or on material of human origin, such as tissues, specimens, and cognitive phenomena

Epidemiological and behavioral studies.

Outcomes research and health services research.

Translational Research

reset

Variable: t\_spectrum

Where does your project fit on the clinical/translational research spectrum?

\* must provide value

T0: Basic Research. Refers to basic biomedical discovery research that can reveal fundamental mechanisms of biology, disease, or behavior. Every stage of translational research builds upon and informs basic research. This award does not fund T0 research. Pre-clinical research (testing may include animal models, human or animal tissues, computer assisted simulations of drug, device or diagnostic interactions within living systems) that connects the basic science of disease with human medicine is eligible.

T1: Preclinical Research. Preclinical research connects the basic science of disease with human medicine. It seeks to move basic discovery into a candidate health application. Research examples include 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 or animal models; computer assisted simulations of drug, device or diagnostic interactions within living systems; testing of interventions for safety and effectiveness in those with and without disease; behavioral and observational studies; outcomes and health services research.

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. (Clinical trials IIB and higher are not funded by this award).

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. Phase 4 Clinical Trials are also part of T3, but are not funded by this award.

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.

# Full Application

- Due early December
- Online RedCap form for name, address, eRA commons name (if you have it), ORCID id, mentoring team, demographics
- Career Development Plan (up to 2 pages)
  - Applicant Background
  - Career Development/Training Activities
- Research Plan (up to 4 pages)
- Other Parts:
  - NIH Biosketches: applicant & mentoring team
  - Letter of Support
  - Signatures

# TL1 Award: Application

## Personal Statement

- Who are you? Why have you chosen a research career?
- Your previous research experience?
- How you believe this training program will change the trajectory of your career or enhance your movement towards your goals

# TL1 Award: Application

## **Proposed Career Development Plan\***

- Where are the gaps in your training that this program will help fill
- How will you fill those gaps. Be as specific as possible.
- How you will meet the NIH requirements for instruction in the responsible conduct of research

**\*This is a career Development Grant**

# TL1 Award: Application

## Research Plan – 4 pages

- Statement of the Research Problem (significance)
- Specific Aims – frame each as an hypothesis
- Methods – good idea to include a list of milestones/benchmarks for success anticipated to achieve the aims
- References (not included in page count)

# Integrating Special Populations

Special Populations encompasses a multitude of groups and communities that are commonly underrepresented in clinical and translational research, and the CCTS is actively working to correct this problem. These groups include, but are not limited to, the following:

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

Not a scored category but applicants are encouraged to think about how their research could include one or more of these groups.

# TL1 Award: Mentoring\*

## Lead mentor

Guiding and encouraging the design and execution of an original, high quality, clinical research project;

Providing career development and counseling

**\*This is a *mentored* career development grant**

# TL1 Award: Mentoring\*

## Two Additional Mentors

Complementary to the interests of the lead mentor

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.
3. The mentoring team must include someone who is either a population focused or lab-based researcher.

**\*This is a *mentored* career development grant**

# Other Parts of the Application

- Current Advising Report (predoc)
- Doctoral Transcript (postdocs)
- NIH Biosketches
  - Format for pre- & post- doctoral fellowships
  - Use Personal Statement to make your case
- Letter of Support

# TL1 Award: Signature Page

Applicant

Lead Mentor

Department Chair



Do not wait until the last minute.

# TL1 Award: Study Section

Members drawn from across the health sciences

Scored using NIH critique form

Overall score and subsection scores

Scored 1 to 9

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

# TL1 Award: Study Section

Evaluation Criteria:

Trainee

Training Plan

Mentors

The Research— including clinical/translational aspects

# Questions?

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