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)
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.
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
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

Clinical and Translational Research Spectrum

T1: Translation to Humans
- Examples include:
  - Human Physiology
  - First in Humans (FIH) (healthy volunteers)
  - Proof of Concept (POC)
  - Phase 1 Clinical Trials

T2: Translation to Patients
- Examples include:
  - Phase 2 Clinical Trials
  - Phase 3 Clinical Trials

T3: Translation to Practice
- Implications for Practice
  - Examples include:
    - Phase 4 Clinical Trials
    - Health Services Research
    - Dissemination
    - Communication
    - Implementation
    - Clinical Outcomes Research

T4: Translation to Population Health
- Implications for Population Health
  - Examples include:
    - Population-level Outcome Studies
    - Social Determinants of Health

Control of Experimental Conditions

Sample Size

Translational Activity

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 2nd 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
Center for Biostatistics Services

Request consultation using Project Request Form on Center homepage

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

Formally 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)

• 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.
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

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TL1 Award: Study Section

Evaluation Criteria:

Trainee

Training Plan

Mentors

The Research— including clinical/translational aspects
Questions?
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