KL2 Mentored Career Development Award

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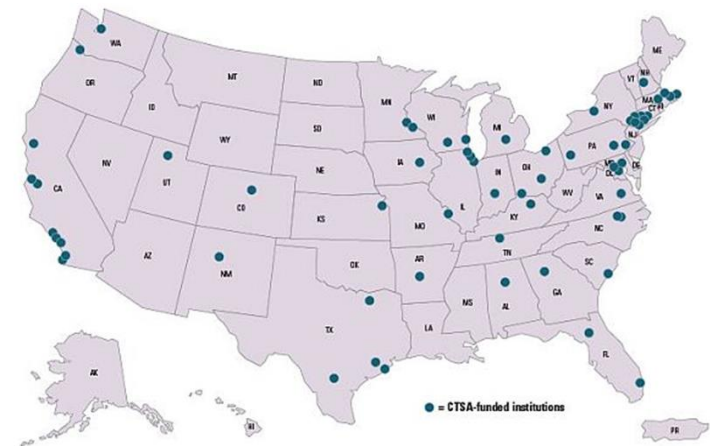(614) 292-1715
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CTSA Clinical & Translational® Science Awards

Accelerating Discoveries Toward Better Health

THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE

Outline

- The Center for Clinical & Translational Science
- The KL2 Grant & Clinical & Translational Science
- Eligibility
- Benefits of the KL2
- Applying for the KL2
- The 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 newest NIH center: National Center for Advancing Translational Science (NCATS)

1,000s of diseases

Treatments for ~ 500

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

Nature. 453. June 12, 2008
NCATS

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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...
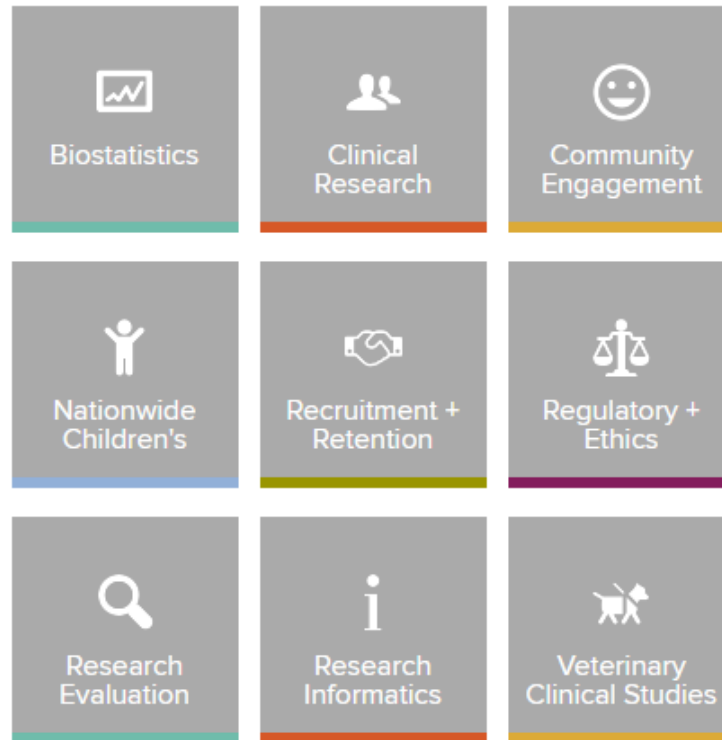
| Diagnostics | Therapeutics | Medical Procedures | Devices | Behavioral Changes |

Source: NCATS

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CCTS Research Services

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

Join the CCTS!

ccts.osu.edu

KL2 Award

- 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 assistant professors on tenure or clinical track

- Up to three years into appointment

- 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

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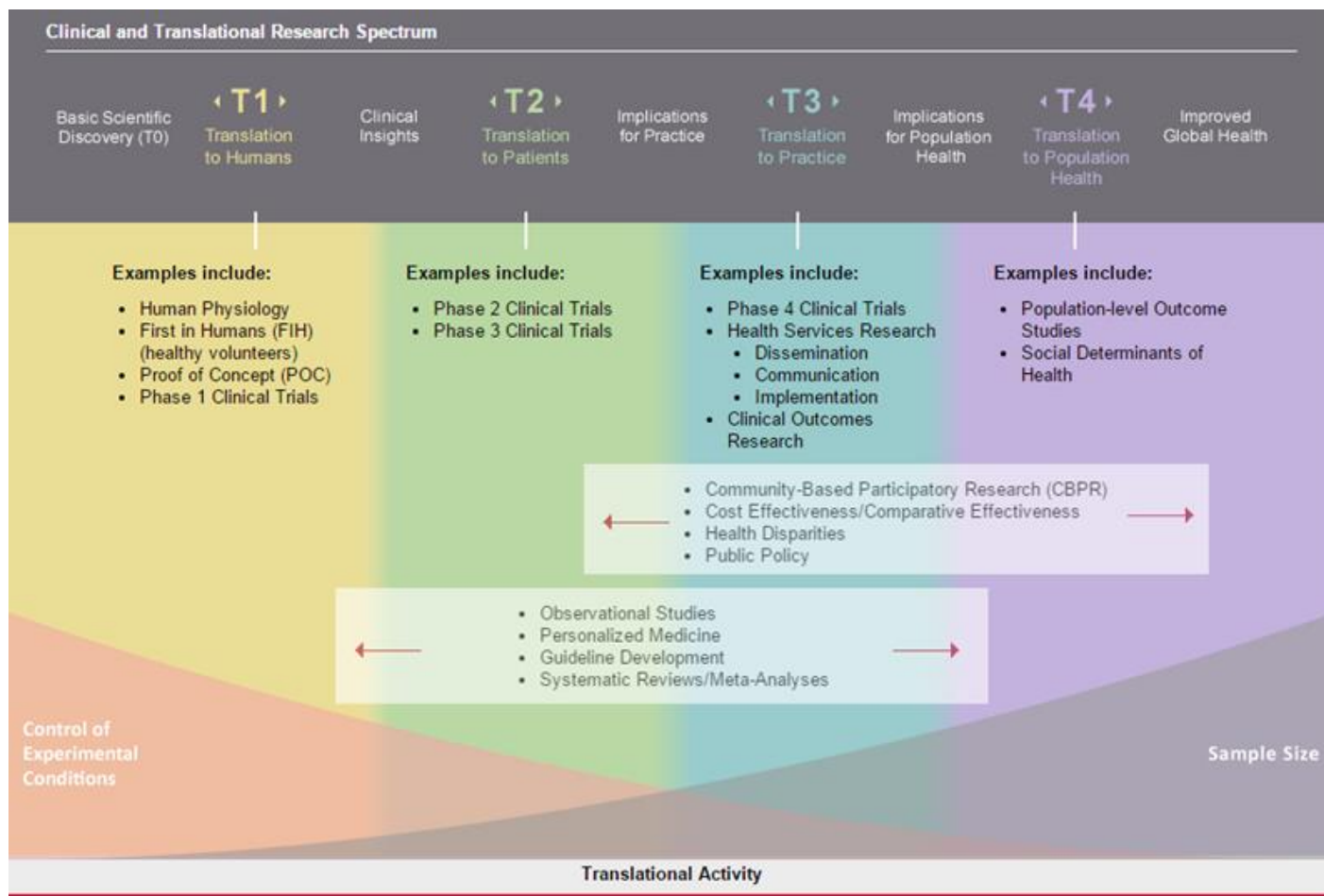
Translational Research

Translation

- The process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

Translational Science

- The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Source: https://ncats.nih.gov/translation/spectrum

Translational Research Spectrum

Career Development Awards

Davis Bremer Path to K	vs	KL2
• For early career physician-scientists/ investigators committed to a career in academic medicine; who have not previously been a PI on an NIH individual or institutional K, or R01 Award or received a pilot award from the CCTS.		• For junior faculty who have not yet been a PI on a major federal or private sector research grant or who have not previously received a K award.
• Applicants must be physicians with OSU Wexner Medical Center credentials.		• For clinical and translational researchers with a research or health-professional doctoral degree.
• Provides salary and fringe support for up to a 10% FTE (capped at $15,000) and up to $50,000 in research expense support for one year.		• Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support).
• Aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards.		• Support to develop an R grant or individual K to fund research at the conclusion of the KL2 funding.
• WHO SHOULD APPLY? If you picture yourself using the data from your project to apply for a K award in two to three years, apply for the Pre-K Davis Bremer.		• WHO SHOULD APPLY? If you picture yourself using the data from the proposed project to apply for an R grant in two to three years, apply for the KL2.

KL2 Award: Eligibility

Junior faculty on the tenure-track or clinical-track with three years since their initial appointment are eligible to apply.

Candidates must have a research or health-professional doctoral degree or its equivalent (PhD, DDS, DVM, OD, MD, DO, PharmD, etc.)

KL2 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 (a Green Card), or some other verification of legal admission as a permanent resident prior to appointment.

KL2 Award: Eligibility & Previous Funding

- You are NOT eligible to participate as KL2 scholar if you are a former or current principal investigator on any NIH research project grant grants or their equivalents. Exception: R03 or R21 grant.

- You are NOT eligible if you are a former or current PI on any foundation or industry, or other government peer-reviewed research or career development grants that are over $100,000 direct costs per year.

KL2 Award: Eligibility & Previous Funding

You are NOT eligible if you are a current or former project leader on sub-projects of program project (P01) or center grants (P50).

But: A prior T32 or F32 appointment is acceptable.

KL2 Award: Eligibility & Career Development Grants

Applicants for KL2 appointments may not simultaneously submit or have pending an application for any other NIH mentored career development award (e.g., K07, K08, K22, K23, K99/R00) that duplicates any of the provisions of the KL2 program.

KL2 Award: Benefits

- **75% salary support and appropriate fringe benefits**
- **(up to salary cap of $120,000)**
    3 years of funding (from CCTS & your college)
- **Research expense support up to $25,000 per year.**
    - Tuition and fees related to career development
    - Research expenses, such as supplies, equipment and technical personnel
    - Travel to research meetings, workshops, or training
    - Research services, such as statistical services including personnel and computer time

KL2 Benefits: Training Curriculum

- Monthly K Lunch & Learn that cover a variety of topics on clinical and translational science and research (currently on the second Tuesday of each month)

- The Business of Science – a three day training program in leadership and project management in science

- The Annual meeting of the Association of Clinical and Translational Science (typically held in April in Washington, DC)

- Verbal Communications skills training

KL2 Benefits: Training Curriculum

- Innovation, Entrepreneurship, & Commercialization
- A consultation with the CCTS Translational Therapeutics Think Tank
- Your Individualized career development and mentorship plan

KL2 Benefits: Launch to Success Grant Writing Course

- A structured, interactive experience to facilitate preparation of an individual K or an R01 grant

- On-going feedback from faculty with success at writing grants and your peers

- Offered during second year of award

Letter of Intent

- **Check Current RFA for Due Date**
- Project Title and 250 word abstract
- Eligibility checklist

The intent of the Letter of Intent is:

1. Help staff organize the Study Section.

2. So applicants can fill-out the eligibility checklist to know that they are eligible.

3. Confirm application support from Dept. chair

Letter of Intent

Full Application

- **Check Current RFA for Due Date**
- Online RedCap form for name, team, demographics
- Project Description
  - Personal Statement
  - Career Development Plan
  - Research Plan
- Other Parts: NIH Biosketches
  - Letters of Support
  - Signatures

KL2 Award: Application

Project Description – 10 page maximum

Personal Statement – 1 page

- 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

KL2 Award: Application

Project Description – 10 page maximum

Proposed Career Development Plan* - 2 pages

- Your five-year goals

- 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 mentored *career development* grant

KL2 Award: Application

Research Plan – 7 pages

- Specific Aims
- Significance
- Innovation
- Approach - include a list of milestones/benchmarks for success anticipated to achieve the aims
- Preliminary studies
- References (not included in page count)

Example of Aims as Milestones

Timeline of grant period:

	6 Months	12 Months	18 Months	24 Months	30 Months	36 Months
Aim 1.						
Collection of primary fibroblast cultures	■					
ILK inhibition in CAFs	■	■				
Assessment of functional role of ILK within thyroid CAFs			■	■		
Assessment of cytokine expression in shILK CAFs			■	■		
Aim 2.						
Creation of shILK thyroid cancer cell culture	■					
Conditioned media effect of proliferation/signal transduction			■	■	■	
Conditioned media effect of migration/invasion			■	■	■	
Co-culture effect on signal transduction			■	■	■	
Aim 3.						
Obtaining IACUC approval	■					
Purchase of Ilk KO mice		■				
Crossing of Ilk KO and Fsp-cre mice			■			
Crossing of Ilk/Fsp and BRAFV600E inducible model				■		
Assessment of CAF-specific Ilk KO on papillary thyroid cancer model					■	■

KL2 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

KL2 Award: Mentoring*

Two Additional Mentors

Complementary to the interests of the lead mentor

It is desirable that one or more be drawn from another discipline

Require one to be a biostatistician

*This is a *mentored* career development grant

Other Parts of the Application

- NIH Biosketches:
  - You & your mentors
- Letters of Support
  - Lead Mentor
  - The other members of your mentorship team

KL2 Award: Protected Time & Salary Coverage Signoff

Signed by your College Dean or your Department or Division chair:

❖ Whoever is the appropriate person to make these commitments

Do not wait until the last minute.

Prior Approval by NCATS

- Prior approval of all research subject to review by IRB or IACUC is required by the NCATS, the funder of the KL2 program.

- No KL2 research can take place until the research is approved by NCATS

- The process takes months

- Goal: Funded projects are submitted for prior approval within weeks of acceptance

Getting Prior Approval

- The KL2 Application requires discussion of human subjects and animal protections.
- Applicants must consult during the application process with CCTS Regulatory Manager Rob Rengel
- IRB/IACUCU approval must be acquired before Prior Approval Submission. Get it now.
- Make sure all personnel on the project have required training

KL2 Award: Study Section

Members drawn from across the health sciences

Scored using NIH K award critique form

http://grants.nih.gov/grants/peer/reviewer_guidelines.htm

KL2 Award: Study Section

Evaluation Criteria:

Clinical/Translational Science

Career Development Plan

Mentoring Team

Questions?

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CitE & SUBMit

Publications supported by the OSU CCTS must **cite the CTSA grant number (UL1TR001070)** and by law, be **submitted to PubMed Central**. For instructions, review the **NIH Public Access Policy** on the CCTS website.

UL1TR001070