

KL2 Mentored Career Development Award

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KL2 Co-Directors



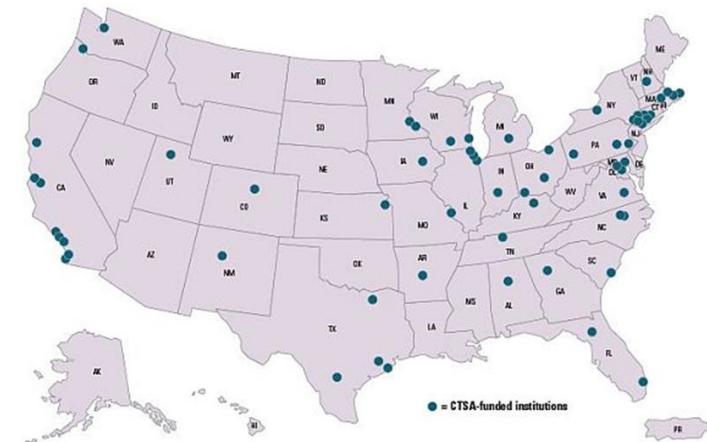
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Who Are We?

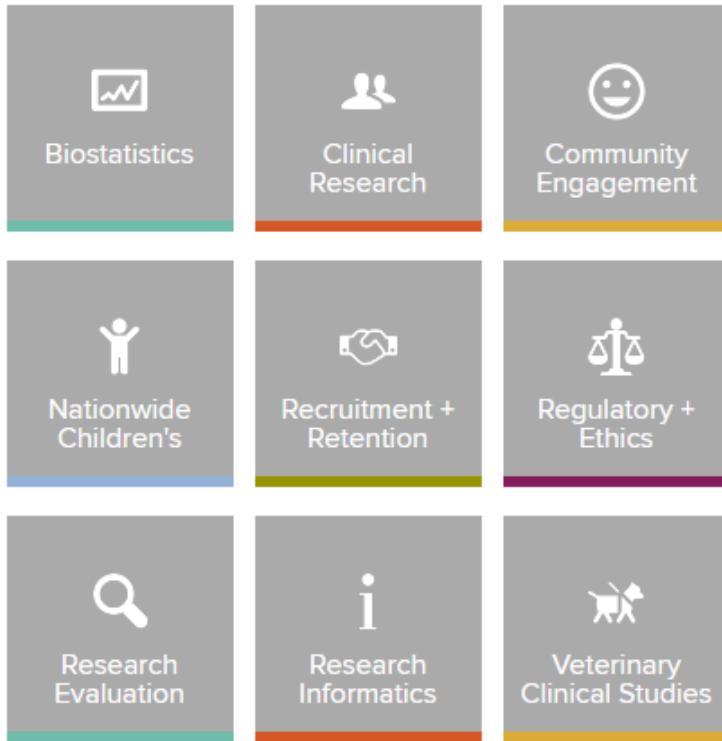
- Center for Clinical and Translational Science
- One of ~60 centers in the US
- Funded by the Clinical & Translational Science Award (CTSA) program
- Part of the National Center for Advancing Translational Science (NCATS)



Purpose:

Turning the scientific discoveries of today into life-changing disease prevention strategies and the health diagnostics and treatments of tomorrow.

CCTS Research Services



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

Join the CCTS!

ccts.osu.edu



ABOUT US NEWS AND EVENTS

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Career Development

Research
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Research

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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

THE OSU CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE INVITES
YOU TO:

VISIT OUR OPEN HOUSE!

Sept. 24, 2019 | 10 am to 2 pm
Prior Hall
376 W 10th Ave., Suite 260

www.ccts.osu.edu

KL2 Grant

- Institutional NIH Career Development Award funded by CTSA program of NCATS
- For investigators who conduct either patient-oriented or translational research
- Targeted to assistant professors on tenure or clinical track
- three years or less 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>

Translational Research

Translation

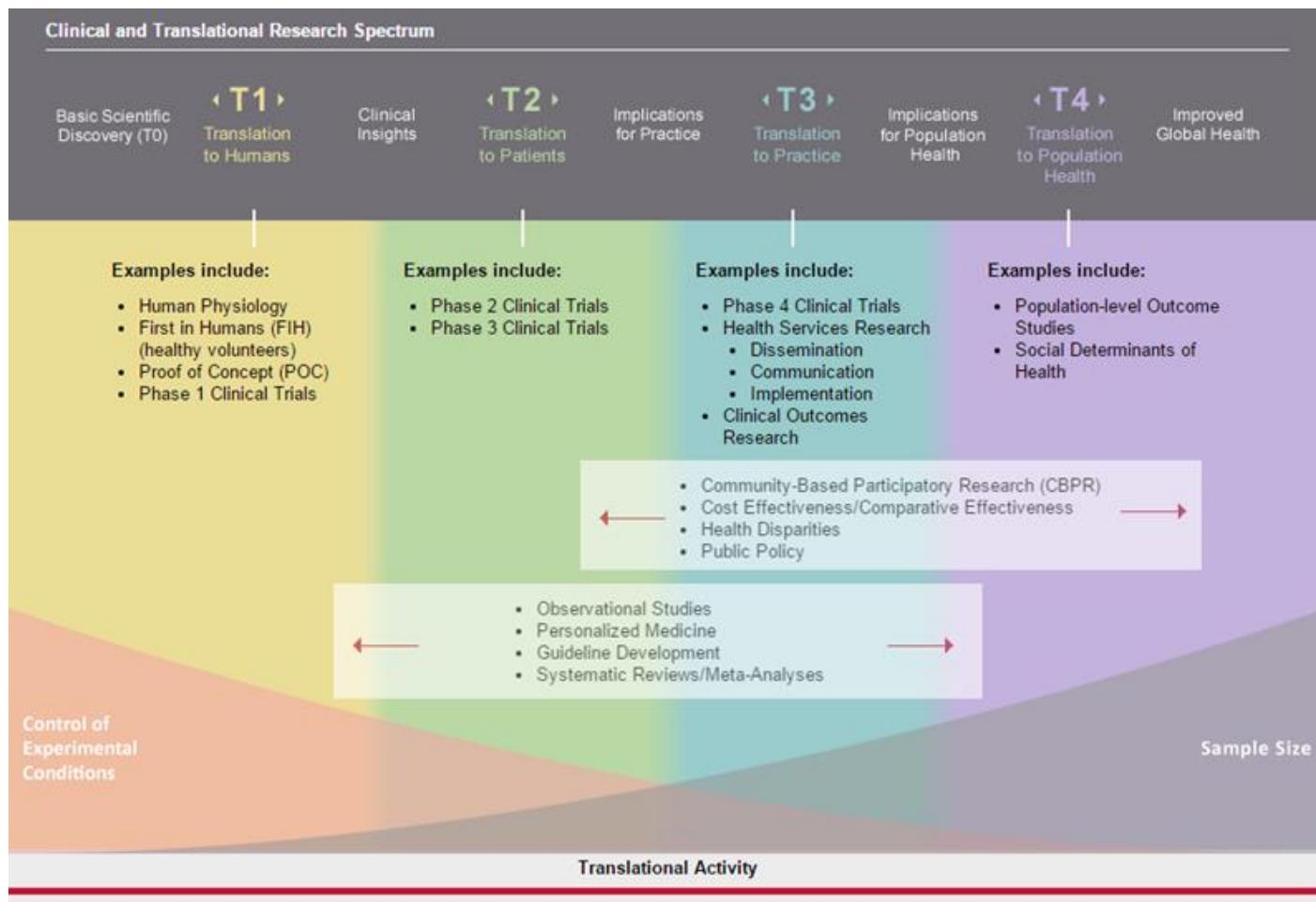
- The process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

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



Source:
<http://catalyst.harvard.edu/pathfinder/>

Career Development Awards

Davis Bremer Path to K	vs	KL2
<ul style="list-style-type: none">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.Applicants must be physicians with OSU Wexner Medical Center credentials.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.Aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards.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.		<ul style="list-style-type: none">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.For clinical and translational researchers with a research or health-professional doctoral degree.Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support).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 the proposed project to apply for an R grant in two to three years, apply for the KL2.

KL2 Grant: Eligibility

Junior faculty on the tenure-track or clinical-track with fewer than 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: 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.

KL2: 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: 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.

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 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
- 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

KL2 Application: Letter of Intent

- **Due Date: October 1, 2019**
- 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

First name
* must provide value

Last name
* must provide value

Email address
* must provide value

Eligibility

I have a research or health-professional doctoral degree or its equivalent (e.g., PhD, DDS, DVM, OD, MD, DO, or PharmD).
* must provide value
 Yes No reset

Citizenship Status (choose one)
* must provide value
 I am a US Citizen.
 I am a permanent resident who possesses a permanent resident card (a Green Card).
 I am a non-citizen national. (Note: This is a person who, although not a citizen of the United States, owes permanent allegiance to the United States. They are generally persons born in outlying possessions of the United States.)
 None of the Above reset

"Have you ever received an NIH career development award, such as K series awards K07, K08, K22, K23? or Are you applying at this time or do you have pending an application for any other NIH mentored career development award, such as a K07, K08, K22, K23?"
* must provide value
 Yes, if any of the above apply to you No, if none of the above apply to you. reset

"Have you ever received an independent (i.e., non-mentored) NIH award as Principal Investigator, such as an RO1 award? (Do not consider NIH Small Grants [R03] or Exploratory/ Developmental [R21] grants or their equivalents) or Have you ever been a project leader on a sub-project of a program project (P01) or center grant (P50)? (Do not consider a prior T32 or F32 appointment.) or Have you ever been PI on a non-PHS peer-reviewed research grant or career development grant that was over \$100,000 direct costs per year?"
* must provide value
 Yes, if any of the above apply to you. No, if none of the above apply to you. reset

KL2 Letter of Intent Subm KL2 Letter of Intent Subm x https://redcap.bmi.osumc.edu/redcap/surveys/?s=dsW8P2

UA PL OSU CCTS NCATS OneSource CTSA PI Portal eRA Commons CCTS Administration HSL CABS

Demographics

Please select your college for which you are full-time employee from the list below.
* must provide value reset

Please select your job title from below.
* must provide value
 Assistant Professor Assistant Professor - Clinical Research Scientist Other reset

For how long have you held your current position?
* must provide value
 Three years or less Four to 6 years More than 6 years reset

Project

Project title
* must provide value

Please provide a 200 to 250 word abstract of your proposed research plan.
* must provide value Expand Submit

Save & Return Later

Full Application

- **Due Date: December 18, 2019**
- Online RedCap form for name, eRA Commons name, ORCID id, demographics
- Project Description
 - Personal Statement
 - Career Development Plan
 - Research Plan
- Other Parts: NIH Biosketches

Letters of Support

Signatures

KL2 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 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 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)

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 now 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

IRB Submission Assistance @ the CCTS

Walk-in Office Hours:

Tuesdays from 12:30 am - 4:30 pm, room 259

Appointments (walk-ins accepted):

Wednesdays from 12:30 pm - 4:30, room 259

Contact: Brandie Dickens at dickens.38@osu.edu

Individualized sessions are intended to help navigate IRB forms, policies, and review procedures.

Special Tuesday focus: IRB Reliance Agreements

KL2 Application

- Human subjects research (up to 3 pages). If your project requires IRB approval, it is considered human subject research for purposes of this grant.
 - Risks to Human Subjects.
 - Adequacy of Protection Against Risks
 - Potential Benefits of the Proposed Research to Human Subjects and Others
 - Importance of the Knowledge to be Gained

KL2 Application

- Live Vertebrate Animal research (up to 3 pages).
 - ❑ Description of Procedures (Vertebrate Animals Section)
 - ❑ Justifications (Vertebrate Animals Section)
 - ❑ Minimization of Pain and Distress (Vertebrate Animals Section)
 - ❑ Method of Euthanasia

KL2 Application

Authentication of Key Biological and/or Chemical Resources

- If applicable, the authentication plan should state how you will authenticate key resources
- Key biological and/or chemical resources include, cell lines, specialty chemicals, antibodies and other biologics

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.

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 Grant: 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 Mentoring

Biostatistics

Your mentorship team must include one biostatistician.

Not sure who that could be? Contact

Guy Brock, PhD

Research Associate Professor

Departments of Biomedical Informatics and Center for Biostatistics.

office: 320-N Lincoln Tower

phone:(614) 366-8504

email: Guy.Brock@osumc.edu

KL2: Mentoring

One Additional Mentor

Complementary to the interests of the lead mentor

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

You may have additional mentors (but do not get extra points for more mentors)

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.

KL2 Award: Study Section

Members drawn from across the health sciences

Scored using NIH K award critique form

Overall score & individual section 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

KL2 Award: Study Section

Evaluation Criteria:

You as an applicant

Clinical/Translational Science

Career Development Plan

Mentoring Team

Questions?

Education Program Manager Stuart Hobbs

Stuart.Hobbs@osumc.edu

614-685-5972

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