

## UT Southwestern CTSA Program KL2 Clinical and Translational Research Scholars

The UT Southwestern CTSA Program is currently accepting applications for two CTSA KL2 Scholars slots, one to begin funding on May 1, 2024, and the other on November 7, 2024. The RFA, with full details, follows this cover letter. Applications for either start dates are due by **March 5, 2024**.

### What is it?

This two-year program is designed for junior faculty who show great promise towards becoming successful independently funded clinical and translational science investigator, and their salary is supported partially by the KL2 grant.

We support **six** KL2 Scholars each year for a two-year term. The two new slots are due to pending graduation of two current Scholars.

### Program Highlights

We expect KL2 Mentored Clinical and Translational Research Scholars will complete the program equipped with the skillset and passion to become successful, independent investigators who make contributions across the entire spectrum of clinical and translational research.

- Two years with significant protected time to focus on research, publications and grant submissions.
- Emphasis on mentoring
- Customized Individual Career Development Plan
- The Scholar will:
  - Develop clinical and translational research competencies
  - Develop an individualized educational development plan
  - Develop critical thinking skills
  - Receive formalized coaching on scientific communication
  - Develop leadership skills
  - Develop a stepwise approach for submission of NIH individual K awards or equivalent career development grants by scientific societies
  - Participate in intensive training and career development for transitioning from K-type to R-type awards after program completion

### Program Faculty

The Scholars program has a broad base of outstanding faculty. It is co-directed by senior faculty MPIs who have complementary strengths in the full spectrum of clinical and translational research and have long standing track records for mentoring and career development of junior research scientists.

### Financial Support

KL2 Scholars will receive 75% of their UT Southwestern institutional base salary (up to the KL2 specific NIH cap of \$160,000). This translates to up to \$120,000 plus fringes for each Scholar per year.

## REQUEST FOR APPLICATIONS

### The KL2 MENTORED CLINICAL AND TRANSLATIONAL RESEARCH SCHOLARS CAREER DEVELOPMENT PROGRAM

Supported by the **UT Southwestern Clinical and Translational Science Award Program** (UTSW CTSA Program), funded by the NIH/NCATS.

**OVERVIEW.** UT Southwestern is transforming its clinical and translational research infrastructure to build a stronger foundation for the future. This initiative, spearheaded by W.P. Andrew Lee MD, Provost and Dean of the Medical School, and Eric Peterson MD, MPH, Vice-Provost and Senior Associate Dean of Clinical Research, has been accelerated by the renewal funding of the NIH Clinical and Translational Science Award to Robert Toto, MD, Associate Dean of Translational Research and Education. This 5-year CTSA award has two linked components:

- **UL1TR003163** Clinical and Translational Science Award Supports Comprehensive Translational and Clinical Research and Administrative Cores.
- **KL2TR003981** Clinical and Translational Research Scholar Career Development Award.

**We are currently soliciting applications for qualified individuals from UT Southwestern and our CTSA Program partner institutions to apply as KL2 Scholars. Application deadline: March 5, 2024. Please submit your application using this link: <https://redcap.link/KL2Spring2024>**

**ELIGIBILITY.** The KL2 is open to applicants from broad academic disciplines from UT Southwestern *as well as our CTSA Program partner institutions*. To be considered, the applicant must:

- Have a doctorate degree (e.g., MD, PhD, DO, among others).
- Must be a US citizen or permanent resident as per NIH funding guidelines.
- Be committed to actively participate in the Program with 75% protected time for research for two consecutive years. (Note: individuals in certain surgical specialties may request permission for reduced research time to 50% pending NIH approval).
- Have a full-time position at UT Southwestern, or one of the UT Southwestern CTSA Program partner Institutions.
- Have commitment from his/her sponsoring Department Chair or Center Director. In the case of applicants from CTSA Program partner institutions, please also include a letter from your Dean.
- Have prior clinical and translational research experience.
- Have a proposed research plan and identified mentors.
- Not be, nor have ever been, a principal investigator on an R01, R29, or subproject of a Program Project (P01), Center (P50, P60, U54) or mentored career development (K-series) grants or equivalent. R03 and R21 grants are permitted.

**KL2 PROGRAM HIGHLIGHTS.** We expect that our Scholars will complete the program equipped with the skillset and passion to become successful, independent investigators who make contributions across the entire spectrum of clinical and translational research.

- **Two years with significant protected time** to focus on research, publications, and grant submissions (**Figure 1, APPENDIX A**).
- **Emphasis on mentoring.** Scholars will develop a productive relationship with a mentoring team that includes the primary research mentor(s), near-peer mentors, career mentors and Program Directors.
- **Customized Individual Career Development Plan.** We will work with each Scholar and his/her mentors to develop a training portfolio uniquely tailored to meet the Scholar's short and long-term goals.
- The Scholar will:
  - a) **Develop clinical and translational research competencies** through completion of required practica and core courses.
  - b) **Develop an individualized educational development plans** created to address each Scholar's unique educational needs and chose career path.

- c) **Refine critical thinking skills** through small group discussions, interactive scientific presentations, and by completing written practica, manuscripts, and grant proposals.
- d) **Formalized coaching on scientific communication.**
- e) **Develop leadership skills** that are critically important for navigating clinical research process and leading multidisciplinary teams.
- f) **Stepwise approach to development of NIH K awards** via practical coursework and writing workshops within the CTSA.
- g) **Intensive training and career development for transitioning from K type to R type awards after program completion** to become independent investigators and drive the clinical research transformation as envisioned by the Office of the Provost and Dean (**APPENDIX B**).

**PROGRAM FACULTY.** The Scholars program has a broad base of outstanding faculty from UT Southwestern and our CTSA Program partner institutions. It is co-directed by three senior faculty MPIs who have complementary strengths in the full spectrum of clinical and translational research and have long standing track records for mentoring and career development of junior research scientists. They are:

- Helen Yin, PhD, Professor of Physiology, Associate Dean of Women’s Careers, co-Director NIH UTSW-UTD FIRST Research Study
- Madhukar Trivedi, MD, Professor of Psychiatry, and Director, Center for Depression Research and Clinical Care
- Keith Argenbright, MD, MMM, Professor of Family and Community Health, Simmons Comprehensive Cancer Center, and Director of the Moncrief Cancer Institute
- Heidi Jacobe, MD, MSCS, Professor of Dermatology, Director of the CTSA Workforce Development Core, Associate Dean of Clinical Research Development, and Director of the Masters of Clinical Science Program. She was a KL2 Scholar graduate and will guide Scholars to design their customized curriculum/training plan
- Scott Smith, PhD., Professor and Chair, UT Southwestern School of Health Professions, and co-Director of the Masters of Clinical Science Program.

#### **FINANCIAL SUPPORT**

UT Southwestern KL2 Scholars will receive 75% of their institutional base salary, up to the NIH KL2 specific salary cap (\$160,000). Additionally, KL2 Scholars will receive a budget for associated coursework, research funds including pilot awards, and access to biostatistics and epidemiological support from the UT Southwestern CTSA Program Cores. Scholars will be supported for two years; renewal of the second year of support will depend on a year-end review of the Scholar’s progress and adherence to deliverable milestones (as outlined in **Figure 1**). We will also accept KL2 applicants from **CTSA Program partner institutions** that commit to support the salary of their own faculty. In this case, the **CTSA Program partner institution** supported Scholars have the same expectations as the KL2 Scholars in terms of the curriculum, however, their salary is not funded from the KL2 Grant.

#### **SCHOLAR APPLICATION**

Please submit your application using this link: <https://redcap.link/KL2Spring2024>

**Deadline: March 5, 2024**

**Required components to be uploaded into the redcap link include:**

1. A curriculum vitae in the standard UT Southwestern promotion & tenure format (at intranet W:\PUB\SMSDEAN\Promotion and Tenure). Applicants from **CTSA Program partner institutions** should also send a CV approved by their institutions. Include past and current grant support at the bottom of the CV.
2. A personal statement (*500 words or less*). Tell us how you arrived at this place in your career. A career in clinical and translational research has many opportunities and challenges. Why are you committed to this career?
3. A NIH Specific Aims page describing research you will be conducting as a Scholar. *Please* include title of your proposed research program.
4. Your career development and training plan as a Scholar in **1000 words or less**. Please include:

- a) Current area(s) of clinical and translational research
  - b) A proposed training plan during your two years as a Scholar. Include information about additional training you need, what you hope to gain from the mentoring and career development opportunities, what courses you think will be most beneficial to your success, and career goals.
5. Name and title of individuals who will be submitting letters of recommendation. These must include: your Department Chair/Center Director with a statement of commitment (75% protected time; except for surgeons at 50% time), your primary scientific mentor(s) who will oversee your research project and an additional professional reference. Letters of reference should be submitted directly to the Program Directors (as per instructions in the redcap document). Additionally, for Applicants from **CTSA Program partner institutions**, please also list the name of your Dean who will be supporting this application.

<b>Highlights of Scholar Application and Selection Timeline</b>
<p>Call for applications issued: <b>January 23, 2024</b> Application deadline: <b>March 5, 2024</b></p> <p>Interviews with members of the Scholars Admission Committee and give a short presentation (10 min. plus 20 min. Q/A). Interviews will be conducted the weeks of March 18 to the 27<sup>th</sup> virtually via Microsoft Teams.</p> <p>Candidate acceptance of offer must be received within a week of official offer.</p> <p>Scholar appointment and program start date: One position will start as early as <b>May 1, 2024</b>. The other position will start on <b>November 7, 2024</b>.</p>

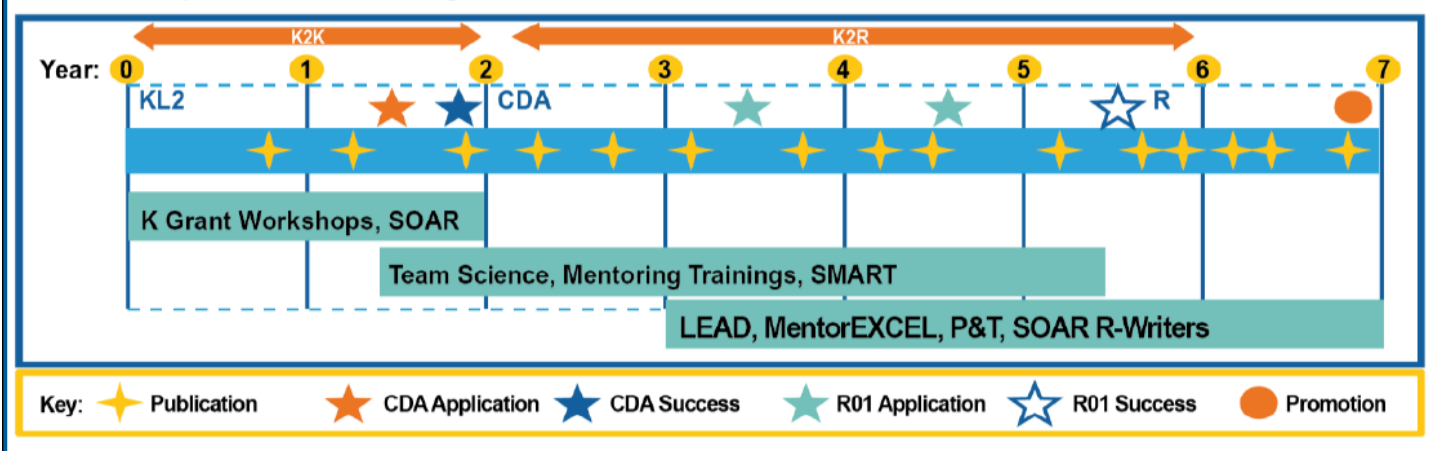
#### **APPENDIX A. SCHOLAR PROGRAM CORE CURRICULUM**

The following are required:

- Regular frequent meetings with the primary research mentor(s). In addition, meet with the larger mentoring team at least three times a year in Scholar Year 1 and twice in Scholar Year 2.
- Tailored didactic course work (see **APPENDIX C**). The KL2 program is not a degree nor certificate program. It has limited required courses and workshops and will require a few elective courses.
  - Required courses include Responsible Conduct of Research, Ethics in Clinical Science, Biostatistics or medical informatics, Clinical Research Management and Leadership and Grant Writing & Funding Strategies.
  - Elective courses on an as needed basis.
- Three interrelated research practica (**Figure 1**)
  - A Clinical and Translational Research Project (chosen by the scholar and mentors).
  - A publishable research manuscript (selected among several).
  - A Capstone extramural research grant application such as those in the NIH K- or R-series or equivalent by the second year.
- Interactive seminars/small group meetings
  - Present a works-in-progress seminar once a year at the weekly Translational Science Forum attended by CTSA Program mentors, faculty, Scholars, Chairs and Division Chiefs.
  - Scholar Round Table Group Meetings every one to two months, to network, to update progress, and/or to discuss professional development topics such as career development, team science, and mentor/mentee relations.
  - Annual KL2 Scholar Retreat

**APPENDIX B. ROADMAP for K2K and K2R transition.** The KL2 program's goal is to train independent investigators in clinical and translational science. They will be prepared for obtaining extramural funding during KL2 training and beyond.

The recommended seven-year life cycle is based on 2 yrs. as KL2 and 5 yrs. as individual Ks. Adapted from Hartmann (Vanderbilt CTSA). Scholars are strongly encouraged to seek a variety of funding opportunities and mechanisms while in training and after graduation (only NIH grants are shown in diagram as stars). Recommended (optional) career development programs are shown in green bars. Selection of courses/workshops is guided by mentors and coordinated by the Curriculum Navigator.



**APPENDIX C. Example of Clinical and Translational Science Course Offerings from the CTM, School of Health Professions (ACR) and Graduate School of Biomedical Sciences (HI).** Note that the CTSA course offerings are currently being revamped, so the below examples are subject to change. Also, KL2 Scholars are only required to take a limited number of courses and/or workshops as this is not a certificate or degree program.

Course #	Course Name	Credit Hours	Course Description
CTM 5107	Responsible Conduct of Research <b>Required</b> (Heitman)	1	<b>Short course.</b> Regulatory requirements of clinical research (IRB, GCP, HIPAA, and investigational filings), ensuring patient safety, interactions with government and industry, contract negotiations, successful strategies, and tactics.
ACR 5301	Conceptual Biostatistics for the Clinical Investigator <b>Required, unless opt out</b> (Wang)	3	Conceptual approach to statistical analysis of biomedical data.
CTM 5301	Introduction to Principles & Methods of Clinical/ Translational Research (Jacobe)	3	Principles in research design; formulation of the research question; identifying primary and secondary structures; use of control groups and pre- specified hypotheses; surrogate measurements; analysis of incomplete data; meaning of P values and confidence intervals; identification of bias and flaws in study design.
HI5303	Evidence Based Medicine and Clinician Decision Support (Moran)		The development and strength of evidence and its application in health care delivery will be the prelude to the design, implementation, operation, and evaluation of clinical decision support (CDS) in the context of electronic health records and other clinical information systems.
HI5302	Health Information Technology (Willet)	3	Creating a foundation to health information technology, this course will introduce health information technology.
CTM 5105	Ethics in Clinical Science <b>Required</b> (Heitman)	1	This course is a systematic examination of the ethical concepts. and standards of responsible conduct of research in biomedical science and clinical investigation.
CTM 5115	Clinical & Translational Research from Proposal to Implementation (Toto)	1	This course reviews basic elements for a research proposal and implementation.

CTM 5118	Successfully Obtaining an R (SOAR) Grant Writing Bootcamp (Yin)	0.5	SOAR is designed to increase NIH R-type grant acquisition success in basic, translational, and clinical research. This day-long boot camp includes topics such as demystifying the grant writing process, grantsmanship, surviving the NIH study section review, writing tips and tricks, navigating NIH requirements, peer-review, etc.
CTM 5106	Grant Writing & Funding Strategies <b>Required (Toto)</b>	1	This course reviews the different types of federal grant mechanisms as well as grants or contracts from research foundations, advocacy organizations and industry. How to write a persuasive, well-reasoned application will be the focus of the course including the budget, resources and environment, preliminary data, and the research plan.
CTM 5208	Essentials of Management & Leadership for Researchers <b>Required</b> (Argenbright)	2	This course is a structured review and discussion of the basics of management and leadership theory and practice. Topics include project management and budgeting, information systems, leadership style, effective interviewing and hiring techniques, conflict resolution, and the basics of organizational culture. Predominant theories and research, as well as shared experiences of the instructor and the group will be discussed to enhance each participant's effectiveness as a manager and leader.
CTM 5302	Biostatistics for Clinical Sciences II (Reisch)	3	Linear and logistic regression models (control of confounding and predictive models); categorical data analysis (binomial and Poisson distributions, analysis of paired categorical data, nonparametric methods for ordinal data); survival analysis (Kaplan-Meier curves. Hazard functions, types of censoring, log-rank tests and generalized Wilcoxon tests, Cox regression model). Prerequisite: CTM 5309 or CTM 5391 or instructor consent.
CTM 5209	Practical Clinical & Translational Research Protocol Development <b>Highly Recommended</b> (Jacobe)	2	This course is the practical application of the concepts taught in Introduction to Principles & Methods of Clinical & Translational Research. We will apply our understanding of team science, foundations of clinical and translational research, and clinical research design and analysis to the creation of a written research proposal, an oral research presentation, and elevator talk. Prerequisite: CTM 5301 and CTM 5106 or instructor consent.
CTM 5307	Epidemiology for the Clinical Investigator (Haley)	3	Concepts of multivariate causality; criteria for establishing causality; risk; rates; incidence, prevalence, and attack rates; incidence density; crude, specific and adjusted rates; relative risk, odds ratio, case-fatality rate, and attributable risk; sampling error, selection bias, information bias, definition bias, and confounding; statistical techniques and experiential introduction to statistical computing for different types of clinical epidemiology studies.
HI5304	Data Analytics (Beauchamp)	3	Students will be exposed to scientific methods and processes to extract knowledge and insights from structured and unstructured data. This course will leverage advanced statistics, data analysis, machine learning, and related data methodologies to analyze, understand, model, and gain novel knowledge from data. Students will be introduced to clinical epidemiology, predictive analytics, comparative effectiveness, and health services research, clinical predication rules, and patient centered outcomes research.

CTM	SOAR Intensive R Grant Writing Workshops Yin	1	This intensive workshop is intended for those writing and submitting R01 level grants. Participants attend each of six two-hour sessions, engaging in a peer review of each other's specific grant section. The sessions are guided by faculty grant coaches, and the grants are reviewed in a Mock Study Section.
CTM 5114	Scientific Communication (TBD)	1	<i>Under development.</i> General writing skills and strategies; how to prepare an empirical article including tips on writing the abstract, introduction, aims, methods, results, and discussion/conclusion sections of a peer reviewed journal article. Students will be required to submit a journal article and review others' articles.
CTM 5113	Advanced Clinical and Translational Research Design & Analysis (TBD)	1	<i>Under development.</i> Critical review and methods critique of scientific journal articles pertinent to academic medicine.
CTM 5117	Mentoring Excellence for Developing Leaders (Argenbright)	1	This is an interactive, participant-based course on mentoring excellence. Its objective is to engage mentors at all points in their career and give them the tools and skills to improve their mentoring. Prerequisite: CTM 5208 or instructor consent.
CTM 5096	Team Science Fundamentals (Yin)	1	<i>Under development.</i> Clinical and translational research is inherently team based and depends on multidisciplinary and transdisciplinary collaborations. Emerging science of team science research shows that scientific team skills can be learned, and that simulations to promote explicit team learning may be most transferable to the real-life work environment. This course will combine web-based learning and in-person class discussions of foundational team science principles.