

KL2 Grant Application Instructions 2019**Submissions accepted:** October 7th, 2019 - October 30th, 2019**IMPORTANT DATES:**

Letters of Intent due	October 30, 2019 by 5:00 pm
Notification to apply	By November 20, 2019
Invited Applications due	January 22, 2020 by 5:00 pm
Finalist interviews	Week of March 2, 2020
Notification of funding	By March 13, 2020
Funding start date	April or May 2020

Please note that funding will be contingent upon successful renewal of the CCTST award, which was reviewed by NIH in September 2019. The grant received an excellent score in a fundable range, but we will not have a final decision on funding until early 2020.

For questions regarding these instructions, please visit <https://cctst.uc.edu/funding/kl2rs/> or contact Krista Newland by phone at (513) 803-5593 or by email at krista.newland@uc.edu.

- 1. Application submission:** Please note that Letters of Intent and full applications must be submitted through the **CCTST Competition and Awards Program Site (CCAPS):** <https://ccaps.research.cchmc.org/welcome>. Log in using your UC ("6+2") or CCHMC username and password. If you do not have a UC or CCHMC username and password, please contact Krista Newland to obtain one.
- 2. Signatures:** The signatures of all participating investigators and their respective division director, departmental director(s), or organization leader are required.
- 3. Application forms and guidelines:** Applications must be assembled as a single PDF file and submitted through CCAPS before 5:00 pm of the application submission deadline date. The application form was modified from the PHS 398 forms located at <http://grants.nih.gov/Grants/Funding/Phs398/Phs398.html> and is attached. This RFA announcement is also published on the CCTST website under Funding Opportunities at <https://cctst.uc.edu/funding>.
- 4. Deadlines:** All deadlines for submissions are firm; extensions will not be granted.
- 5. CCTST Membership:** All applicants for KL2 grant consideration, including the letter of intent (LOI) stage, must be CCTST members. CCTST membership is free and open to all. For online membership registration, go to <https://cctst.uc.edu/user/register>.
- 6. Background:** The CCTST is supported by an NIH Institutional Clinical and Translational Science Award (CTSA). Integral to the mission of the CCTST is to train selected junior faculty members to conduct clinical and translational research. The CTSA KL2 Research Scholars Program represents a career step between MD fellowship training or post-doctoral PhD training and application for mentored grants such as K01s, K08s, and K23s; R01 awards; or their equivalents.

The Cincinnati CTSA KL2 program will support KL2 Scholars for 2 consecutive 12-month appointments. At the end of each grant year, Scholars must submit a "Progress to Date" report demonstrating sufficient progress and need for continued support. **Throughout the award period, at least 75% of the KL2 Scholars' full-time professional effort must be devoted to KL2 research and career development activities, including attending the required biweekly K Scholars meeting** (currently

held on the 1st and 3rd Wednesday mornings of each month from 10:00-11:30 am). The remainder of the KL2 Scholar's time may be devoted to other clinical or academic pursuits aligning with the objectives of the award. For example, based on a 55-hour work week, a KL2 Scholar can devote up to – but not more than – a total of 13.75 hours per week, on average, to clinical, teaching, and administrative duties. **KL2 Scholars may not accept or hold any other Public Health Service (PHS) award that duplicates the provisions of this career award.** Scholars are expected to apply for external research grant support (generally an NIH K23 or R01 grant) during the period of KL2 support. **The applicant's home division or department must guarantee a 3rd year of 75% protected time in the event that the Scholar has applied for but not yet received independent research grant support by the end of the 2nd year of KL2 support.**

CT2 Scholars: In order to expand the reach of the KL2 Program, up to 2 CT2 Scholars may be appointed each year in addition to the 2 KL2 Scholars. The training program is identical to that of the KL2 Scholars, but the 75% salary support is covered by their home Division or Department, and research support is covered by the CCTST. The home Division or Department must agree to provide this salary support before a CT2 Scholar may be appointed. If a KL2 Scholar leaves the program early because they obtain external grant support, a CT2 Scholar may be appointed as a KL2 Scholar in his or her place.

7. Definitions of Translational Research

Pre-Clinical Research

Pre-clinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.

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 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.

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.

8. Eligibility:

Scholar Candidates

KL2 Scholars must have a research or health-professional doctoral degree or its equivalent. Applicants must be a United States Citizen or non-citizen national, or have legal admission into the United States as a permanent citizen at the time of application.

Scholar Appointments

Candidates must have a full-time faculty appointment at the University of Cincinnati, Cincinnati Children's, or the Cincinnati Veterans Affairs Medical Center at the time of the Award. The eligibility of potential candidates holding VA appointments will be confirmed with NCATS Office of Grants Management and Program staff prior to the individual being appointed to the program.

Selection Restrictions

The Institutional Career Development Core will support early-career post-doctoral translational researchers. In keeping with the type of mentoring and career development being provided by the CTSA Program, a KL2 scholar candidate who is already in the process of applying for an independent mentored career development grant, a P01 grant, or R01 grant is likely too senior for the KL2 award.

At the time of their appointments, scholars must not have pending an application for any other PHS mentored career development award (e.g. K07, K08, K22, K23) that duplicates any of the provisions of the K component. Former or current PDs/PIs on any NIH research project grant [this does not include NIH small grants (R03), exploratory Developmental (R21) or SBIR, STTR (R43, R44 grants)] or equivalent non-PHS peer reviewed grants that are over \$100,000 direct costs per year, or project leaders on sub-projects of Program project (P01) or center grants (P50) are NOT eligible to participate as scholars. Appointed scholars are encouraged to apply for individual mentored K awards (e.g. K07, K08, K22, K23) and independent awards (R01, R03, R21); if successful, scholars may be required to reduce effort on the mentored career award to a minimum of six-person months and hold concurrent support from their mentored career award and a competing PHS research grant on which they are the PD/PI or component lead or terminate the KL2 appointment depending on Program requirements (See [NOT-OD-08-065](#)). Scholars are expected to apply for NIH K awards (e.g., K23, K08) or independent research grant (e.g., R01) support *during* the period of KL2 support. Current or recent (i.e. completed within the last calendar year) Children's Procter Scholar, Trustee Grant, Place Outcomes Award, or CCTST Pilot award recipients are likewise ineligible. Past recipients whose proposed KL2 project does not duplicate their Procter Scholar, Trustee Grant, Place Outcomes Award, or CCTST Pilot project may be eligible for a KL2.

Members of underrepresented racial, ethnic, and socioeconomic groups and candidates with disabilities are strongly encouraged to apply.

9. **Overview of Review Process:** The review of applications is performed in 3 phases: (1) LOI review, (2) application scientific review, and (3) administrative review. During the first phase, the 2-page LOIs will be scored and ranked, and the top applicants will be invited to submit formal 12-page applications. The number of applicants invited to apply will vary, judged by number and the merit of applications received. No critiques will be provided to applicants during the LOI stage. During the second phase, the 12-page applications will be reviewed by 3-4 scientific reviewers (1 of whom may come from an outside institution having a KL2 program), who will score the applications following KL2 program guidelines. During the final phase, applicant scores will be tabulated and ranked, and the top applicants will be interviewed by the KL2 program leaders. Following interviews, KL2 program leaders will meet to discuss and determine awardees. Critiques from the second phase of the review will be provided to the applicants after awards are announced.
10. **Letter of Intent:** The LOI consists of the following, in **one pdf**:
1. Application face page (see application forms document: first page)
 2. Applicant's 1) career development objectives (including mentor(s) and mentorship plan) and 2) research objectives, in **1 page**. Please ensure that a career development plan is submitted, or the LOI will not be accepted.
 3. Applicant's Biosketch
 4. Checklist (see application forms document: last page)

No other supplemental material will be accepted for the LOI. All LOI applications must be submitted through the CCTST CCAPS online system. **The LOI must be received by 5:00 pm on October 30, 2019. LOIs received after the deadline will not be reviewed.**

11. **Mentor Requirements:** KL2 Scholars must identify an approved KL2 primary mentor and at least 1 other mentor. A list of primary mentors meeting KL2 criteria is below.

Name	Department (Institution)	Area of Research Expertise
Roauf Amin, MD	Pulmonary (CCHMC)	Cardiovascular morbidity of sleep disorders
Lynn Babcock, MD	Emergency Medicine (CCHMC)	Pediatric injury; traumatic brain injury
Joseph Broderick, MD	Neurology and Rehabilitation Medicine (UC)	Ischemic and hemorrhagic stroke
Hermine Brunner, MD, MSc, MBA	Rheumatology (CCHMC)	Biomarker discovery, medications for lupus
J.P. Clancy, MD	Pulmonary (CCHMC)	Airway cellular biology, CFTR in cystic fibrosis
Robert Coghill, PhD	Behavioral Medicine and Clinical Psychology (CCHMC)	Neural mechanisms of pain
Laura Conforti, PhD	Nephrology and Hypertension (UC)	Role of immune system in cancer, autoimmune disease
George Deepe, MD	Infectious Diseases (UC)	Host response to fungal pathogens; immune regulators of resistance and susceptibility
Lee Denson, MD	Gastroenterology, Hepatology, & Nutrition (CCHMC)	Therapeutic approaches in inflammatory bowel disease
Prasad Devarajan, MD	Nephrology (CCHMC)	Mechanisms, biomarkers and novel therapies for acute kidney injury and nephritis
Jeff Epstein, PhD	Behavioral Medicine and Clinical Psychology (CCHMC)	Diagnosis and treatment of ADHD
Alberto Espay, MD, MSc	Neurology and Rehabilitation Medicine (UC)	Parkinson's Disease, other movement disorders
Carl Fichtenbaum, MD	Infectious Diseases (UC)	Dyslipidemia and cardiovascular disease in HIV
Goodman, Michael	Surgery (UC)	Coagulation and post-traumatic inflammation
Gordon Gillespie, PhD, RN	Nursing Research (UC/Nursing)	Workplace violence against healthcare workers
Christy Holland, PhD	Cardiology (UC)	Diagnostic and therapeutic ultrasound and image-guided targeted drug delivery
David Hui, PhD	Pathology and Laboratory Medicine (UC)	Cardiometabolic diseases, including atherosclerosis, obesity, and diabetes
Heidi Kalkwarf, PhD, RD	Gastroenterology, Hepatology, & Nutrition (CCHMC)	Bone mineral density in infants and children
Winston Kao, PhD	Ophthalmology (UC)	Corneal development and wound-healing
Khurana-Hershey, Gurjit, MD PhD	Asthma Research (CCHMC)	Genomics of allergic inflammation with a focus on cytokines and signal transduction
Alex Lentsch, PhD	Surgery (UC)	Inflammation, liver injury, military medicine
Kevin Li, PhD	Winkle College of Pharmacy (UC/Pharmacy)	Drug delivery, non-invasive pharmacokinetics
Michael Lyons, MD	Emergency Medicine (UC)	HIV screening and prevention
Maurizio Macaluso, MD, DPH	Biostatistics and Epidemiology (CCHMC)	Sexual and reproductive health
Peter Margolis, MD, PhD	James Anderson Ctr. for Health Systems Excellence (CCHMC)	Network-based learning health systems
Jareen Meinzen-Derr, PhD	Biostatistics and Epidemiology (CCHMC)	Pediatric cochlear implants, neonatal outcomes
Nehal Parikh, DO	Neonatology (CCHMC)	Perinatal brain injury/delayed brain development
David Plas, PhD	Cancer & Cell Biology (UC)	Signal transduction control of cancer cell metabolism

Scott Powers, PhD	Behavioral Medicine and Clinical Psychology (CCHMC)	Bio-behavioral therapies in migraines
Tim Pritts, MD PhD	Surgery (UC)	Hemorrhage and the host response to injury
Marc Rothenberg, MD, PhD	Allergy and Immunology (CCHMC)	Eosinophilic esophagitis
Richard Ruddy, MD	Emergency Department (CCHMC)	Multicenter pediatric emergency research
Nathan Salomonis, PhD	Biomedical Informatics (CCHMC)	Methods for evaluating whole genome transcriptome datasets
Michael Seid, PhD	Pulmonary Medicine (CCHMC)	Health care quality and outcomes
Samir Shah, MD	Hospital Medicine (CCHMC)	Efficiency and quality of care of hospitalized children
Kenneth Sherman, MD, PhD	Digestive Diseases (UC)	Viral hepatitis and drug hepatotoxicity
Lori Stark, PhD	Behavioral Medicine and Clinical Psychology (CCHMC)	Nutrition in cystic fibrosis and preschool obesity
Susan Thompson, PhD	Center for Autoimmune Genomics/Etiology (CCHMC)	Molecular basis of juvenile rheumatoid arthritis
Bruce Trapnell, MS, MD	Pulmonary (CCHMC)	Rare lung diseases, macrophage transplantation
Alexander Vinks, PharmD, PhD	Clinical Pharmacology (CCHMC)	Pharmacokinetic/pharmacodynamic modeling, pharmacogenetics
Waltz, Susan	Cancer Biology (UC)	Signaling in hormonally regulated cancers
Alison Weiss, PhD	Molecular Genetics (UC)	Tissue models for gastrointestinal diseases
Jim Wells, PhD	Developmental Biology (CCHMC)	Organoids: 3-dimensional tissues from pluripotent stem cells
Jeffrey Whitsett, MD	Neonatology and Pulmonary Biology (CCHMC)	Lung morphogenesis, gene delivery/therapy
Theresa Winhusen, PhD	Psychiatry & Behavioral Neuroscience (UC)	Substance abuse treatment
Hector Wong, MD	Critical Care Medicine (CCHMC)	Sepsis and septic shock
Margaret Zeller, PhD	Behavioral Medicine (CCHMC)	Barriers to weight management

Proposed primary mentors not appearing on this list **must be pre-approved** before the application process. **To qualify**, mentors must send an email to the program directors (with NIH Biosketch attached) stating that they are 1) currently externally funded (generally, at least \$300,000 of grant funding per year) and recognized as independent investigators who are actively involved in clinical or translational research; 2) have a track record as a successful mentor (as exemplified in a table of trainees); 3) have adequate protected time (generally at least 5% effort) for mentoring, and 4) agree to participate in a mentor training workshop (4 sessions, 8 hours total) if they have not already participated in all 4 sessions. Primary mentors will interact closely with the Scholar and provide guidance to develop a tailored career development plan as part of an interdisciplinary mentoring team.

Primary KL2 mentors are required to have completed (or to complete in the first year of the KL2 award) a mentoring workshop facilitated by the faculty development offices at CCHMC and the UC COM, an 8-hour program (four 2-hour sessions held periodically) covering the following competencies: maintaining effective communication; aligning expectations; assessing understanding; addressing equity and inclusion; fostering independence; and promoting professional development. All four sessions are required: if mentors miss a session, they must make it up at the subsequent mentoring workshop. Furthermore, KL2 applicants and their proposed mentors are required to submit with the KL2 application a written mentoring agreement/individual development plan specifying: (1) the applicant's planned research activities (planned abstracts, papers, grant applications); (2) planned educational activities; (3) planned professional/career development activities (e.g., skills development, progress towards promotion, networking, work-life balance, plans for independence from mentor); (4) support for the applicant (protected time, resources, advocacy, emotional support); (5) communication (e.g., frequency and structure of meetings, progress reports, feedback, confidentiality); and (6) personal conduct/interpersonal relationships (e.g., plans for managing conflicts, authorship order) [see sample Mentorship Agreement Template and sample Individual Development Plans below and on CCTST

website]. Mentorship agreements and associated individual development plans do not count against the 12-page application limit. The effectiveness of the mentoring relationship will be evaluated during the course of the Scholar's award period.

12. Scholar Requirements: Each Scholar is expected to submit an individual K or R (or equivalent, such as PCORI or VA merit) application during Year 2. To ensure that all KL2 Scholars have, or develop, competency in key areas of translational research, we will require Scholars to complete a series of courses, either prior to or during their KL2 award period. These courses include the following; course descriptions and syllabi can be found at <http://med.uc.edu/eh/divisions/epi/programs/courses>. Scholars may substitute courses for the required courses if appropriate, other than **Team Science and Scientific Integrity**, which are required for all Scholars.

Course #	Course Title	Credits	Semester
BE-7022	Introduction to Biostatistics	3	U/F/S
BE-7076	Introduction to Epidemiology	2	U/F/S
BE-9075	Design & Management of Field Studies in Epidemiology	3	S
BE-9066	Clinical and Translational Research Scholars Seminar	1	S
BE-7067 OR GNTD-7003	Scientific Integrity Ethics in Research	1-2 1	U (hybrid) S
BE-7040	Collaboration & Team Science (alternatively, 2 Team Science workshops)	2	S
BE-8062 OR BMIN-7099	Introduction to Medical Informatics OR Introduction to Bioinformatics	3 3	F TBA
Total		15-16	

F = Fall S = Spring U = Summer (Semesters marked in green indicate ONLINE)

KL2 Scholars have the opportunity for **externships** with outside organizations, such as a pharmaceutical company, clinical research organization, or another CTSA institution. The goals of these externships include obtaining “real-world” experience in clinical and translational research, team science, or both, and also supplementing one’s training with opportunities not available locally. Externships are similar in many aspects to co-op experiences, for which the University of Cincinnati is internationally known, except that the organization offering an externship will not be expected to provide stipends. Drs. Kahn and Blackard – Directors of the KL2 Program – will work with the Scholar and his/her mentors to individualize the externship experience to the Scholar’s interests and needs. Externship opportunities will be available locally, regionally, and nationally and will typically range from 1 week to 1 month. For out-of-town externships, the CCTST will provide travel and room and board expenses through an application process. Also available for Scholars are **reverse externships**. Scholars may invite an expert in a relevant field to visit UC or CCHMC and provide guidance to the Scholar regarding his or her research. Finally, the program has launched a **Scholar exchange program** with the University of Kentucky and Indiana University, and all Scholars will have the opportunity to apply for these.

13. Budget Guidelines: The award provides up to 2 years of funding, with the second year of support contingent on adequate progress in Year 1. Scholars may request 75% of their 12-month salary up to a maximum of \$102,200, plus fringe benefits on the awarded salary, plus \$25,000 for research-related expenses (see below). The Scholar’s department may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale from non-federal sources; however, supplementation may not come from federal funds unless specifically authorized by the federal program

from which such funds are derived. Departmental supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the Program.

Within each KL2 Scholar’s total award, up to \$25,000 annually may be requested for research and career development support, which may include the following expenses: (1) tuition and fees related to career development, e.g., in the UC Master of Science in Clinical and Translational Research or the Certificate in Clinical and Translational Research programs; (2) research expenses, such as supplies, equipment, and technical personnel; (3) travel to research meetings, workshops, or training (KL2 applicants must allow approximately \$1,700 for travel to the Translational Science annual meeting in Washington each April); and (4) other project infrastructure including relevant data sets. Salaries for mentors, secretarial and administrative staff, etc. are not allowed as part of the KL2 Program. Externships and reverse externships do not need to be included in the Scholar’s budget, as there is a separate budget for these opportunities.

Biostatistical and REDCap (data capture) support will be provided at no charge to KL2 Scholars through the CCTST during the Scholar’s 2 years of CCTST KL2 support. Applicants are encouraged to obtain methodologic support through the CCTST while preparing their KL2 application.

14. **Letters of Support:** Applications must include a letter of support from the applicant’s primary mentor and division director or departmental chairperson. Included in the division director’s/department chair’s letter of support must be a statement regarding the priority of the research proposal for the division or department, and a guarantee of 75% protected time for the 2 years of CCTST KL2 funding and a 3rd year if necessary (see section 6 above).
15. **Signatures:** For the applications, the signature of the investigator and his/her respective division director or departmental chairperson(s) are required. No signatures are required for the LOI.
16. **Application forms** (modified from SF424) may be downloaded from the CCTST CCAPS site or the CCTST website, <https://cctst.uc.edu/funding/kl2rs>. Applications must be submitted as single-spaced text with a minimum of one-half inch margins and 11-point Arial or Helvetica font.
The career development plan and research plan are limited to a total of 12 pages, combined.
17. **Composition of research proposal:** Research proposals and competing renewals should include the following (please also see “2019 KL2 application forms” document). For additional guidance, applicants may refer to the “Career Development Instructions for NIH and Other PHS Agencies” document (<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/career-forms-d.pdf>):

Required Elements and Page Limits	Instructions/Format
Face Page	Check all appropriate IBC, IACUC, IRB, or Radiation Safety approvals or indicate pending if submitted
Project Summary/Abstract	State the application’s broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe the research design and methods for achieving the stated goals (30 lines of text).
Project Narrative	Describe the relevance of this research to public health (no more than 3 sentences). For example, how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
Detailed budget	Within the guidelines of this RFA, provide a budget for the first and second year budget periods using the forms provided.
Budget justification	Provide a justification for the first and second year budget periods using the forms provided.
Biosketches	Provide a biographical sketch for the candidate and Mentor (co-Mentor(s) and any other

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(maximum 5 pages each)	senior/key personnel if desired), using the form provided.
Other support	Provide other support information for the candidate and Mentor, using the form provided.
Specific Aims (1 page)	<p>Complete using blank pages.</p> <p>State precisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved.</p> <p>List succinctly the specific objectives of the research proposed; e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p>
Candidate Information and Goals for Career Development (12 pages, combined with Research Strategy)	<p>Complete using blank pages.</p> <p>1. Candidate's Background</p> <ul style="list-style-type: none"> • Describe your past scientific history, indicating how the award fits into past and future research career development. • If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. • Any additional information not described in the Biographical Sketch Format Page, such as research and/or clinical training experience, may be included in this section. <p>Suggested points to include:</p> <ul style="list-style-type: none"> • Describe the candidate's commitment to an academic career in Clinical / Translational Research. Include a description of all the candidate's professional responsibilities in the grantee institution and elsewhere and show their relation to the proposed activities on the career award. • Present evidence of the candidate's ability to interact and collaborate with other scientists. • Describe prior training and how it relates to the objectives and long-term career plans of the candidate. • Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience. • Provide evidence of the candidate's potential to develop into an independent investigator. • Include a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the KL2 program and related career development activities. The mentor or department chair must agree and provide a statement in the application documenting that this percent of the candidate's time will be protected. <p>2. Career Goals and Objectives</p> <ul style="list-style-type: none"> • Describe your short-term and long-term career development goals. • Justify the need for the award by describing how the career development award will enable you to develop and/or expand your research career. <p>3. Candidate's Plan for Career Development/Training Activities During Award Period, including any planned externships or reverse externships</p> <ul style="list-style-type: none"> • Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award. • For mentored career development awards, describe any structured activities that are

Required Elements and Page Limits	Instructions/Format
	<p>part of the developmental plan, such as coursework, workshops or externships that will help you learn new techniques or develop needed professional skills. The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects. If coursework is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, other than research, in which you expect to participate.</p> <ul style="list-style-type: none"> • Briefly discuss each of the activities, other than research, in which you expect to participate. • For each activity, other than research, explain how it relates to the proposed research and to the career development plan. Indicate the percentage of time to be dedicated to each activity by year, expressed in person months. • Describe the professional responsibilities/activities including other research projects) beyond the minimum required 75% effort commitment to the KL2 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator conducting patient-oriented research. • You are encouraged to include a timeline, including plans to apply for subsequent grant support. <p>4. Mentor statement</p> <p>The Lead Mentor and Co-Mentor(s) statement must document their role and willingness to participate in the project and explain how they will contribute to the development of the candidate's research career. Each statement should contain all the following components:</p> <ul style="list-style-type: none"> • The plan for the candidate's training and research career development. Include information not only about research, but also about other developmental activities, such as seminars, scientific meetings, training in RCR, and presentations. Discuss expectations for publications over the entire period of the proposed project. Define what aspects of the proposed research project the candidate will be allowed to continue to pursue as part of his/her independent research program. • The source of anticipated support for the candidate's research project for each year of the award period. • The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period. • The candidate's anticipated teaching load for the award period (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research. • A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. Describe the mentor's (or co-mentor's) previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral fellows), number of persons mentored, and career outcomes. <p>Note for co-mentor statements: Co-mentors must also address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this CDA.</p> <p>If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, then the mentor or a member of the mentoring team should include</p>

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	<p>information in the statement to document leadership of the clinical trial (in addition to the information above). Include the following: source of funding; ClinicalTrials.gov Identifier (e.g., NCT87654321), if applicable; a description of how your expertise is appropriate to guide the applicant in any proposed clinical trials research experience; and a statement/attestation that the mentor will be responsible for the clinical trial. The mentor must have primary responsibility for leading and overseeing the trial and must describe how she/he will provide this oversight (be careful not to overstate the candidate's responsibilities). Include details on the specific roles/responsibilities of the applicant and mentor, keeping in mind that the terms of a career development award do not always permit the candidate to lead a clinical trial.</p>
<p>Research Strategy (12 pages, combined with career development plan)</p>	<p>Complete using blank pages.</p> <p>The Research Plan is a major part of the overall career development goal. It is important to relate the proposed research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan. Also describe how the research and other developmental activities will enable the candidate to launch and conduct an independent research career or enhance an established research career.</p> <p>For most types of research, the research plan should include: a specific hypothesis and list of the specific aims and objectives that will be used to examine the hypothesis (in the Specific Aims page), a description of the methods/approaches/techniques to be used in each aim, a discussion of possible problems and how they will be managed, and alternative approaches that might be tried if the initial approaches do not work.</p> <p>A Career Development Award (CDA) Research Plan is expected to be tailored to the experience level of the candidate and to allow him/her to develop the necessary skills needed for further career advancement. Reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the sole part(s) of a CDA Research Plan. Although candidates for mentored career development awards are expected to write the Research Plan, the mentor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful. Although it is understood that CDA applications do not require the extensive detail usually incorporated into regular research grant applications, a fundamentally sound Research Plan that includes a reasonably detailed Research Strategy section should be provided.</p> <p>Consider organizing the Research Strategy in the order and using the instructions provided below. Please include Preliminary Studies, as applicable, within the following sections.</p> <ol style="list-style-type: none"> 1. Significance <ul style="list-style-type: none"> • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. 2. Innovation <ul style="list-style-type: none"> • Explain how the application challenges current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. 3. Approach <ul style="list-style-type: none"> • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately, include how the data will be

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	<p>collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</p> <ul style="list-style-type: none"> • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. • Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
<p>Training in the Responsible Conduct of Research (1 page)</p>	<p>Complete using blank pages.</p> <ul style="list-style-type: none"> • Applications must include a plan to obtain instruction in the responsible conduct of research. This section should document prior instruction in responsible conduct of research during the applicant's current career stage (including the date of last occurrence) and propose plans to receive instruction in responsible conduct of research. The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the sponsor/mentor in responsible conduct of research instruction must be described. • The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12.4.1_application.htm#Training): format, subject matter, faculty participation, duration of instruction, and frequency of instruction.
<p>Institutional Environment (1 page)</p>	<p>Complete using blank pages.</p> <ul style="list-style-type: none"> • Specify specific resources that support the proposed research. Describe the institution's research and career development opportunities related to your area(s) of interest, including the names of key faculty members and other investigators relevant to your proposed developmental plan and capable of productive collaboration with the candidate. Indicate how the necessary facilities and other resources will be made available for both career enhancement and the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.
<p>Statement of how the research is translational (no page limit but please be succinct)</p>	<p>Complete using blank pages.</p> <p>See section 7 above.</p>
<p>Protection of Human Subjects (no page limit but please be succinct)</p>	<p>Complete using blank pages.</p> <p>This section is required for applicants whose project involves human subjects. <i>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</i></p> <p>For more information, see section 3.1 at the following link: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1</p>
<p>Vertebrate Animals (no page limit but please be succinct)</p>	<p>Complete using blank pages.</p> <p>This section is required for applicants whose project involves vertebrate animals. If so you must address the following five key points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s) provide this information before discussing the five points. Although no specific page limitation applies to this</p>

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	<p>section of the application, be succinct.</p> <ol style="list-style-type: none"> 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. 2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers. 3. Provide information on the veterinary care of the animals involved. 4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. 5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations. <p>If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must submit to the NIH awarding office detailed information as required in points 1-5 above and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance then an appropriate Assurance will be required (see Part III Section 2.2 Vertebrate Animals for more information).</p> <p><i>Do not use the vertebrate animal section to circumvent the page limits of the research strategy.</i></p>
<p>Select Agent Research (no specific page limitation applies, but please be succinct)</p>	<p>Complete using blank pages.</p> <p>This section is required for applicants whose project involves select agents.</p> <p>Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf.</p> <p>If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> 1. Identify the Select Agent(s) to be used in the proposed research. 2. Provide the registration status of all entities* where Select Agent(s) will be used. <ul style="list-style-type: none"> ○ If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed. <p>*An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."</p> 3. Provide a description of all facilities where the Select Agent(s) will be used. <ul style="list-style-type: none"> ○ Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s). ○ Describe plans for appropriate biosafety, bio-containment, and security of the Select Agent(s). ○ Describe the bio-containment resources available at all performance sites.
<p>Bibliography and References Cited (no page limitation applies)</p>	<p>Complete using blank pages.</p> <p>Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication.</p>

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	Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.
<p>Letter of Support by Department / Division Chair</p>	<p>Instructions: The letter should comment on the applicant's qualifications for a future career as an independent translational research scientist. The letter should also describe the Department/Division Chair's commitment to the candidate and the candidate's career development, independent of the receipt of the KL2. It is also essential to document commitment to the retention, development, and advancement of the candidate during the period of the award. The letter should generally document the individual's agreement to provide adequate time, support, equipment, facilities, and resources to the candidate for research and career development activities, including the following:</p> <ul style="list-style-type: none"> a) Agree to release the candidate from other duties and activities so that the candidate can devote the required percentage of time for development of a research career (75% or 9 person-months) b) Describe actions that will be taken to ensure that the candidate can devote the required time to research career development (e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year). If the candidate's clinical or teaching responsibilities will be reduced, describe how this will be accommodated (e.g., hiring additional staff, reassigning staff, etc.). c) Describe the candidate's academic appointment, bearing in mind that the appointment must be full-time, and that the appointment and the continuation of salary should not be contingent upon the receipt of this award. d) Describe the proportion of time currently available for the candidate's research and what the candidate's institutional responsibilities will be if an award is made. e) Describe how the institution will provide the candidate with appropriate office and laboratory space, equipment, and other resources (including access to clinical and/or other research populations) to carry out the proposed Research Plan. f) Describe how the institution will be supportive of any proposed mentor(s), other staff, and/or collaborations with other faculty consistent with the career development plan. g) Commit to a third year of funding at 75% effort if the KL2 Scholar does not obtain an NIH K award or R-level award by year 3. <p>The Department/Division Chair should be aware of the CT2 Scholars and discuss feasibility with the applicant if the faculty member is selected as a CT2 instead of a KL2 Scholar. Briefly, in order to expand the reach of the KL2 Program, up to 2 CT2 Scholars may be appointed each year in addition to the 2 KL2 Scholars. The training program is identical to that of the KL2 Scholars, but the 75% salary support is covered by the home Division or Department, and research support is covered by the CCTST (all costs are covered by the CCTST for KL2 Scholars). The home Division or Department must agree to provide this support before a CT2 Scholar may be appointed. If a KL2 Scholar leaves the program early because they obtain external grant support, a CT2 Scholar may be appointed as a KL2 Scholar in his or her place. If an applicant for the KL2 program is a finalist, he or she should discuss with the Department/Division Chair <i>before the interview</i> whether the CT2 program is a feasible option. Applicants who are finalists will be notified in March, 2020 if they were selected as a KL2 or CT2 Scholar.</p>
<p>Letters of support from collaborators or consultants</p>	Include if appropriate. Letters should briefly describe their anticipated contributions and document their role and willingness to participate in the project. The letters should also briefly describe research materials, data, guidance, or advice each person will provide.
<p>Mentoring agreement</p>	Sample available at https://cctst.uc.edu/funding/kl2rs . Scholars may use another mentoring agreement template if they prefer.
<p>Individual</p>	Sample available at https://cctst.uc.edu/funding/kl2rs . Scholars may use another IDP template if

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development plan	they prefer.
Diversity Questionnaire and Checklist	Complete using forms provided

4. **Submission of applications:** LOIs and invited applications must be submitted electronically in the CCTST CCAPS online program at <https://ccaps.research.cchmc.org/welcome>.