KL2 Grant Application Instructions 2021

Funding Period: 4/1/22 – 3/31/24

Letter of Intent Submissions accepted: July 1, 2021 – August 31st 2021 by Midnight

IMPORTANT DATES:

<table>
<thead>
<tr>
<th>Letters of Intent due</th>
<th>August 31st, 2021 by Midnight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification to apply</td>
<td>By September 30th, 2021</td>
</tr>
<tr>
<td>Invited Applications due</td>
<td>November 2nd, 2021 by Midnight</td>
</tr>
<tr>
<td>Finalist Interviews</td>
<td>Week of January 10th, 2022</td>
</tr>
<tr>
<td>Notification of funding</td>
<td>By February 1, 2022</td>
</tr>
<tr>
<td>Funding start date</td>
<td>April 1, 2022</td>
</tr>
</tbody>
</table>

For questions regarding these instructions, please visit https://www.cctst.org/programs/kl2ct2scholars or contact Krista Metz by email at krista.newland@uc.edu.

1) Application submission

Please note that applications must be submitted through the CCTST Competition and Awards Program Site (CCAPS) at 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 Metz to obtain one.

2) Application forms and guidelines

Applications must be assembled as a single PDF file and submitted through CCAPS before midnight 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 can be downloaded from the CCTST website at https://www.cctst.org/programs/kl2ct2scholars. Applications must be submitted as single-spaced text with a minimum of one-half inch margins and 11-point Arial or Helvetica font. PLEASE SEE FULL APPLICATION INSTRUCTIONS BELOW for specifics regarding required elements.

3) Deadlines

All deadlines for submissions are firm; extensions will not be granted.

4) CCTST Membership

All applicants for KL2 grant consideration, must be CCTST members. CCTST membership is free and open to all. For online membership registration, go to https://cctst.uc.edu/user/register.

5) 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 (e.g. an NIH K or R01 award) 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 provided by their home Division or Department, and research support is provided by the CCTST. CT2 Scholars are provided additional research support because their salary support is provided by their Division or Department (see section 11: Budget Guidelines). 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.

6) 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 appointment cannot be contingent upon the receipt of this award.

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. After appointment as a KL2 Scholar, 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). If a faculty member currently holds an internal grant from UC or CCHMC they may be ineligible for a KL2: please check with the Program Directors before applying for the KL2. Past recipients of these awards whose proposed KL2 project does not duplicate this work may be eligible for a KL2. If a faculty member has an internal or NIH K award, or any other internal award, pending at the time they apply for the KL2, they may be ineligible for a KL2: please notify the KL2 Program Directors before applying for the KL2.

Research
• Research must be considered translational. See: Definitions of Types of Translational Research.

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

7) Overview of Review Process
The review of applications is performed in 3 phases:
1. LOI review
   • Top applicants will be invited to submit formal 12-page applications
2. Application scientific review
   • Critiques will be provided to the applicants after awards are announced
3. In-person interviews for finalists

8) Mentor Requirements
KL2 Scholars must identify an approved KL2 primary mentor and at least 1 other mentor. See the following link for a list of primary mentors.

Proposed primary mentors not appearing on this list must be pre-approved before the application process. To qualify, mentors must send an email or compose a letter to the program directors (with NIH Biosketch attached) stating that they 1) are currently externally funded (generally, at least $300,000 of external 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) have participated in all four sessions of the 8-hour mentor training workshop offered at CCHMC and UC (see below). If they have not participated in the mentor training, they must agree to participate by the end of the first year of the Scholar’s KL2 program. 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 and CT2 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.

9) 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 recommend that Scholars 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](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.

**Required Courses:**

<table>
<thead>
<tr>
<th>Course #</th>
<th>Course Title</th>
<th>Credits</th>
<th>Semester</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE-7040</td>
<td>Collaboration &amp; Team Science (alternatively, 2 Team Science workshops)</td>
<td>2</td>
<td>S</td>
</tr>
<tr>
<td>BE-7067 OR GNTD-7003</td>
<td>Scientific Integrity Ethics in Research</td>
<td>1-2</td>
<td>U (hybrid)</td>
</tr>
</tbody>
</table>

**Suggested Courses:**

<table>
<thead>
<tr>
<th>Course #</th>
<th>Course Title</th>
<th>Credits</th>
<th>Semester</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE-7022</td>
<td>Introduction to Biostatistics</td>
<td>3</td>
<td>U/F/S</td>
</tr>
<tr>
<td>BE-7076</td>
<td>Introduction to Epidemiology</td>
<td>2</td>
<td>U/F/S</td>
</tr>
<tr>
<td>BE-9075</td>
<td>Design &amp; Management of Field Studies in Epidemiology</td>
<td>3</td>
<td>S</td>
</tr>
<tr>
<td>BE-9066</td>
<td>Clinical and Translational Research Scholars Seminar</td>
<td>1</td>
<td>S</td>
</tr>
<tr>
<td>BE-8062 OR BMIN-7099</td>
<td>Introduction to Medical Informatics OR Introduction to Bioinformatics</td>
<td>3</td>
<td>F TBA</td>
</tr>
</tbody>
</table>

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. 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 **Visiting Scholar exchange program** with the University of Kentucky and Indiana University.
Additional opportunities are also available with the University of Texas and University of California, Los Angeles, and all Scholars will have the opportunity to apply for these.

10) Budget Guidelines

For KL2 Scholars, 75% salary support up to $102,200/year + fringe and $25,000 research costs per year for up to 2 years are allowed (the second year of support is contingent on adequate progress in Year 1); in addition, a commitment for institutional funding for a 3rd year of salary support is required, if needed. This is the guidance that applicants should follow when creating a budget for the application. If an applicant is chosen as a CT2 Scholar, he or she will receive 75% salary support from the Division or Department, and an additional $15,000 per year in research costs (total of $40,000 in research costs for 2 years), as well as a 3rd year of salary support if needed. The CT2 award provides additional research funding due to the fact that salary support is provided by the Division.

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.

Research funds 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);
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 K Scholars through the CCTST during the Scholar’s 2 years of CCTST KL2 or CT2 support. Applicants are encouraged to obtain methodologic support through the CCTST while preparing their KL2 application. Biostatistical support and core facility support is provided through voucher programs for K Scholars.

11) Full Application Instructions

The letter of intent must be accepted to apply.

| Face Page |
| Check all appropriate IBC, IACUC, IRB, or Radiation Safety approvals or indicate pending if submitted. Signatures required. |
| Project Summary/Abstract |
| The project summary is a succinct and accurate description of the proposed work. This section should be informative to other persons working in the same or related fields and understandable to a scientifically literate reader. In addition to summarizing the research project to be conducted under the career development award, describe the candidate’s career development plan, the candidate’s career goals, and the environment in which the career development will take place. |
### Content: State the application’s broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe the research design and methods for achieving the stated goals.

**Format:** This section is limited to 30 lines of text.

### Project Narrative

**Content:** Describe the relevance of this research to public health - 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.

**Format:** This section is limited to 3 sentences.

### Detailed Budget and Budget Justification

Within the guidelines of this RFA, provide a budget and justification for the first and second year budget periods.

**Format:** Complete using forms provided at KL2 Website under “Application details”

### Biosketches and Other Support

Provide a biographical sketch and other support for the candidate and Mentor (co-Mentor(s) and any other senior/key personnel if desired).

**Format:** Complete using forms provided at KL2 Website under “Application details” or at [https://grants.nih.gov/grants/forms/biosketch.htm](https://grants.nih.gov/grants/forms/biosketch.htm). This section is limited to 5 pages each.

### Candidate Information and Goals for Career Development

(12 pages max, combined with Research Plan)

**Content:** Organize your attachment into three sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Candidate’s Background, Career Goals and Objectives, and Candidate’s Plan for Career Development/Training Activities During Award Period.

**Format:** Complete using blank pages. This section is limited to 12 pages, combined with Research Strategy. 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-f/career-forms-f.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/career-forms-f.pdf)

#### 1. Candidate’s Background

- 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. Alternatively if your work has changed direction, the reasons for the change should be indicated.

Suggested points to include:

- 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.
2. Career Goals and Objectives

- 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.
- If applicable describe how this award will help you to serve as a mentor to early career investigators.

3. Candidate’s Plan for Career Development/Training Activities During Award Period, including any planned externships or reverse externships

- Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches and data analysis and interpretation.
- Describe any structured activities that are part of the developmental plan, such as coursework, workshops or externships that will help you learn new techniques or develop needed professional skills.
- 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. For more information about calculating person months, see NIH’s Frequently Asked Questions on 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.

Research Plan Section
(12 pages max, combined with candidate information and career development plan; specific aims page not included in limit)

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.

For most types of research, the research plan should include:

- A specific hypothesis,
- A list of the specific aims and objectives that will be used to examine the hypothesis,
- 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.

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.

Specific Aims

Content: State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved. 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).

Format: Complete using blank pages. 1 page maximum.

Research Strategy

Content: Organize the Research Strategy in the specified order and use the instructions provided below. Start each section with the appropriate heading – Significance, Innovation, Approach. Explain the relationship between the candidate’s research on the CDA and the mentor’s ongoing research program. Please include Preliminary Studies, as applicable, within the following sections. Please include an explanation of how the research is translational.

Format: Complete using blank pages. 6 page maximum.

1. Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
- 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

- 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

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan section, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate. Resources and tools for rigorous experimental design can be found at the Enhancing Reproducibility through Rigor and Transparency website.
- For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster randomized trial or an individually randomized group-treatment trial. Additional information is available at the Research Methods Resources webpage.
- 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.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for additional information.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.
- If you are proposing to gain clinical trial research experience (i.e., you will not be leading an independent clinical trial), briefly describe your role on the clinical trial.
Training in the Responsible Conduct of Research

**Content:** Mentored CDA applications should describe a plan to acquire instruction in the responsible conduct of research (RCR). Attach a description of plans for obtaining or providing instruction in RCR. This section should document prior instruction or participation in RCR training during the applicant’s current career stage (including the date instruction was last completed). This section should also propose plans to either receive instruction or provide instruction (e.g., to participate as a course lecturer) to meet the frequency requirement of RCR training.

The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the NIH Grants Policy Statement, Section 12.4.1.4: Training in the Responsible Conduct of Research. The plan may include career stage-appropriate individualized instruction or independent scholarly activities. Instruction and activities should 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 mentor in RCR instruction must be described.

1. **Format:** Describe the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable).
2. **Subject Matter:** Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics).
3. **Faculty Participation:** Describe the role of the mentor(s) and other faculty involvement in the instruction.
4. **Duration of Instruction:** Describe the number of contact hours of instruction, taking into consideration the duration of the program.
5. **Frequency of Instruction:** Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant’s current career stage, including the inclusive dates instruction was last completed.

**Format:** Complete using blank pages. 1 page maximum

Plans and Statements of Mentor(s) and Co-Mentor(s)

All mentored career development applications should identify any and all co-mentors involved with the proposed research and career development program. The mentor and each co-mentor must provide a statement as described below.

**Content:** The mentor and co-mentor(s) (if applicable) must each 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 include all of the following:

- 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.

**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. If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, then the
A mentor or a member of the mentoring team should include 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;
- 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.

**Format:** Complete using blank pages. 6 page maximum

### Environment and Institutional Commitment to Candidate

**Content:** 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.

**Format:** Complete using blank pages. 1 page maximum.

### Protection of Human Subjects

This section is required for applicants whose project involves human subjects. **Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.**

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](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)

**Format:** Complete using blank pages. No page limit but should be succinct.

### Vertebrate Animals

This section is required for applicants whose project involves vertebrate animals. **Do not use the vertebrate animal section to circumvent the page limits of the research strategy.**

See the following pages for more information:
- NIH’s Office of Laboratory Animal Welfare website
- NIH’s Vertebrate Animals Section Worksheet
- NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirements (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one)

**Format:** Complete using blank pages. No page limit but should be succinct.

### Select Agent Research

This section is required for applicants whose project involves select agents. Select Agents are hazardous biological agents and toxins that have been identified by HHS 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. The CDC and the Animal APHIS Select Agent Programs jointly maintains a list of these agents. See the Federal Select Agent Program website See also the NIH Grants Policy Statement, Section 4.1.24.1: Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents).

**Format:** Complete using blank pages. No page limit but should be succinct.
Bibliography and References Cited

Provide a bibliography of any references cited. 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. 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.

Format: Complete using blank pages. No page limit

Letters of Support from Collaborators, Contributors, and Consultants

Include letters of support from collaborators, contributors, and consultants who will contribute to the scientific development or execution of CDA application’s proposed project.

Content: Applications should identify collaborators, contributors, and consultants involved with the proposed research and career development program, and not already included in the “Plans and Statements of Mentor(s) and Co-Mentor(s)” section. 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. Letters from consultants should include rates/charges for consulting services.

Format: Complete using blank pages. 6 page maximum

Institutional Commitment by Department / Division Chair (Letters of Support)

Content: The sponsoring division or department must provide a document that describes its commitment to the candidate and the candidate’s career development, independent of the receipt of the CDA. It is also essential to document the institution’s commitment to the retention, development, and advancement of the candidate during the period of the award. The “Institutional Commitment to Candidate’s Research Career Development” attachment should generally document the institution’s agreement to provide adequate time, support, equipment, facilities, and resources to the candidate for research and career development activities. See the list below for specific items to include in the document.

In the document describing its institutional commitment, the applicant organization must:

1. 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, as specified by the FOA. For most K awards, commitment of at least 75 percent or nine person months of time is required.
   a. NIH and other PHS agencies use the concept of “person months” as a metric for determining percent of effort. For more information about calculating person months, see NIH’s Frequently Asked Questions on Person Months.
2. 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.).
3. Describe the candidate’s academic appointment, bearing in mind that the appointment must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award.
4. 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.
5. 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.
6. 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.
7. 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.

Signatures: The institutional commitment must be dated and signed by the person who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the Division Director or Chair of the department. The signature must appear over the signer’s name and title at the end of the statement. If the candidate will be working outside of the
applicant institution (i.e., sponsoring institution), signatures from both the applicant/sponsoring institution and host institutions are required. The sponsoring institution, through the submission of the application and in the institutional commitment section, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies. 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 before the interview whether the CT2 program is a feasible option. Applicants who are finalists will be notified by February 1, 2022 if they were selected as a KL2 or CT2 Scholar.

**Format:** Complete using institutional letterhead

---

**Mentoring Agreement**
Sample available at [https://www.cctst.org/programs/kl2ct2scholars](https://www.cctst.org/programs/kl2ct2scholars) under Application details> Additional resources. Scholars may use another mentoring agreement template if they prefer.

**Individual Development Plan**
Sample available at [https://www.cctst.org/programs/kl2ct2scholars](https://www.cctst.org/programs/kl2ct2scholars) under Application details> Additional resources. Scholars may use another IDP template if they prefer.

**Diversity Questionnaire and Checklist**
Complete using forms provided at KL2 Website under “Application details”