

# 2023 UCLA CTSI KL2 GRANT SUBMISSION FULL APPLICATION INSTRUCTIONS

## **IMPORTANT NOTES**

- Submission link will only be provided to the applicants who are invited to submit full applications.
- Deadline: February 24, 2023 by 5:00 PM

## **PROJECT SUMMARY/ABSTRACT (30 lines of text maximum)**

- Provide an abstract of the entire application. Include the candidate's immediate and long-term career goals, key elements of the research career development plan, and a description of the research project.

## **SPECIFIC AIMS (1 page maximum)**

- 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.
- 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.

## **PROGRAM PLAN (12 pages maximum)**

The Program Plan is from the candidate indicating his/her CTSI KL2 Program research project and training goals, how these goals align with the CTSI mission, his/her future career plans, and how this award will be career-advancing in clinical and translational research. The Program Plan should follow the structure and format for NIH K Award submissions.

**For this section, please follow the NIH guide for [Career Development \(K\) Instructions](#), with the following additional instructions:**

### **Candidate's Background**

- Describe the candidate's commitment to an academic career in biomedical research. Include a description of all of 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.
- If the candidate has completed their terminal research degree (e.g. PhD) or end of post-graduate clinical training (e.g. residency, fellowship), whichever date is later, before January 1, 2017, please describe their career path and experience since completion of training.
- 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 research 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.

### **Career Goals and Objectives**

- 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. It is

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important to justify the award and how it will enable you to develop or expand your research career. You may include a timeline, including plans to apply for subsequent grant support.

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; (2) that justifies the need for further career development to become an independent investigator; and (3) that utilizes the relevant research and educational resources of the institution.

### Candidate's Plan for Career Development/Training Activities During Award Period

- The education plan is an essential component of the proposal and should be tightly integrated with the research plan.
- The candidate and the mentor are jointly responsible for the preparation of the career development plan. A timeline is often helpful. The sponsor/mentor may form a mentoring team (or an advisory committee) to assist with the development of the program of study or to monitor the candidate's progress through the career development program.
- 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.
- Describe the professional responsibilities/activities (including other research projects) beyond the minimum required 9 person-months (75% effort full-time professional effort) commitment to the KL2 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.
- Describe the plans for obtaining future funding (e.g. individual NIH K or R awards).

### Research Strategy

- A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate not only the quality of the candidate's research thus far, but also the innovation, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application should also describe the relationship between the mentor's research and the candidate's proposed research plan.
- If more than one mentor is proposed, the respective areas of expertise and responsibility should be described.
- Organize the Research Strategy in the specified orders and start each section with the appropriate section heading – Significance, Innovation and Approach. Please make sure to address the NIH criteria to [enhance reproducibility of research findings through increased scientific rigor and transparency](#).
- **Significance**
  - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
  - **RIGOR OF THE PRIOR RESEARCH**: 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 project in one or more broad fields.
  - Describe how the concepts, method, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
- **Innovation**

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- Explain how the application challenges current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentations or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- **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.
  - **SCIENTIFIC RIGOR**: Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
  - 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 analysis 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.

### AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

- If applicable to the proposed science, briefly describe the methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. **No more than 1 page is suggested.**
- Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

### PROTECTION OF HUMAN SUBJECTS

- If your proposed project involves human subjects, please refer to the [PHS Human Subjects and Clinical Trials Information, Section 3.1](#) for instructions.
- If your project involves human specimens and/or data from subjects, you must provide a justification in this section for your claim that no human subjects are involved.

### INCLUSION OF WOMEN, MINORITIES, AND INCLUSION ACROSS THE LIFESPAN

- If your proposed project involves human subjects, please refer to the following instructions.
  - Women & Minorities: [PHS Human Subjects and Clinical Trials Information, Section 2.4](#)
  - [Across the Lifespan: PHS Human Subjects and Clinical Trials Information, Section 2.3.a.](#)

### INCLUSION ENROLLMENT REPORT(S)

[Inclusion Enrollment Report\(s\)](#) are required for all human subjects studies unless your study falls under [Exemption 4](#) and no other exemptions.

- [Planned Enrollment Report template](#)

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- [Cumulative \(Actual\) Enrollment Report template](#): You must enter cumulative enrollment counts if your proposed study will use an existing dataset or resource.

### DATA AND SAFETY MONITORING

- Plans for data and safety monitoring must be included for research involving human subjects even if the study is not a clinical trial.
- Please refer to the [PHS Human Subjects and Clinical Trials Information, Section 3.3](#).

### VERTEBRATE ANIMALS

- If vertebrate animals are involved in the project, please refer to [Career Development \(K\) Instructions, Section 13](#).

### TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH (1 page maximum)

- Please refer to [Career Development \(K\) Instructions, Section 6](#).
- 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. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process or may not be reviewed.
- The background, rationale and more detail about instruction in the responsible conduct of research can be found in <http://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html>.

### LETTERS OF SUPPORT FROM MENTORING TEAM (6 pages maximum)

- **One letter of support from the primary mentor.**
- **Additional letters of support from co-mentors and/or collaborators.**
- **Mentor's letter should go first followed by the co-mentor(s) and/or collaborator(s) letter(s).**
- The candidate must name a primary mentor who, together with the candidate, is responsible for the planning, directing, monitoring, and executing the program. The primary mentor's letters should detail the candidate's capabilities, accomplishments, and commitment to developing an academic career in translational research; a preliminary research training plan, including area of focus and specific projects; potential associate mentors to enhance training expertise; additional plans for the candidate's professional development; departmental support for the candidate's future academic career development. The candidate may also nominate co-mentors as appropriate to the goals of the program.
- The mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training and placing independent investigators.
- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- Where feasible, women, individuals from diverse racial and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models.
- The application must include a statement from the mentor providing: 1) information on his/her

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research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the candidate to move from the mentored stage of his/her career to independent research investigator status during the project period of the award including what aspects of the proposed research the candidate will be able to take into their independent position; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.

- Similar information must be provided by the co-mentor(s). If more than one co-mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate. If any of the co-mentors are not located at the sponsoring institution, a statement should be provided describing the mechanism(s) and frequency of communication with the candidate, including the frequency of personal meetings.
- The mentor must agree to provide annual evaluations of the candidate's progress as required in the annual progress report.
- Consultant(s)/Collaborator(s): Collaborators and consultants do not need to provide their biographical sketches. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration. Collaborators/consultants are generally not directly involved in the development of the career of the candidate as an independent investigator.

### INSTITUTIONAL LETTER OF SUPPORT FROM DEPARTMENT CHAIR OR DIVISION CHIEF (2 pages maximum)

- Provide assurances that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to research and related career development activities. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent clinician scientist, e.g. clinic responsibilities, teaching and administration, and/or additional research activities.
- If applying as a current trainee (e.g. postdoc, fellow), the letter should also confirm that the candidate will be appointed as faculty (e.g. Assistant Professor) by the start of the grant.
- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan.
- Describe any resources from the institution that will be made available to the candidate to conduct his/her research or execute the educational plan.
- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan.
- Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.

### BUDGET AND BUDGET JUSTIFICATIONS

- UCLA CTSI KL2 Translational Science awardees will receive annual support (see table below) for up to 3 years.

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Scholar Salary (75% effort)	\$75,000
Scholar Fringe Benefits Research Expenses ( <i>UCLA applicants must include TIF</i> ) Tuition/Career Development ( <i>excludes scientific memberships</i> ) Statistical Support	\$53,000
Travel for scientific conferences	\$2,000
<b>MAXIMUM DIRECT COSTS/YEAR</b>	<b>\$130,000</b>

- Prepare the NIH-formatted **detailed budget** and **budget justification** for each year of the three years of support. Please use a separate [Form Page 4](#) for the detailed budget for each year. Budgets on [Form Page 5](#) are NOT acceptable.
- **Common unallowable expenses:** membership fees, general liability insurance, general office supplies and computers (project specific items are allowed and must be clearly justified).

### OTHER COMPONENTS OF THE KL2 APPLICATION

- [NIH-formatted Biosketch \(NOT-OD-21-073\)](#) of the CTSI KL2 candidate
- [NIH-formatted Other Support Pages](#) of the CTSI KL2 candidate with **current, past and pending grants**. Please also review the NIH notices below regarding concurrent support.
  - [Salary Supplementation and Compensation on Research Career Development \("K"\) Awards](#)
  - [Concurrent Support from a Mentored K Award and a Research Grant](#)
- **Mentoring Team [NIH-formatted Biosketches \(NOT-OD-21-073\)](#)**. The primary mentor's biosketch should go first followed by the co-mentor(s) biosketch(es).
- **Bibliography & References Cited.**
- **Letters of Support for use of equipment, data, specimens, and community partners** (when applicable). Other letters of support submitted under this field will be removed during the administrative review process.

#### Formatting

- **Format Attachments:** <https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm>
- **Headers and Footers:** Do not include headers or footers in your attachments. We will add headers, footers, page numbers, bookmarks and a table of contents when we assemble your grant application upon submission.

#### CTSI Online Submission

- Submission link will only be provided to the applicants who are invited to submit full applications.
- **Questions???** Please email [CTSIWD@mednet.ucla.edu](mailto:CTSIWD@mednet.ucla.edu) and allow 1-2 business days for responses.