

**KL2 Mentored Research and Career Development Program
2020 KL2 Grant Application Instructions**

IMPORTANT DATES:

Competitive Letters of Intent due
Invitations to Apply
Applications due
Funding start date

December 18, 2019 by 5:00 pm
January 6, 2020
March 16, 2020 by 5:00 pm
July 1, 2020

For questions regarding these instructions, please visit http://iims.uthscsa.edu/ed_kl2_App_Info.html or contact Kathlynn Wray by phone at (210) 567-4330 or by email at wrayk@uthscsa.edu.

1. **Application submission:** Please submit Letters of Intent and full applications via the online application system linked on our website. <https://apply-uthscsa.smapply.io>

If you have issues or questions please contact Kathlynn Wray, wrayk@uthscsa.edu.

2. **Signatures:** The signatures of all participating investigators and their respective division director, departmental chairperson(s), or organization leader are required.
3. **Application forms and guidelines:** Applications must be uploaded to our online application system <https://apply-uthscsa.smapply.io> before 5:00 pm of the application submission deadline date. The application form was modified from the PHS 398 forms page located at <http://grants.nih.gov/Grants/Funding/Phs398/Phs398.html>
4. **Deadlines:** All deadlines for submissions are firm; extensions will not be granted.
5. **Background:** The Mentored Research Career Development (KL2) Program supports Clinical and Translational Research Scholars who are selected on a competitive basis for a 2-year program of mentored research. Scholars are expected to apply for independent research funding – usually a K08, K23, or R01 – in Year 2 of their KL2 award. Because there is often a long lag period between applying for a grant and receiving it, **the Scholar's home department must guarantee a 3rd year of salary support at 75% effort should the Scholar not obtain independent funding by the end of Year 2.** This NIH-sponsored program targets individuals who are affiliated with the Clinical and Translational Science Award (CTSA), which encompasses all University of Texas Health Science Center at San Antonio schools and our diverse public and private partners in South and Central Texas: the VA, military bases, UTSA, UT College of Pharmacy (San Antonio campus), the UT School of Public Health (San Antonio regional campus), and UT Austin.
6. **Definitions of Translational Research:**
Translation 1 ("T1"): from basic science to health application
Translation 2 ("T2"): from health application to evidence-based guideline
Translation 3 ("T3"): from evidence-based guideline to health practice
Translation 4 ("T4"): from health practice to health impact in the population
7. **Eligibility:**
 - Candidates for the KL2 Scholar program are early career faculty (Instructor or Assistant Professor) who have a professional doctoral degree or are completing postdoctoral training with an impending academic appointment that is not contingent on receipt of a KL2 award. KL2 Scholars will be recruited from a wide range of health professions and related fields, including all specialties of medicine and surgery, nursing, psychology and other behavioral

sciences, dentistry, pharmacy, pharmacology, epidemiology, biostatistics, allied health sciences, health services research, biomedical engineering, and other postdoctoral professions. All applicants must have evidence of strong academic achievement and scholarship, as well as personal attributes such as a strong work ethic and integrity.

- Applicants must be US citizens or non-citizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-155) or some other verification of legal admission as a permanent resident. Applications will be accepted from persons whose residence application is pending, but the residency requirement must be met prior to receiving a KL2 award. Individuals on temporary or student visas are not eligible.
- Applicants must be able to commit at least 75% of full-time professional effort to this Career Development Program and its related clinical/translational science research activities (50% effort may be permitted for surgeons).
- Applicants who are dually employed by UT Health San Antonio and the VA may be restricted from the KL2 Scholar award, depending upon the extent of commitment (percent effort) to the VA. Federal salaries cannot be considered part of the required 75% KL2 institutional commitment.
- Applicants must not be, or have been, a principal investigator on an R01 award or a project leader on a subproject of a Program Project (P01), Center (P50, P60, U54) grant, or other equivalent research grant award. Applicants may also not have another mentored research career development (K-series) grant application under consideration at the time they receive a KL2. Eligible applicants may have received prior support on an Institutional or Individual NRSA grant (F or T) or NIH small grant (R03, R21).
- Please note that NIH rules preclude individuals funded by the KL2 program from receiving additional federal funds for the portion of effort not covered by the KL2 program.

8. **Letter of Intent:** The LOI consists of a summary no longer than 1 page outlining the applicant's career development objectives (including mentor(s) and mentorship plan) and research objectives, the letter of support from your Department Chair or Division Chief guaranteeing your 3rd year of protected time, and an applicant biosketch in NIH format (<https://grants.nih.gov/grants/forms/biosketch.htm>). All LOI applications must be submitted via our online application system <https://apply-uthscsa.smapply.io>. An eligibility checklist, diversity questionnaire and demographic information will be required as a fillable portion when you submit your LOI online. Your LOI will be scored and successful applicants will be contacted by January 6, 2020 with an invitation to submit a full KL2 application. **Thus, the LOI is required and must be received by 5:00 pm on Wednesday, December 18, 2019.** If you have any questions or issues please contact Kathlynn Wray at wrayk@uthscsa.edu.
9. **Overview of Review Process:** The review of applications is performed in 2 phases: (1) scientific review, and (2) applicant interview. The full applications will be reviewed by 2-4 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 KL2 program leaders and a community member. Following interviews, KL2 program leaders will meet to discuss and determine awardees. Critiques from the scientific review will be provided to the applicants after awards are announced.
10. **Mentor Requirements:** KL2 Scholars must identify a primary mentor and at least 1 other co-mentor. In general, proposed primary mentors should be currently 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; have a track record as a successful mentor (as exemplified in a table of trainees); and have adequate protected time (generally at least 5% effort) for mentoring. 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 UT Health San Antonio. This 8-hour program (four 2-hour sessions, held each semester) covers the following competencies:

maintaining effective communication; aligning expectations; assessing understanding; addressing equity and inclusion; fostering independence; and promoting professional development. 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 links to sample Mentorship Agreement Template and sample Individual Development Plans below]. The effectiveness of the mentoring relationship will be evaluated during the course of the Scholar's award period.

11. **Scholar Requirements:** Each Scholar is expected to attend KL2 SPARK peer-mentoring sessions, SOAR career development sessions, and individual meetings with KL2 program directors, all of which are scheduled on Thursday mornings. The Scholar must also 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, UTHSCSA offers didactic courses through our Master of Science in Clinical Investigation – Translational Science (MSCI-TS) program and Certificate in Translational Science (see http://iims.uthscsa.edu/ed_msci_overview.html and http://iims.uthscsa.edu/ed_certificate_in_ts.html).
12. **Externships:** A new feature for KL2 Scholars is an opportunity for externships with outside organizations, such as other CTSA hubs, IIMS partner institutions, pharma/biotechnology companies (e.g., Eli Lilly), and San Antonio community organizations. 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. Scholars are encouraged to include possible externship plans in their full application.
13. **Budget Guidelines:** The award provides up to 2 years of funding, with the 2nd year of support contingent on adequate progress in Year 1. A 3rd year of salary must be provided with 75% protected time **by the Scholar's sponsoring department** should the Scholar not receive independent funding by the end of the 2-year KL2 award period. Scholars may request 75% of their 12-month salary up to a maximum of \$112,500 (in other words, Scholars whose institutional base salary is less than \$150,000/year will receive 75% of their institutional base salary plus fringe benefits from the KL2 award; Scholars whose institutional base salary exceeds \$150,000/year will receive \$112,500 plus fringe benefits from the KL2 award; Scholars whose institutional base salary is less than \$150,000/year will receive 75% of their institutional base salary) plus fringe benefits on the awarded salary. 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.

In addition to salary and fringe, up to \$25,000 annually is awarded for research and career development support, which may include the following expenses: (1) tuition and fees related to career development, e.g., didactic courses in the MSCI-TS or the Certificate in Translational Science programs; (2) research expenses, such as supplies, equipment, and technical personnel; (3) travel to externships, research meetings, workshops, or training (KL2 applicants must allow \$1,500 for travel to the Translational Science annual meeting in Washington each spring); 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.

Biostatistical and REDCap support will be provided at no charge to KL2 Scholars through the Department of Epidemiology and Biostatistics during the Scholar's 2 years of KL2 support.

- 14. Letters of Support:** Applications must include letters 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 KL2 funding and a 3rd year, if necessary, funded by the sponsoring academic department. The primary mentor's letter should indicate whether he/she is willing to participate in the mentor training workshops.
- 15. Application forms** (modified from SF424) may be downloaded from UTHSCSA IIMS KL2 Applications forms page http://iims.uthscsa.edu/ed_KL2_App_Forms.html. Applications must be submitted as single-spaced text with a minimum of one-half inch margins and 11-point Arial font. **The career development plan and research plan are limited to a total of 12 pages, combined.**
- 16. Composition of Research Proposal:** Research proposals should include the following. For additional guidance regarding the Specific Aims, Career Development Plan, Research Strategy, and other sections, 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-e/career-forms-e.pdf>)

Required Elements and Page Limits	Instructions/Format
Face Page	Part of LOI
Project Summary/Abstract	<p>The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should include a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information.</p> <p>The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness and translational nature of the project. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person in this section. This section must be no longer than 30 lines of text, and follow the required font and margin specifications.</p>
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 (maximum 5 pages each)	Provide a biographical sketch for the candidate and Mentor (co-Mentor(s) and any other senior/key personnel if desired), using the NIH format, which can be found here: https://grants.nih.gov/grants/forms/biosketch.htm .
Other support	Provide other support information for the candidate and Mentor, using the form provided.
KL2 Career Development Plan (12 pages, combined with Research plan)	<p>Complete using blank pages.</p> <p>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; if your work has changed direction, the reasons for the change should be indicated. Any additional information not described in</p>

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	<p>the Biographical Sketch Format Page, such as research and/or clinical training experience, may be included in this section.</p> <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 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. • 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 Describe your short-term and long-term career goals and objectives, and how the career development award is envisioned to enable you to develop and/or expand your research career. It is important to justify the need for the award. You are encouraged to include a timeline, including plans to apply for subsequent grant support (i.e., to become an independent investigator).</p> <p>3. Candidate's Plan for Career Development/ Training Activities During Award Period, including any planned 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. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. • 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. 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 he/she has 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. • 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.

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	<p>4. Mentor statement</p> <p>The Lead Mentor and Co-Mentor(s) statement may include the following:</p> <ul style="list-style-type: none"> • The plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project and define what aspects of the proposed research project the candidate will be allowed to take with him/her to start their own research program. • Any additional sources 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 period of the award, if applicable (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 an NIH K award or an R-level award by the end of the project period of the award. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes. • His/her willingness to participate in the mentor training workshops. http://opa.uthscsa.edu/entering-mentoring
<p>Specific Aims (1 page)</p>	<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>
<p>Research Strategy (12 pages, combined with career development plan)</p>	<p>Complete using blank pages.</p> <p>Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.</p> <p>(a) Significance</p> <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. <p>(b) Innovation</p> <ul style="list-style-type: none"> • Explain how the application challenges current research or clinical practice

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	<p>paradigms.</p> <ul style="list-style-type: none"> 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. <p>(c) Approach</p> <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 in Item 21 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. 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. (see example on website- http://iims.uthscsa.edu/ed_KL2_App_Forms.html)
<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.
<p>Statement of how the research is translational (no page limit but please be succinct)</p>	<p>Complete using blank pages.</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>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 5 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 5 points. Although no specific page limitation applies to this section of the application, be succinct.</p> <ol style="list-style-type: none"> 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.

Required Elements and Page Limits	Instructions/Format
	<ol style="list-style-type: none"> 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 3 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"> o 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"> o Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s). o Describe plans for appropriate biosafety, bio-containment, and security of the Select Agent(s). o 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. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon</p>

Required Elements and Page Limits	Instructions/Format
	when preparing any section of the application.
Diversity Questionnaire Checklist (required by NIH)	Part of LOI
Letter of Support by Department / Division Chair	Instructions: The letter should comment on the applicant's qualifications for a future career as an independent translational research scientist. <i>Please indicate the resources that you will provide to support the candidate's research. Be specific as to amount of space, number and kind of staff, clinical and lab resources, and dollars you will make available to the scholar.</i>
Letters of support from collaborators or consultants	Include if appropriate.
Mentoring agreement	Sample available at https://iims.uthscsa.edu/ed_KL2_App_Forms.html
Individual development plan	Sample available at https://iims.uthscsa.edu/ed_KL2_App_Forms.html

For questions, please contact Kathlynn Wray at wrayk@uthscsa.edu or 210-567-4330.