K12 Mentored Research and Career Development Program
2023 K12 Grant Application Instructions

IMPORTANT DATES:

Competitive Letters of Intent due	**January 9, 2023 by 5:00 pm**
Invitations to apply	**January 20, 2023**
Applications due	**March 20, 2023 by 5:00 pm**
Estimated funding start date	**July 1, 2023-September 1, 2023**

For questions regarding these instructions, please visit https://iims.uthscsa.edu/ed_kl2_App_Info.html or contact Kathlynn Wray 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/prog/KL2

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

2. **Application forms and guidelines:** Applications must be uploaded to our online application system https://apply-uthscsa.smapply.io/prog/KL2 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

3. **Deadlines:** All deadlines for submissions are firm; extensions will not be granted.

4. **Background:** The Mentored Research Career Development (K12) Program supports Clinical and Translational Research Scholars who are selected on a competitive basis for a 2-3-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 K12 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 Department of Veterans Affairs, military bases, UTSA, UT College of Pharmacy (San Antonio campus), the UT School of Public Health (San Antonio regional campus), and UT Austin.

   The K12 Program is supported by the CTSA grant, which is currently up for renewal. Therefore, funding for the K12 Program is contingent on successful renewal of the CTSA grant. Of note, the new CTSA grant has a focus on translational science (see definitions below). The K12 program will seek to strike a balance between clinical and translational research and translational science. Once selected for a K12 award, K12 program directors will work with the Scholar and their mentoring team to incorporate translational science into the Scholar's research and career development plans.

5. **Definitions**

   Translational Research: The endeavor to traverse a particular step of the translational process for a particular target or disease.

   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

Translational Science: The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

6. Eligibility:

- Candidates for the K12 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 K12 award. K12 Scholars will be drawn 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, informatics, 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 K12 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 research activities (50% effort may be permitted for surgeons).
- Applicants who are dually employed by UT Health San Antonio and the Department of Veterans Affairs may be restricted from the K12 Scholar award, depending upon the extent of commitment (percent effort) to the VA. Federal salaries cannot be considered part of the required 75% K12 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 K12. 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 K12 program from receiving additional federal funds for the portion of effort not covered by the K12 program.

7. **Letter of Intent**: The Letter of Intent (LOI) section upload, consists of a summary no longer than 1 page outlining the applicant's career development objectives, mentor(s) and mentorship plan, and research objectives; the letter of support from the applicant's Department Chair or Division Chief guaranteeing a 3rd year of protected time; and the applicant's 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/prog/KL2. 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 20, 2023 with an invitation to submit a full K12 application. **Thus, the LOI is required and must be received by 5:00 pm on Monday, January 9, 2023.** If you have any questions or issues, please contact Kathlynn Wray at wrayk@uthscsa.edu .

8. **Overview of Review Process**: The review of full 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 K12 program), who will score the applications following K12 program guidelines. During the final phase, applicants' scores will be tabulated and ranked, and the top applicants will be interviewed by K12 program leaders and a community member. Following interviews, K12 program leaders will meet to discuss and determine awardees. Critiques from the scientific review will be provided to the applicants after awards are announced.

9. **Mentor Requirements:** K12 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 K12 mentors are required to have completed (or to complete in the first year of the K12 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, K12 applicants and their proposed mentors are required to submit with the K12 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.

10. **Scholar Requirements:** Each Scholar is required to attend K12 SPARK peer-mentoring sessions, SOAR career development sessions, CTS Roundtable sessions, and individual meetings with K12 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 K12 Scholars have, or develop, competency in key areas of translational research, UT Health San Antonio 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).

11. **Externships and Virtual Visiting Professorships:** K12 Scholars may arrange 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. K12 applicants are encouraged to include possible externship plans (virtual or in-person, travel restrictions permitting) in their full application.

    2nd-year K12 Scholars will also have the opportunity to participate in the Virtual CTSA Visiting Scholars Program. In that program, Scholars apply to visit another CTSA hub virtually in order to network with faculty at that hub who have expertise in the Scholar's field of research, and to deliver a CTSA Grand Rounds presentation that will be streamed across the CTSA Consortium. K12 applicants need not propose plans to participate in this program in their K12 application; instead, they will have a chance to plan the visit during their 2nd year as a Scholar.

12. **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 K12 award period. Scholars may request 75% of their 12-month salary up to a maximum of $120,000 plus fringe benefits (in other words, Scholars whose institutional base salary is less than $160,000/year will receive 75% of their institutional base salary plus fringe benefits from the

K12 award; Scholars whose institutional base salary exceeds $160,000/year will receive $120,000 plus fringe benefits from the K12 award; 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 $28,000 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 (K12 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 K12 Program.

Biostatistical and REDCap support will be provided at no charge to K12 Scholars through the IIMS Biostatistics and Study Design Program during the Scholar's 2 years of K12 support.

13. **Letter of Support:** Applications must include letters of support from the applicant's primary mentor. The primary mentor's letter should indicate whether he/she is willing to participate in the mentor training workshops.

14. **Application forms** (modified from SF424) may be downloaded from UT Health San Antonio IIMS K12 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. ***Note: When uploading in the Survey Monkey Apply application system, the 1-page Specific Aims page will be uploaded together with (right before) the Research Plan – totaling 13 pages maximum.**

15. **Composition of Research Proposal:** Research proposals should include all required elements (see table below). 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	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. 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. 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**.
Detailed budget	Within the guidelines of this RFA provide a budget for the first and second year budget periods using the forms provided.

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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.
K12 Career Development Plan (12 pages, combined with Research plan)	Complete using blank pages. **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 the Biographical Sketch Format Page, such as research and/or clinical training experience, may be included in this section. Suggested points to include: • Describe your commitment to an academic career in Clinical/Translational Research. Include a description of all of your 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 your research efforts to this point in your research career, including any publications, prior research interests and experience. • Provide evidence of your potential to develop into an independent investigator. • Include a statement that you will commit at least 9 person-months (75% of full-time professional effort [at least 6 person-months for surgeons]) to the K12 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 your time will be protected. **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). **3. Candidate's Plan for Career Development/ Training Activities During Award Period, including any planned externships** • 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. You must demonstrate you have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects. If coursework is included, provide course

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	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 K12 award. Explain how these responsibilities/activities will help ensure your career progression to achieve independence as an investigator conducting clinical and translational research. **4. Mentor statement** The Lead Mentor and Co-Mentor(s) statement may include the following: • 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 clinical or 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 award period. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., career development awardees, postdoctoral students, graduate students,), number of persons mentored, and career outcomes. • Their willingness to participate in the mentor training workshops. http://opa.uthscsa.edu/entering-mentoring
Specific Aims (1 page)	Complete using blank pages. State precisely the proposed career development and research goals and summarize the expected outcome(s) including the impact that the results of the proposed career development and 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.
Research Strategy (12 pages, combined with career development plan)	Complete using blank pages. 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. (a) Significance • 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.

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	(b) Innovation • Explain how the application challenges current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, tools or interventions to be developed or used, and any advantage over existing methodologies, tools, or interventions. (c) Approach • 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. Note NIH's 2023 data management and sharing policy: https://oir.nih.gov/sourcebook/intramural-program-oversight/intramural-data-sharing/2023-nih-data-management-sharing-policy • 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 managing 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.
Training in the Responsible Conduct of Research (1 page)	Complete using blank pages. • Applications must include a plan to obtain instruction in the responsible conduct of research, as per NIH requirements (see https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html and https://iims.uthscsa.edu/search_results.html?cx=002444289691723714690%3Ax741qhn9_ii&cof=FORID%3A11&cx=002468566007256985446%3Ariqm3q0eyqs&ie=UTF-8&as_q=rcr&sa=Search&cof=FORID%3A11&ie=UTF-8). The UTHSCSA MSCI-TS course entitled Responsible Conduct of Patient-Oriented Research (TSCI 5070) is a 2-credit–hour course designed to train participants in the responsible conduct of patient-oriented clinical research.
Institutional Environment (1 page)	Complete using blank pages. • Specify specific resources that support the proposed research.
Statement of how the research is translational (no page limit but please be succinct)	Complete using blank pages.
Protection of Human Subjects (no page limit but please be succinct)	Complete using blank pages. 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.*
Vertebrate Animals (no page limit but	Complete using blank pages. **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

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please be succinct)	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. 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. 2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers. 3. Provide information on the veterinary care of the animals involved. 4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. 5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations. 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). *Do not use the vertebrate animal section to circumvent the page limits of the research strategy.*
Select Agent Research (no specific page limitation applies, but please be succinct)	Complete using blank pages. **This section is required for applicants whose project involves select agents.** 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. 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. 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. 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. *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." 3. Provide a description of all facilities where the Select Agent(s) will be used. Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s). Describe plans for appropriate biosafety, bio-containment, and security of the Select Agent(s). Describe the bio-containment resources available at all performance sites.
Bibliography and References Cited	Complete using blank pages. 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, year of publication, and PMID/PMCID/DOI.

Required Elements and Page Limits	Instructions/Format
(no page limitation applies)	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.
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 clinical/translational researcher. *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.*
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 .