PART 1. OVERVIEW INFORMATION

<table>
<thead>
<tr>
<th>Funding Opportunity Title</th>
<th>CTSI K12 Mentored Career Development Scholar Award</th>
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<tbody>
<tr>
<td>Awarding Organization</td>
<td>Utah Clinical and Translational Science Institute (CTSI)</td>
</tr>
<tr>
<td>Federal Prime Sponsor</td>
<td>Federal Prime Sponsor</td>
</tr>
<tr>
<td>Activity Code</td>
<td>K12 Training Program</td>
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Summary of the Funding Opportunity Purpose

The purpose of the CTSI K12 Mentored Career Development Scholar Award is to support the career development of junior faculty members. These scholars will make a commitment to focus their research endeavors on clinical and translational research using the principles of translational science in order to advance health. Early stage investigators with faculty appointments at either the University of Utah or CTSI partner institutions, including Intermountain Healthcare, Utah Department of Health, University of Nevada at Reno, and Veterans Affairs Salt Lake City Health Care System are eligible to apply.

Eligibility Criteria

The applicant for the CTSI Mentored Career Development Scholar Award must be supported by both their Department Chair, and Division Chief to apply for this competitive award. Applicant must be involved in clinical and translational (T1-T4) research. The CTSI recommends that applicants to have reviewed and understand the eligibility criteria as well as obtain the required departmental support prior to beginning the application process.

Key Dates

<table>
<thead>
<tr>
<th>Posted Date</th>
<th>November 16th, 2022</th>
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<tr>
<td>Pre-Application Due Date</td>
<td>January 17th, 2023</td>
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<tr>
<td>Pre-Application Notification</td>
<td>February 7th, 2023</td>
</tr>
<tr>
<td>Full Application Due Date</td>
<td>5 pm MT, Monday, April 3rd, 2023</td>
</tr>
<tr>
<td>Merit Review</td>
<td>April/May 2023</td>
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</table>
The purpose of this opportunity is to ensure that a diverse pool of highly trained translational scientists is available to address the Nation’s clinical and translational (T1-T4) research needs to enable tailoring treatment according to the biology and preferences of the individual patient. The objective of the CTSI K12 Mentored Career Development Scholar Award program is to provide tailored research and career development opportunities to fit the needs of each candidate while offering strong didactic education, mentored research, interdisciplinary works-in-progress seminars, and team-building experiences. The research and training plans will address clinical and translational research and translational science competencies. The Award will provide salary and research support for a sustained period of 2 years.
The applicant for the CTSI Mentored Career Development Scholar Award must be supported by both their Department Chair, and Division Chief to apply for this competitive award. Applicant must be involved in clinical and translational (T1-T4) research. The CTSI recommends applicants to have reviewed and understand the eligibility criteria as well as gain the appropriate departmental support prior to beginning the application process.

The CTSI highly encourages applications from individuals from racial and ethnic groups that are underrepresented in health-related sciences on a national basis; women, and individuals with disabilities; and individuals from disadvantaged backgrounds. Applicants conducting all areas of clinical and translational research are eligible. Priority will be given to applicants conducting research (at any point in the translational spectrum) that addresses NCATS priorities (climate change & environmental health, health equity for underrepresented populations, rural health, and maternal health) and/or issues of disparities either because of rurality or underrepresented and disadvantaged groups. This is in accordance with the National Institutes of Health (NIH) strategic plan in which underrepresented and disadvantaged groups include:

- Ethnic groups that have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders.
- Individuals with disabilities.
- Individuals from disadvantaged backgrounds.
- Individuals living in rural or frontier communities.

Section II. Program Directors, Mentors, and Other Descriptions

Program Directors
The Utah CTSI K12 Mentored Career Development Scholar Award Director is Dr. Maureen A. Murtaugh and Associate Directors are Drs. Ingrid Nygaard, and Michael Varner. Dr. Murtaugh is a Professor of Epidemiology in the Department of Internal Medicine. Drs. Nygaard and Varner are Professors of Obstetrics and Gynecology. The leadership team’s experience and backgrounds are complementary, providing a depth of understanding of the issues that junior faculty face in their pursuit of success in academia. All are experienced mentors with a strong history of research funding.

Interdisciplinary Mentoring Team
We require that the mentor team is composed of at least three mentors from three different areas of expertise with complementary clinical and translational research strengths. Strong mentors are a key component to a faculty’s success. The Utah CTSI K12 Mentored Career Development Scholar Award program requires that the selected mentors are established investigators, preferably acknowledged experts in their field supported by NIH or other competitive award grants. The K12 Mentored Career Development Scholar Award Program requires mentors to:

- For the application:
  - Assist applicant with writing and approve his/her career development plan.
  - Write a Letter of Support indicating his/her role with the Scholar during the award period.
  - Help develop the specific plan for subsequent extramural funding (external K or R01/R01 equivalent), including a timeline of grant submission.

- During award period:
  - Participate in approved mentor training (before or during award period):
    - CIMER Entering Mentoring Training
▪ Research Education (REd): Research Mentoring Certificate Program
▪ Or completion of equivalent activity (please describe)
  • Meet with scholar and K12 directors at a kick-off meeting at the beginning of the award period.
  • Meet regularly with scholar to monitor research progress and provide advice on course work, research strategies, publications, and career goals. Mentor(s) is encouraged to maintain an open-door policy for their scholars.
  • Attend and provide critical feedback regarding mentee’s presentation skills and progress after research presentations.
  • Guide scholar in the completion of the required Individual Development Plan (IDP) that includes the required and optional translational research and translational science elements (see K12 Required and Optional Training Activities) to establish education and training goals and report progress.
  • Maintain an environment to achieve the research goals of the scholar.
  • Encourage mentee in completion of training program required learning activities.
  • Guide mentee in development and submission of an extramural grant proposal.
  • Maintain scientific productivity with continuity in extramural funding and team-based clinical and/or translational research projects that stimulate technical, intellectual, and professional development of scholar.

Department Chair and Division Chief Support (1-page limit)
Dedicated support from a Department Chair and Division Chief (unless there is no Division Chief) is also a key component to a faculty’s success. The Utah CTSI K12 Mentored Career Development Scholar Award program requires that the nominated candidate’s Department Chair and Division Chief, if applicable, must submit a letter of institutional support.

Section III. Eligibility Information

Candidate Eligibility
The CTSI K12 Mentored Career Development Scholar Award is a competitive award, and it is recommended that applicants have reviewed and understand the eligibility criteria. Eligible candidates must:

▪ Show evidence of performance in clinical and translational research and a commitment to continue a career in clinical and translational research to advance health.
▪ A K12 scholar candidate who is poised to submit an independent mentored career development grant, Program Project Grants/Center Grants or equivalent grant is likely too senior for the K12 award. The candidate must confirm that either a) they have never submitted an external K award application, or b) confirm that an external K application was not discussed and has not been resubmitted. The candidate must confirm that they are not planning on an external K submission within the first year of the award period. If an external K award has been submitted and is pending, the scholar is not eligible to apply.
▪ Scholars must have the anticipated ability to complete the entire two-year proposed program.
▪ Devote 75% FTE (9 person months) (for surgeons, 50% FTE – 6 person months) to research and career development activities during the award period.
▪ At the time of award, be a U.S. citizen, non-citizen national, or be able to provide legal proof of lawful admission for permanent residence. Individuals on temporary or student visas are not eligible.
▪ At the time of award, must be a later stage postdoctoral fellow or hold a junior faculty appointment (instructor or assistant professor) at either the University of Utah or CTSI partner institutions, including Intermountain Healthcare, Utah Department of Health, University of Nevada at Reno, and Veterans Affairs Salt Lake City Health Care System.
▪ Have a MD, PhD, DO, PharmD, DNP, DNS; an equivalent doctoral level health science degree; or an equivalent doctoral level degree in a field that interacts with healthcare from an accredited domestic or foreign institution.
▪ 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 apply.

- Demonstrate both a long-term dedication to advancing translational science to improve clinical care as well as a good relationship between planned training and short- and long-term career goals.

Scholar Responsibility
CTSI requires participating K12 Mentored Career Development Scholars to:

- Meet quarterly with the K12 Mentored Career Development Scholar Program Leadership Team to evaluate progress.
- Meet regularly with their mentoring team.
- Obtain a ProTracks account and request all appropriate CTSI services using ProTracks.
- Provide progress reports as requested and a final report. The second year of funding is contingent upon satisfactory review of the progress reports.
- Attend these required CTSA/CTSI events:
  - CTSI K-Club and present at least once during the award period. (monthly)
  - CTSI Translational Science Symposium. (annually)
  - ACTS Translational Science Conference (at least once during award period)
  - Clinical and Translational Science Seminars (quarterly)
- Identify and acknowledge CTSI grant on all related publications and presentations (e.g., oral, poster, etc.) and comply with the NIH public access policy. To learn more about how to cite the training grant and comply with the NIH public access policy, click here.
- Scholars may not accept or hold any other PHS award that duplicates the provisions of this career award during the period of this award. Scholars are required to receive Leadership Team prior approval before accepting other PHS award support while in the program.
- Provide contact information and updates on research and career activities when requested.
- Participate fully in the VPCAT Research Scholar Program, unless already completed
- Adhere to all University research regulatory and compliance policies.

Section IV. Award Information

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<thead>
<tr>
<th>Funding Instrument</th>
<th>Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.</th>
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<tr>
<td>Application Types Allowed</td>
<td>Invited New and Resubmissions</td>
</tr>
<tr>
<td>Anticipated # of Award(s)</td>
<td>Five</td>
</tr>
<tr>
<td>Award Budget</td>
<td>Award budgets, $157,334 per year, are composed of salary, benefits, and other program-related expenses, as described below.</td>
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<tr>
<td>Award Project Period</td>
<td>Individuals may receive 2 years of CTSI K12 Mentored Career Development Scholar Award support. The 2nd year of funds are contingent upon satisfactory review of progress reports and submission of applications for external funding.</td>
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Other Award Budget Information

| Salary | The K12 Mentored Career Development Scholar Award Program will provide salary and fringe benefits up to a total maximum of $127,334 per year for the award recipient. The total salary/benefits requested must |
be based on a full-time, 12-month faculty appointment. The K12 Mentored Career Development Scholar Award requires the candidate to devote a minimum of 75% FTE (9 person months) (for surgeons, 50% FTE – 6 person months) to conducting their career development-related research. The remaining effort (25% FTE) may be devoted to other research, clinical, and teaching activities consistent with the objectives of the award.

The total salary and benefits requested, up to $127,334/year, must be based on a full-time faculty appointment. Fringe benefits, based on the College/School/CTSI partner institutions' rate and percent of effort, are included in the $127,334/year. The salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other faculty members of equivalent qualifications, rank, and responsibilities in the College/School/CTSI partner institution concerned. If full-time, 12-month salaries are not currently paid to comparable faculty members, the salary proposed must be appropriately related to the existing salary structure. **Confirmation of salary may be required prior to the issuance of an award.**

**The College/School/CTSI partner institution must agree to provide matching support of department/division funds** when the 75% FTE (50% FTE for surgeons) of actual salary base or NIH Cap and benefits is greater than the $127,334 award. The departmental/divisional match must be completed through appropriate institution accounting procedures. The supplementation may not be from Federal funds unless specifically authorized by the CTSI Partner Mentored Career Development Scholar Award Program. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the career award. For more information about the salary cap: [http://grants.nih.gov/grants/policy/salcap_summary.htm](http://grants.nih.gov/grants/policy/salcap_summary.htm).

| Research-Related Expenses | The CTSI K12 Mentored Career Development Scholar Award Program will provide research development support for the award recipient **up to a total maximum of $27,500 per year**. These costs may be used for the following expenses: (a) tuition and fees related to career development; (b) research expenses, such as supplies, books, service fees, and technical personnel; and (c) statistical services including personnel and computer time. **Unallowable costs** include clerical and administrative salaries, office supplies, telephone costs, postage, and membership dues.

The K12 Mentored Career Development Scholar Award follows the stipulations laid out in the NIH [Grants Policy Statement](https://grants.nih.gov/grants/policy/). Scholars should assure they exercise proper stewardship over funds and that costs charged to the award are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. |
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<tr>
<td>Travel</td>
<td>Each year the CTSI K12 Mentored Career Development Scholar Award Program will provide a <strong>maximum of $2,500</strong> for one domestic professional meeting/ conference (foreign travel expense is not allowed).</td>
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</table>
Section V. Pre-Application Submission Information

The Pre-application process requires applicants to submit Specific Aims, a current Other Support document, NIH Biosketch, Eligibility Determination Form, and Letter of Institutional Support from the candidate’s Department Chair and Division Chief. This pre-application process can be accessed here: https://redcap01.brisc.utah.edu/ccts/redcap/surveys/?s=RL38L3YDPY

A. Letter of Intent (1-page limit)
Include both long term career goals and specific career development goals that can be chosen from the Required and Optional Training Activities document.

B. Specific Aims (1-page limit)
In this section, state concisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the proposed research results will exert on the research field. Focus your specific aims to convince reviewers that you can be successful given the 2-year timeframe and available funding.

List the specific proposed research objectives, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, address a critical barrier to progress in the field, or to develop new technology. As you write your Specific Aims, ensure that you have addressed:

• The overall goal
• The significance of your proposed project
• The important problem your work will solve or the critical barrier (or gap) to progress in the field of health or medicine that will be addressed
• What do you propose to do in this project
• Your commitment to translational research
• How your project (either immediately or in subsequent work based on it) will improve scientific knowledge, technical capability, and/or clinical practice in the field

C. Candidate NIH Biographical Sketch (5-page limit)
The candidate must submit a NIH Biographical Sketch. Please follow the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies provided in Section K.240 and https://grants.nih.gov/grants/forms/biosketch.htm when preparing the biosketch.

D. Other Support Document
The candidate must submit a current NIH Other Support document. Please follow NIH instructions found here: https://grants.nih.gov/grants/forms/othersupport.htm

E. Eligibility Determination Form
The candidate must complete and submit the Eligibility Determination form, found here.

F. Letter(s) of Institutional Support
Dedicated support from a Department Chair and Division Chief (unless there is no division chief) is also a key component to a faculty’s success. The Utah CTSI K12 Mentored Career Development Scholar Award program requires that the nominated candidate’s Department Chair and Division Chief (unless there is no division chief) must submit together a letter of institutional support assuring:

• The nominated CTSI K12 Mentored Career Development Awardee will have at least 75% FTE (9 person months) (for surgeons, 50% FTE – 6 person months) dedicated to research and career development during the 2-year award period.
• Assurance that applicant’s clinical and/or teaching responsibilities will be adjusted to allow protected time as below.
• Protected Research Time & Matching Support:
  o 75% of [her/his/their] time is protected for research and career development activities.
  o 50% of [her/his/their] time is protected for research and career development activities (surgeons only)
  o Matching support: This award provides $127,334 for scholar salary and benefits. The department will cover any gap between the applicant salary and benefits and the K12 Career Development Scholar Award-covered salary and benefits.
Plan for reduction of clinical or operational responsibilities to allow 75% (50% for surgeons) for research activities.

- The department assures the scholar will have the equipment, facilities, and resources necessary for a structured research career development experience.
- It is essential to document the department’s commitment to the retention, development, and advancement of the candidate during the period of the award.

The letter must be signed by both the department chair and division chief, unless there is no division chief.

Section VI. Full Application and Submission Information

General Instructions
The Utah CTSI K12 Mentored Career Development Scholar Award Program requires all applicants to adhere to the following instructions when preparing their application. Failure to adhere to instructions may result in administrative rejection of the application. Please see Checklist at end of instructions for attachment compiling guidance.

1. University of Utah Internal Process: The K12 Mentored Career Development Scholar Award Application does not require prior consideration by the University of Utah Office of Sponsored Projects (OSP).
2. Recommended Supplemental Instructions: As appropriate, the CTSI recommends applicants to utilize the most recent version of the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies when completing the application.
3. Font Size: 11 point, not condensed
4. Font Type: Arial, Georgia, Helvetica, Palatino Linotype
5. Spacing: Single space or no more than six lines of type within a vertical inch (2.54 cm)
6. Page Size: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
7. Margins: At least 0.5 inch (1.27 cm) in all directions
8. Internet URLs: Other than the NIH Biographical Sketches, URLs directing reviewers to websites that contain additional information about the proposed research are unallowable. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. In the biosketch, you may provide a hyperlinked URL to a full list of your published work. This hyperlinked URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required.
9. Narrative Organization: The content of the narrative should be structured as outlined in the Program Application instructions below. The start of each section should be on a new page and clearly labeled with the section title. Organize application as the checklist at end of FOA outlines.
10. Tables, Graphs, Figures, etc.: All tables, graphs, figures, diagrams, and charts must be included within the overall page limit.
11. Notice of Proprietary Information: Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, that is financial or commercial, or that is confidential or privileged, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the paragraph. Indicate at the beginning of the Research Plan which pages contain asterisks and a note stating: "The following sections marked with an asterisk contain proprietary/privileged information that [name of applicant] requests not be released except for purposes of review and evaluation."
12. Recommended Document Size: Size of each document cannot exceed 15 MB.

Program Application

1. Utah CTSI K12 Mentored Career Development Scholar Award Application
   Applicants who all selected for full application will receive the REDCap link. Applications must be submitted no later than 5 pm on Monday, April 3, 2023.
2. Other Project Information

A. Facilities & Other Resources *(no page limit)*

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine & electronic shop) and extent to which they would be available to the project. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. Describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.

B. Equipment *(no page limit)*

If applicable, list major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.

C. Bibliography & References Cited *(no page limit)*

Provide a bibliography of any references cited in the Project Narrative. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” NIH maintains a list of such journals.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. Active hyperlinks in this section are not allowed. The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

3. Biographical Sketches

A. Candidate NIH Biographical Sketch *(5-page limit)*

The candidate must submit a NIH Biographical Sketch. Please follow the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies provided in Section K.240 and https://grants.nih.gov/grants/forms/biosketch.htm when preparing the biosketch.

B. Mentors, Advisory Committee Member(s), and/or Collaborator(s) NIH Biographical Sketch *(5-page limit per biosketch)*

The candidate must submit a NIH Biographical Sketch utilizing the https://grants.nih.gov/grants/forms/biosketch.htm format for their named mentors. Also provide biosketches for optional advisory committee members, and/or collaborators, if applicable. Please follow the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies.
4. Specific Aims (1-page limit)

It is expected that specific aims will be similar in scope to those submitted in the pre-application. In this section, state concisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the proposed research results will exert on the research field. Focus your specific aims to convince reviewers that you can be successful given the 2-year timeframe and available funding.

List the specific proposed research objectives, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, address a critical barrier to progress in the field, or to develop new technology. **As you write your Specific Aims, ensure that you have addressed:**

- The overall goal
- The significance of your proposed project
- The important problem your work will solve or the critical barrier (or gap) to progress in the field of health or medicine that will be addressed
- What do you propose to do in this project
- Your commitment to translational research
- How your project (either immediately or in subsequent work based on it) will improve scientific knowledge, technical capability, and/or clinical practice in the field

5. Application Narrative (12-page limit)

Candidates are limited to 12 pages total for Career Development Plan and Research Strategy. Specific Aims page is limited to 1 page and does not count in the 12-page total for Career Development and Research Strategy. CCTS advises applicants to utilize the instructions provided in Section K.410 of the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies when preparing the application narrative.

**Candidate Section (included in 12-page limit, suggest 4-5 pages)**

**A. Candidate Background**

- Describe the candidate’s commitment to clinical and translational research.
- Describe all of the candidate’s professional responsibilities in the grantee institution and elsewhere and describe their relationship 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 candidate’s objectives and long-term career plans.
- Describe the candidate’s research efforts to this point in their research career, including any publications, prior research interests, and experience.
- Provide evidence of the candidate’s potential to develop into an independent investigator.
- If applicable, describe the candidate’s prior clinical trials research efforts, prior research interests and experience.
- Include a statement that you will commit at least 9 person months (75% FTE) (for surgeons, 6 person months - 50% FTE) to the K12 Career Development Scholar Award research program.

**B. Career Goals and Objectives**

- Describe a systematic plan that demonstrates the following:
  - A logical progression from prior research and training experiences to the training and research experiences that will occur during the award period and then to principal investigator status.
  - Justify the need for further career development to become an independent investigator and advance your career goals and objectives.
  - Applicant 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.
  - A timeline that includes plans for publications and external grant submissions during the award period.
• Describe how data collected during the grant period will be used to apply for additional funding.

C. Candidate’s Plan for Career Development/Training Activities During Award Period
• Describe the professional responsibilities/activities that will help ensure career progression to a principal investigator including the following:
  • Didactic, conference, mentorship, and research experiences planned during the award period.
  • Use of relevant research and educational resources at the institution including those of the Utah CTSI (Required and Optional Training Activities).
• Describe the professional responsibilities/activities including other research projects beyond the minimum required 9 person months (75% fulltime professional effort) (for surgeons, 6 person months – 50% fulltime professional effort) commitment to the career award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.

Research Strategy (included in 12-page limit, suggest 7-8 pages)
A sound research project that is consistent with the candidate’s level of research development and objectives of their career development plan must be provided. The research description should demonstrate the quality of the candidate’s research thus far and the novelty, significance, creativity, and approach of the proposed research, as well as the candidate’s ability to carry out the research during the award period. The application should describe the relationship between the mentors’ research and the candidate’s proposed research plan. Describe the respective areas of expertise and responsibility of each mentor.

Organize the Research Strategy in the order specified below, using the guidelines provided. Start each section with the appropriate section heading: Significance, Innovation, and Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited immediately following the proposal narrative section. It is highly advised to consider and write towards the criteria outlined in Part 3, Section I.

• Significance
  - Explain the importance of the problem or critical barrier to progress in translational science that the proposed project addresses.
  - Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
  - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice.
  - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved. Explain the importance of the problem or critical barrier to progress in the field that the project addresses.

• Innovation
  - Explain how your proposed project challenges and seeks to shift current research or clinical practice paradigms.
  - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).

• Approach
  - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the 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, 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.
- Explain how your results from the proposed project will form a foundation for future 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.
- Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.
- 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 identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.
- Discuss the candidate’s Preliminary Studies as part of the Approach section.

6. **Training in the Responsible Conduct of Research (RCR)** *(1-page limit)*

Applications must include a plan to obtain instruction in the responsible conduct of research (RCR). Describe a plan to acquire instruction in the RCR. See NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies for information on the NIH Policy on Training in the RCR. Documentation of candidate’s CITI Certification and Good Clinical Practice should be included in the appendices.

Attach a description of plans for obtaining 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) and propose plans to either receive instruction or participate as a course lecturer, etc., in order to meet the once every 3-year requirement. The plan should address how applicants plan to incorporate the five instructional parts outlined in the NIH Policy on Instruction in RCR:
- Format - 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);
- Subject Matter - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics;
- Duration of Instruction - the number of contact hours of instruction, taking into consideration the duration of the program; and
- Frequency of Instruction - instruction must occur during each career stage and at least once every three years.

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.

7. **Mentor(s), Co-Mentor(s), Consultant, Collaborators Section**

   **A. Plans and Statements of Mentors and Co-Mentor(s)** *(6-page limit)*

   The mentors 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. This **statement/letter should be on letterhead** and include all of the following:

   - The mentor’s area of expertise and how this will enhance the candidate’s development.
• The plan for the candidate’s training and research career development, as pertinent to the mentor’s role. It is anticipated that 1 mentor will serve as the primary mentor, though this is not required. The plans for supervision and mentoring (see below) may differ amongst the mentors, commensurate with the anticipated needs.
• This description of this plan should include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations
• 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 source of anticipated support for the candidate’s research project for each year of the award period, if applicable.
• The nature of any resources that will be committed to the candidate during the award period, as applicable (e.g., lab space, database access, clinical recruitment assistance, etc).
• 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.
• The mentor should confirm willingness to participate in mentor training before or during the award period. Options are listed below:
  ▪ CIMER Entering Mentoring Training
  ▪ Research Education (REd): Research Mentoring Certificate Program
  ▪ If mentor has previously completed mentor training, please provide a description.
• The primary mentor (or if none, each mentor) should describe their proposed plan for transitioning the candidate from the mentored stage of his/her career to either an external K award or to independent investigator stage by the end of the project period of the award.

B. Letters of Support from Advisory Committee Members, Collaborators, Contributors, and Consultants, if applicable

Letters of support from collaborators, contributors, and consultants will be required for any such person who will contribute to the scientific development or execution of CDA application’s proposed project. (Some applicants may not have such individuals on the research team.) Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rates/charges for consulting services. 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.

8. Description of Institutional Environment (1-page limit)

Describe the institution’s research and career development opportunities related to your area of interest, including the names of key faculty members (not previously mentioned), who are relevant to your proposed developmental plan. Refer to resources descriptions in the Facilities and Other Resources, indicating how the necessary facilities and resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations. Please limit to items not mentioned elsewhere in the application.

9. Human Subjects Related Documentation (if applicable, no page limit)

A. Fill out the document entitled: NIH Human Subjects and Clinical Trials Worksheet Forms G. This document also includes instructions for additional required documents that must be submitted with your application. These additional documents are highlighted in yellow.
  i. For section 1.4, “1.4 Clinical Trial Questionnaire”, please see this link for assistance answering these questions: https://grants.nih.gov/ct-decision/index.htm
ii. The answers in this section will determine how much of this worksheet must be filled out and also which additional documents must be included according to the table in this section.

iii. For additional help with this worksheet and the required additional documents, please see this CTSI webpage: https://ctsi.utah.edu/administration/internal-funding-opportunities/internal-funding-help-and-faqs

1. Templates for the additional documents can be found under the FAQ “For the supplemental documents requested in the NIH Forms G Human Subjects and Clinical Trials Worksheet, are there any directions or templates available?”

B. Include a PDF of completed draft IRB application *don’t submit yet, leave in ‘in progress’ state!

Don’t submit to IRB until notified by CTSI (process will commence after award notification).

Note: If applicant’s IRB is approved via an amendment/ancillary study, the parent protocol MUST be included with an explanation of exactly what is being supported by the proposed research.

C. Informed Consent/Assent

If applicable, candidates MUST include copies of their pending-IRB approval consent and assent documents.

11. Vertebrate Animals (if applicable, no page limit)

If Vertebrate Animals are involved in the project, applicants should include a Vertebrate Animal Section which includes: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. For additional information on creating a Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section. Although no specific page limitation applies to this section of the application, be succinct.

If applicant has received IACUC approval, applicant must provide IACUC approval number and date of approval. If an award is issued, verification of IACUC Approval must be submitted to NCATS prior to beginning research connected to vertebrate animals.

12. Resource Sharing Plan(s) (no page limit)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See https://grants.nih.gov/policy/sharing.htm.

13. Authentication of Key Biological and/or Chemical Resources (no page limit)

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. No more than one page is suggested. If not applicable, include an attachment that states this.
• Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or 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.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award (see NOT-OD-17-068).

14. CITI Certificate/Human Subjects Education Assurance (no page limit)

Provide a copy of the applicant and mentors up to date CITI certificates.

15. Good Clinical Practice (GCP) Training (no page limit)

Provide a copy of the applicant and mentors up-to-date GCP Training certificate.

16. Budget and Budget Justification (no page limit)

Please follow the instructions within the CTSI K12 FOA Guidelines and Instructions, Salary/ Benefit Determination Sheet, and the Detailed Budget Sheet. Include the Budget Justification in the Application (see Checklist) and the detailed budget sheet in the online application.

17. Appendix (if applicable)

The CTSI K12 Career Development Scholar Award Program appendix guidelines will adhere to the NIH Appendix Policy. The only allowable appendix materials are:

• For applications proposing clinical trials, may include 1) clinical trial protocols and 2) investigator’s brochure from Investigational New Drug (IND), as appropriate.

• For all applications, may include blank surveys, questionnaires, data collection instruments

PART 3. APPLICATION REVIEW AND AWARD INFORMATION

Section I. Criteria Review

Important Update: See NOT-OD-17-105 for updated review language.

Applications will be reviewed utilizing the NIH Review Criteria. Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted in support of biomedical and behavioral research are evaluated for scientific and technical merit.

Overall Impact

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate’s potential for a productive, independent scientific research career in a clinical and translational field, taking into consideration criteria below in determining the overall impact score.

For this particular announcement, note the following: Reviewers should evaluate the candidate’s potential for developing an independent research program that will make important contributions to the field, taking into
consideration the years of research experience, the likely value of the proposed research career development as a vehicle for developing a successful, independent research program.

**Scored Review Criteria**

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

**Candidate**

- Does the candidate have the potential to develop as an independent and productive researcher in **Clinical and Translational Research**?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate’s academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate’s commitment to meeting the program objectives to become an independent investigator in research?
- Do the reference letters address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

**Career Development Plan/Career Goals and Objectives**

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate’s prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate’s research and career development progress?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

**Research Plan**

- Are the proposed research questions, design, and methodology of significant scientific and technical merit?
- Is the prior research that serves as the key support for the proposed project rigorous?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Is the research plan relevant to the candidate’s research career objectives?
- Is the research plan appropriate to the candidate’s stage of research development and as a vehicle for developing the research skills described in the career development plan?
- If proposed, will the clinical trial experience contribute to the proposed research project?

**Mentors**

- Are the qualifications of the mentors in the area of the proposed research appropriate?
- Do the mentors adequately address the candidate's potential and his/her strengths and areas needing improvement?
• Is there adequate description of the quality and extent of the mentors’ proposed roles in providing guidance and advice to the candidate?
• Is the description of the elements of the research career development activities, including formal course work adequate?
• Is there evidence of the mentors’, consultant's, and/or collaborator's previous experience in fostering the development of independent investigators?
• Is there evidence of the mentors’ current research productivity and peer-reviewed support?
• Is active/pending support for the proposed research project appropriate and adequate?
• Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?
• If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

**Environment & Institutional Commitment to the Candidate**

- Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?

**Additional Review Criteria**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

**Protections for Human Subjects.** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

**Inclusion of Women, Minorities, and Individuals Across the Lifespan.** When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals across the lifespan (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed.

**Vertebrate Animals.** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the
appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

**Biohazards.** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

**Resubmissions.** For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

**Additional Review Considerations**

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

**Training in the Responsible Conduct of Research (RCR).** All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in RCR. Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant’s career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) Format - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only online instruction is not acceptable); 2) Subject Matter - 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 - the role of the mentor(s) and other faculty involvement in the fellow’s instruction; 4) Duration of Instruction - the number of contact hours of instruction (at least eight contact hours are required); and 5) Frequency of Instruction - instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as Acceptable or Unacceptable, and the summary statement will provide the consensus of the review committee (See NOT-OD-17-105).

**Resource Sharing Plans.** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

**Authentication of Key Biological and/or Chemical Resources.** For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

**Budget and Period of Support.** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

**Section II. Anticipated Announcement, Just-in-Time Information, and Award Dates**

After the criteria review of the application is completed, the Program Manager will contact the applicant with decision details. For applicants being considered for funding, the manager will contact the applicant to provide ‘Just-in-Time’ content, including:
• Updated Collaborative IRB Training Initiative (CITI) and Good Clinical Practice (GCP) Training Assurances for both candidate and mentor(s).
• Updated Other Support document.

At this time, applicants will also be notified to submit IRB/IACUC applications for approval.

Section III. Reporting

Awardees and their associated mentor(s) will be required to timely submit an annual, written progress report(s) and a final progress report to the Utah CTSI K12 Career Development Scholar Award Program Manager. In addition to the reports, other requested documents for either or both the awardee or mentor(s) will include updated NIH formatted biographical sketch, Individual Development Plan, Other Support Forms, and copies of any publications, abstracts, and/or presentations completed during the project period. Awardees will be given further details at their face-to-face meeting with the Manager.

Section IV. Program Contacts

Scientific/Research Contacts

Maureen A. Murtaugh, PhD, RDN  
Director, Utah CTSI K12 Mentored Career Development Scholar Award Program  
Professor of Epidemiology, University of Utah  
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Associate Director, Utah CTSI K12 Mentored Career Development Scholar Award Program  
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Program Manager

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Grants and Contracts Manager, Utah CTSI  
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Email: lyalya.sultanova@hsc.utah.edu
## Part 4. Application Checklist

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<td>• Abstract</td>
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<td>• Bibliography &amp; References Cited</td>
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<td>• Candidate NIH Biographical Sketch</td>
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<td>• Mentor(s), Advisory Committee Member(s), and/or Collaborator(s) NIH Biographical Sketch(es)</td>
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<td>• Introduction to Application (for RESUBMISSIONS only)</td>
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<td>• Specific Aims</td>
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<td>• Application Narrative</td>
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