PART 1. OVERVIEW INFORMATION

Funding Opportunity Title	*CTSI Partner Mentored Career Development Scholar Award*
Awarding Organization	Utah Clinical and Translational Science Institute (CTSI) and Primary Children's Hospital Foundation (PCHF)
Summary of the Funding Opportunity Purpose	The purpose of the CTSI Partner Mentored Career Development Scholar Award is to support the career development of junior faculty members who have made a commitment to focus their research endeavors on clinical or translational research in order to advance health. Early stage investigators with faculty appointments at Primary Children's Hospital 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 or translational (T1-T4) research with a Clinical and Translational Science focus. The CTSI recommends applicants to have reviewed and understand the eligibility criteria as well as gain the appropriate nominations prior to beginning the application process.

Key Dates

Posted Date	June 23, 2021
Full Application Due Date	**5 pm, Monday, September 1, 2021**
Merit Review	September 2021
Award Notification	October 15, 2021
Earliest Start Date	**January 1, 2022**

TABLE OF CONTENTS

PART 2. FULL TEXT OF ANNOUNCEMENT

Section I. Funding Opportunity Description

The purpose of this opportunity is to ensure that a diverse pool of highly trained 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 Partner 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 Award will provide salary and research support for a sustained period (up to 2 years) to ensure a future cadre of well-trained scientists.

Early stage investigators with faculty appointments at Primary Children's Hospital are eligible to apply.

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 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html.

Priority will be given to applicants conducting research (at any point in the translational spectrum) that addresses 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 Partner Mentored Career Development Scholar Award Director and Associate Directors are Drs. Maureen A. Murtaugh, 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 Co-Directors' 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 proven mentoring records of accomplishment.

Vice President's Clinical and Translational (VPCAT) Research Scholars Program

The design of the VPCAT Research Scholars Program offers intensive mentorship and support to junior faculty in the University of Utah Health Sciences committed to careers in clinical or translational research. This 2-year, competitive program is open to junior faculty from all Colleges, Schools, and CTSI partner institutions. *CTSI Partner Mentored Career Development Scholars are guaranteed acceptance into this program and are required to participate fully in the VPCAT program as part of their award*. For further information, click here.

Mentor Responsibilities

A strong mentor(s) is a key component to a faculty's success. The Utah CTSI Partner Mentored Career Development Scholar Award program requires that the selected mentor(s) are established investigators,

preferably acknowledged experts in their field supported by NIH or other competitive award grants. The Partner Mentored Career Development Scholar Award Program requires mentor(s) 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.

- During 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 online Individual Development Plan (IDP) 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.

Dean, Department Chair, or Division Chief Responsibilities

Dedicated support from a Dean, Department Chair, or Division Chief is also a key component to a faculty's success. The Utah CTSI Partner Mentored Career Development Scholar Award program requires that the nominated candidate's Dean, Department Chair, or Division Chief should ***submit a letter of institutional support assuring***:

- The nominated CTSI Partner Mentored Career Development Scholar Award Scholar has 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.
- Agree to provide mandatory departmental ***matching support*** when 75% (50% for surgeons) of actual salary base or NIH Cap is greater than salary/benefits requested.

Institutional Commitment to the Candidate's Research Career Development *(1 page limit)*

The institution must provide a *document on institutional letterhead* that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the CDA. The document will include the institution's agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution will provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award. The letter of commitment **must** ensure a minimum of 75% FTE (50% FTE for surgeons) protected time for research each year. The department agrees to provide mandatory departmental/ divisional matching support when 75% (50% for surgeons) of actual salary base or NIH Cap is greater than salary support requested from grant funds.

The letter must be signed by both the department chair and division chair, unless there is no division chief. The letter must contain the following bullet points:

- ***Protected research time & Matching Support****:*
  - ***75***% of [her/his/their] time is protected for research and career development activities.
  - ***50***% of [her/his/their] time is protected for research and career development activities (surgeons only)

- ***Matching support:*** This award provides $110,000 for scholar salary and benefits. The department will cover any gap between the applicant salary and benefits and the Partner Mentored Career Development Scholar covered salary and benefits.

- ***Scientific mentorship: {explain}***
- ***[Clinical and/or teaching] mentoring: {explain}***

For further instructions, see Section V. Program Application # 9.

Section III. Eligibility Information

Candidate Eligibility

The CTSI Partner 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 science research and a commitment to continue a career in clinical and translational science to advance health.
- Confirm that either a) they have never submitted an external K award application, or b) confirm that an external K application is unscored and not resubmitted or has been withdrawn. If an external K award has been submitted and is pending, you are not eligible to apply.
- ***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 hold a junior faculty appointment (instructor or assistant professor) at Primary Children's Hospital.
- 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.
- Be within 10 years of completing post-doctoral or clinical training.
- Not have been the Principal Investigator or equivalent on an NIH research project grant (R01, U01, U10), a subproject of a program (P01) or center grant (U54), or equivalent Public Health Service (PHS) research grant awards.
- 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.
- Indicate commitment to interdisciplinary research and education.
- ***Proof of IRB submission or approval is a requirement of applications involving human subjects research*** (see Section V).

Scholar Responsibility

CTSI requires participating Partner Mentored Career Development Scholars to:

- Meet quarterly with the Partner Mentored Career Development Scholar Program Co-Directors and Manager to evaluate progress.
- Obtain a ProTracks account and request all appropriate CTSI services using ProTracks.
- Provide at least one annual progress report and a final report. The second year of funds is contingent upon satisfactory review of progress report.
- Attend the monthly CTSI K-Club and present at least once during the award period.
- Identify and acknowledge CTSI grant on all related publications and presentations (e.g., oral, poster, etc.). To learn more about how to cite the training grant, 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 Co-Directors 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, including:

- Meet regularly with VPCAT Senior and scholar's scientific/primary mentor(s).
- Participate in Orientation (mandatory), Leadership, and Skills sessions.
- Meet with the VPCAT Mentoring team (VPCAT Senior, Scientific, program staff) at [minimum] three defined times during the two-year program: an initial meeting at program start, mid-program meeting at the end of the first year, and final meeting at the end of the two-year program.
- Submit Individual Development Plans (IDP), program reports, and other information as requested, at a minimum of three defined times: beginning, middle, and program end.
- Funding and scholarly activity:
  - Submit at least one extramural grant application during the two years of the program.
    i. All proposal submissions should be coordinated with the VPCAT team and mentors at least 10 weeks prior to submission. Attend a campus-based grant writing workshop (facilitated by the program) prior to proposal submission.
    ii. Submit proposals to Partner Mentored Career Development Scholar Award mentors, career and science mentors and CTSI Peer Grant Review Program prior to agency submission.
    iii. Share full-submitted grant proposals with VPCAT staff.
    iv. Share reviewer feedback with the VPCAT Program and mentors.
  - Submit at least two research manuscripts citing the CTSI grant during the two years of the program.
  - Submit and present research abstract(s) at a professional society meeting each year. Attend the NCATS annual meeting at least once during the award.
  - Present at CTSI K-Club at least once each year; attend regularly.
  - Adhere to all University research regulatory and compliance policies.

Section IV. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	Invited New and Resubmissions
Anticipated # of Award(s)	Two
Award Budget	Award budgets, $138,000 per year, are composed of salary, benefits, and other program-related expenses, as described below.
Award Project Period	Individuals may receive up to 2 years of CTSI Partner Mentored Career Development Scholar Award support. The 2nd year of funds is contingent upon satisfactory review of progress reports and submission of applications for external funding.

Other Award Budget Information

Salary	The Partner Mentored Career Development Scholar Award Program will provide salary and fringe benefits **up to a total maximum of $110,000** for the award recipient. The total salary/benefits requested ***must*** be based on a full-time, 12-month faculty appointment. The Partner 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 $110,000/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 $110,000/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/CCTS 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 $110,000 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. The total salary may not exceed the legislatively mandated salary cap: http://grants.nih.gov/grants/policy/salcap_summary.htm.
Other Program-Related Expenses	The CTSI Partner Mentored Career Development Scholar Award Program will provide research development support for the award recipient **up to a total maximum of $25,500 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 Partner Mentored Career Development Scholar Award follows the stipulations laid out in the NIH Grants Policy Statement. 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.
Travel	Each year the CTSI Partner Mentored Career Development Scholar Award Program will provide a **maximum of $2,500** for one domestic professional meeting/ conference (foreign travel expense is not allowed).

Section V. Application and Submission Information

General Instructions

The Utah CTSI Partner 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 Partner 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
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 or Bibliography & References Cited documents, 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.
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 Partner Mentored Career Development Scholar Award Application

Applicants must submit their application in REDCap at https://redcap01.brisc.utah.edu/ccts/redcap/surveys/?s=RL38L3YDPY no later than 5 pm on Monday, August 2, 2021.

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 ESI's 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. Each reference must include the **names of all authors** (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Provide any references cited in this application utilizing the American Medical Association Style.

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. Mentor(s), 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 mentor(s), advisory committee, and/or collaborators. Please follow the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies.

4. Application Narrative ***(maximum of 12 Pages)***

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 or 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 his/her research career, including any publications, prior research interests, and experience.
- Provide evidence of the candidate's potential to develop into an independent investigator.
- Include a statement that you will commit at least 9 person months (75% FTE) (for surgeons, 6 person months - 50% FTE) to the Partner Mentored 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 and 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.
- 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 (https://ctsi.utah.edu/).
- 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.

The didactic and research components must be designed to develop necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. ***The candidate and primary mentor are jointly responsible for the career development plan***. A career development timeline is highly advised.

5. Research Plan Section

A. Specific Aims (1 page limit, NOT included in 12 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(s) involved. 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 a candidate writes their Specific Aims, consider the following:*

- What is your overall goal? What do you propose to do in this project?
- How is your career and research aligned with translational science?
- Describe the significance of your proposed project and commitment to translational research.
- Will it solve an important problem or address a critical barrier to progress in the field of health or medicine?
- Will it improve scientific knowledge, technical capability, and/or clinical practice in the field?
- Describe what makes your project innovative translational science.

B. 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 his/her 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, as well as the candidate's ability to carry out the research during this 2-year award period. The application should describe the relationship between the mentor's research and the candidate's proposed research plan. If more than one mentor is proposed, describe the respective areas of expertise and responsibility.

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 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.
  - If your study(s) involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample but it must also be addressed here in the Approach section.
  - 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 (see **Section V - 13**).

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;
- Faculty Participation - the role of the mentor(s) and other faculty involvement in the instruction;
- 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. The role of the mentor in RCR instruction must be described.

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

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

The mentor(s) and co-mentor(s) (if applicable) must 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 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.
- The source of anticipated support for the candidate's research project for each year of the award period.
- The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
- The candidate's anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee, and administrative assignments, and the portion of time available for research.
- A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. 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.

All mentored career development applications should identify any and all co-mentors involved with the proposed research and career development program. Co-mentors must specifically address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also, describe the nature of any resources that will be committed to this CDA. Statements from the mentor(s) and co-mentor(s) documenting their role and willingness to participate in the project. *Do not place these statements in the Appendix*.

B. Letters of Support from Advisory Committee Members, Collaborators, Contributors, and Consultants (6 page limit)

Attach all appropriate letters of support. 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.

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

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's 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.

9. Institutional Commitment to the Candidate's Research Career Development *(1 page limit)*

The institution should provide a *document on institutional letterhead* that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the CDA. The document should include the institution's agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award. The letter of commitment **must** ensure a minimum of 75% FTE (50% FTE for surgeons) protected time for research each year and agreement to provide mandatory departmental/ divisional matching support when 75% (50% for surgeons) of actual salary base or NIH Cap is greater than salary support requested from grant funds.

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

A. Proof of IRB Approval or Submission

Documentation of IRB Approval or proof of IRB application submission must be provided. CTSI will **administratively withdraw** applications with neither proof of IRB submission or approval.

B. Informed Consent/Assent

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

C. IRB Approved via Amendment/Ancillary Study

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

D. Clinical Trial

If a clinical trial is proposed, candidate MUST include:

1. If testing a drug or device, documentation that an IND/IDE has been obtained, or a FDA letter that the study is IND-exempt or the IDE has been waived and product information, such as the clinical investigator brochure, package insert, or description of the device.
2. Data and Safety Monitoring Plan. For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. For further guidance, please see the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies, *Section 3.3.*

E. Protection of Human Subjects

If the proposed research uses human research subjects, specimens, and/or data, candidate MUST explain how you plan to recruit patients, collect samples, and protect participant data using the following outline. For further guidance, please see the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies*, Section 3.1.*

1. Risks to Human Subjects: explain who the subjects are, sampling plan, rationale for involvement of vulnerable population, study group assignment, and procedures.
2. Adequacy of Protection against Risks: describe recruitment and informed consent, as well as plans to minimize risks listed above, as well as data safety monitoring.
3. Potential Benefits of Proposed Research to Human Subjects and Others: what are benefits relative to risks.
4. Importance of Knowledge to be Gained: include how any risks are reasonable given importance of this new knowledge.

F. Inclusion of Women and Minorities

If the proposed research uses human research subjects, specimens, and/or data, candidate MUST address, at a minimum, the following four points. For further guidance, see the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies, *Section 2.4*.

1. Describe the planned distribution of subjects by sex/gender, race, and ethnicity for each proposed study and complete the format in the Planned Enrollment Report. (Instructions for completing this form are in Section 5.8 of the SF424 application package and Section 4.3 of DHHS PHS Supplemental Instructions.)
2. Describe the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. Provide a compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial, or ethnic group that comprises the population under study.
4. Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects. This is particularly important if difficulty recruiting certain groups is anticipated.

G. PHS Inclusion Enrollment Report

If the proposed research uses human research subjects, specimens, and/or data, candidate MUST complete and include the PHS Inclusion Enrollment Report. Applicants should follow the instructions provided in ***Section K.500*** of the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies*, Section 2.9* when preparing the form.

H. Inclusion of Individuals Across the Lifespan

For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section. For further guidance, see the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies, *Section 2.3.a.*

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

If Vertebrate Animals are involved in the project, applicants should include (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 review of the 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 the Partner Mentored Career Development Scholar Award Program Manager 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*** mentor(s) up to date CITI certificate.

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

Provide a copy of the applicant ***and*** mentor(s) up-to-date GCP Training certificate.

16. Budget and Budget Justification ***(no page limit)***

Please follow the instructions within the *CTSI Partner Mentored Career Development Scholar Award 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 Partner Mentored Career Development Scholar Award Program appendix guidelines will adhere to the **new** 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 *1)* blank informed consent/assent forms and *2)* blank surveys, questionnaires, data collection instruments

Section VI. Submission Process

Applicants should submit their applications on or before the deadline (see **Part 1**). The application should consist of the attachments outlined in **Part 4**. For any questions, please contact the Program Manager (see **Part 3**, **Section IV**).

PART 3. APPLICATION REVIEW AND AWARD INFORMATION

Section I. Criteria Review

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

The Utah CTSI Internal Advisory Committee will review applications 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 Science**?
- 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 clinical and translational research?
- Do the letter(s) of support 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

- Are there adequate plans for evaluating the candidate's research and career development progress?
- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- 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 the candidate's prior training and research experience appropriate for this award?

Research Plan

- Are the proposed research questions, design, and methodology of significant scientific and technical merit?

- Is there a strong scientific premise for the 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?

Mentor(s)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) 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 mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's 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?

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, Children, and Older Adults*.** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children 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:

- If Human Subjects are involved, updated IRB review status or Approval assurance. Pending or out of date approvals are not acceptable.

- If Vertebrate Animals are involved, updated IACUC review status or Approval assurance. Pending or out-of-date approvals are not acceptable.

- Updated Collaborative IRB Training Initiative (CITI) and Good Clinical Practice (GCP) Training Assurances for both candidate ***and*** mentor(s).

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 Partner Mentored 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 Partner Mentored Career Development Scholar Award Program
Professor of Epidemiology, University of Utah
Phone: 801-585-9216; Email: maureen.murtaugh@hsc.utah.edu

Ingrid Nygaard, MD
Associate Director, Utah CTSI Partner Mentored Career Development Scholar Award Program
Professor of Obstetrics and Gynecology, University of Utah
Phone: 801-585-7746; Email: ingrid.nygaard@hsc.utah.edu

Michael Varner, MD
Associate Director, Utah CTSI Partner Mentored Career Development Scholar Award Program
Distinguished Professor of Obstetrics and Gynecology, University of Utah
Phone: 801-581-7260; Email: michael.varner@hsc.utah.edu

Program Manager

Jennifer Zitterkoph
Grants and Contracts Manager, Utah CTSI
27 S Mario Capecchi Dr, Bldg 379; Salt Lake City UT 84133
Phone: 801-213-1504; Email: jennifer.zitterkoph@hsc.utah.edu

Part 5. Application Checklist

Application	Submission Method	Length/Limit
Application	Save file as "Application_PI Last Name.pdf" and upload as a **single file**	
• Applicant and Proposal Information		Not Applicable
• Abstract Provide summary of the proposed activity suitable for dissemination to the public. If should contain description of the project and objectives (including career development goals) and methods to be employed		1 Page limit
• Facilities & Other Resources		No page limit
• Equipment (if applicable)		No page limit
• Bibliography & References Cited		No page limit
• Candidate NIH Biographical Sketch		5 page limit
• Mentor(s), Advisory Committee Member(s), and/or Collaborator(s) NIH Biographical Sketch(es)		5 page limit (per bio)
• Introduction to Application (<u>for RESUBMISSIONS only</u>)		1 page limit
• Application Narrative		12 page limit
• Candidate Section		
• Candidate Background		*Part of 12 page limit*
• Career Goals and Objectives		*Part of 12 page limit*
• Candidate's Plan for Career Development/Training Activities During Award Period		*Part of 12 page limit*
• Specific Aims		1 page limit *(NOT Counted in 12 Page Limit)*
• Research Strategy		*Part of 12 page limit*
• Training in the Responsible Conduct of Research (RCR)		1 page limit
• Mentor(s), Co-Mentor(s), Consultant, Collaborators Section		
• Plans and Statements of Mentor(s) and Co-Mentor(s)		6 page limit
• Letters of Support from Advisory Committee Members, Collaborators, Contributors, and Consultants		6 page limit
• Description of Institutional Environment		1 page limit
• Institutional Commitment to the Candidate's Research Career Development		1 page limit
• Human Subjects Related Documentation *(If applicable)*		
• Proof of IRB Submission or Approval		*No page limit*
• Informed Consent/Assent Document(s)		*No page limit*
• IRB Approved via Amendment/Ancillary Study Document(s)		*No page limit*
• Clinical Trial Document(s)		*No page limit*

	• Protection of Human Subjects		*No page limit*
	• Inclusion of Women and Minorities		*No page limit*
	• Inclusion of Children		*No page limit*
	• Vertebrate Animals *(If applicable)*		No page limit
	• Resource Sharing Plan(s)		No page limit
	• Authentication of Key Biological and/or Chemical Resources		No page limit
	• Budget Justification		No page limit
	• Appendix *(optional, please see instructions)*		No page limit
□	**PHS Inclusion Enrollment Report**	Save as "InclusionEnrollReport_PI Last Name.pdf" and upload	No page limit
□	**Detailed Budget Sheet**	Save as "DetailedBudget_PI Last Name.pdf" and upload	No page limit