## PART 1. OVERVIEW INFORMATION

<table>
<thead>
<tr>
<th>Funding Opportunity Title</th>
<th>CCTS/PPH KL2 Mentored Career Development Scholar Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awarding Organization</td>
<td>Utah Center for Clinical and Translational Science (CCTS) in collaboration with the University of Utah Program for Personalized Health (PPH)</td>
</tr>
<tr>
<td>Federal Prime Sponsor</td>
<td>National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS)</td>
</tr>
<tr>
<td>Federal Award Number</td>
<td>KL2TR001065</td>
</tr>
<tr>
<td>Catalog of Federal Domestic Assistance #</td>
<td>93.350</td>
</tr>
<tr>
<td>Activity Code</td>
<td>KL2 Training Program</td>
</tr>
<tr>
<td>Summary of the Funding Opportunity Purpose</td>
<td>The purpose of the CCTS/PPH KL2 Mentored Career Development Scholar Award is designed to support the career development of junior faculty members who have made a commitment to focus their research endeavors on clinical or translational research with a clear Precision Medicine emphasis in order to advance health. Early stage investigators with faculty appointments at the University of Utah, Intermountain Healthcare, Utah Department of Health, and Veterans Affairs Salt Lake City Health Care System are eligible to apply.</td>
</tr>
<tr>
<td>Eligibility Criteria</td>
<td>The applicant for the CCTS/PPH KL2 Mentored Career Development Scholar Award must be nominated by their College Dean, Department Chair, and/or Division Chief to apply for this competitive award. Applicant must be involved in clinical or translational (T1-T4) research with a precision medicine focus. The CCTS recommends applicants to have reviewed and understand the eligibility criteria as well as gain the appropriate nominations prior to beginning the application process. To determine if you are eligible, please complete the Eligibility Determination Form, which can be accessed from the Competition Space online system.</td>
</tr>
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</table>

### Key Dates

<table>
<thead>
<tr>
<th>Posted Date</th>
<th>November 28, 2016</th>
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<tbody>
<tr>
<td>Application Due Date</td>
<td>February 10, 2017 (EXTENDED)</td>
</tr>
<tr>
<td>Merit Review</td>
<td>February-March 2017 (see Part 3, Section I) (REVISED)</td>
</tr>
<tr>
<td>Award Notification</td>
<td>By or before March 24, 2017 (see Part 3, Section II) (REVISED)</td>
</tr>
<tr>
<td>Earliest Start Date</td>
<td>April 1, 2017 (REVISED)</td>
</tr>
<tr>
<td>Announcement Expiration Date</td>
<td>February 10, 2017 at 5:00 pm (EXTENDED)</td>
</tr>
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PART 2. FULL TEXT OF ANNOUNCEMENT

Section I. Funding Opportunity Description

The University of Utah Center for Clinical and Translational Science (CCTS), in collaboration with the University of Utah Program in Personalized Health (PPH), aims to ensure that a diverse pool of highly trained scientists are available in appropriate scientific disciplines to address the Nation’s clinical and translational (T1-T4) research needs to tailor treatment according to the biology and preferences of the individual patient.

The objective of the KL2 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 CCTS/PPH KL2 Award will provide salary and research support for a sustained period (up to 2 years) to ensure a future cadre of well-trained scientists who aim to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people in order to advance health.

Candidates aiming to further their careers and research towards innovative approaches for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person are encouraged. Increasing the success of the biomedical workforce to integrate investigation of mechanisms of disease with prevention, treatment, and cure, resolved at the level of the individual, is important of future contributions to solutions for providing high value health care by improving outcomes while decreasing cost.

Early stage investigators with faculty appointments at the University of Utah, Intermountain Healthcare, Utah Department of Health, and Veterans Affairs Salt Lake City Health Care System are eligible to apply. Colleges, Schools, and Departments are encouraged to select their strongest candidate(s) aligned with Precision Medicine research.

Colleges and Schools may nominate up to two candidates. Departments with more than 100 faculty members may nominate up to two candidates for the award. Departments with fewer than 100 faculty members may nominate one candidate for the award.

Colleges, Schools, and Departments are encouraged to identify candidates who will increase diversity on a national or institutional basis. The CCTS encourages selection of individuals from racial and ethnic groups that are underrepresented in health-related sciences on a national basis; individuals with disabilities; and individuals from disadvantaged backgrounds.

CCTS administers the funding under the National Institutes of Health (NIH) Grants Policy Statement.
Section II. Program Directors, Mentors, and Other Descriptions

Program Directors

The Utah CCTS KL2 Scholar Program Co-Directors are Drs. Maureen A. Murtaugh and David Turok. Dr. Murtaugh is an Associate Professor of Epidemiology in the Department of Internal Medicine. Dr. Turok is an Associate Clinical Professor of Obstetrics and Gynecology and Co-Director of the Obstetrics and Gynecology’s Fellowship in Family Planning Program. 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. Both 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 and schools in the Health Sciences. In 2015, the program aligned with the CCTS KL2 Scholar Program. The CCTS requires all KL2 Scholars to participate fully in the VPCAT program. For further information, click here.

Mentor Responsibilities

A strong mentor(s) is a key component to a faculty’s success. The Utah CCTS KL2 program requires that the selected mentor(s) are established investigators and prefer acknowledged experts in their field supported by NIH or other competitive award grants. The KL2 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 providing advice on course work, research strategies, publications, and career goals. Mentor(s) is encouraged to maintain an open-door policy for their scholars.
  - Each year, 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) 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 and guide them in development and submission of an extramural grant proposal.
  - Identify and acknowledge CCTS/PPH KL2 grant on all related presentations (oral, poster, etc.) and publications. To learn more about how to cite the training grant, click here.
  - Ongoing 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 CCTS KL2 program requires that the nominated candidate’s Dean, Department Chair, or Division Chief should submit a letter of institutional support assuring:

- The nominated CCTS KL2 Scholar has at least 75% FTE (9 person months) (for surgeons, 50% FTE – 6 person months) dedicated to research and career development during the two-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.

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

**Section III. Eligibility Information**

**Candidate Eligibility**

The CCTS/PPH KL2 Mentored Career Development Scholar Award is a competitive award, and it is recommended that applicants have reviewed and understand the eligibility criteria. To determine eligibility, it is advised that applicants complete the *Eligibility Determination Form*, which can be accessed from the *Competition Space* online system. Eligible candidate must:

- Show evidence of performance in clinical and translational science related to *Precision Medicine* research and a commitment to continue a career in clinical and translational science to advance health.
- **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).
- Have you received 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 5 years of completing post-doctoral or clinical training.
- Not have been the Principal Investigator or equivalent on an NIH research project grant (R01, R03, R21, 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.
- Candidates must indicate their commitment to interdisciplinary research and education.
- For research that involves human subjects, have submitted their Institutional Review Board (IRB) application by the time of application submission. *Proof of IRB submission or approval is a requirement of the application* (see Section V).

**Scholar Responsibility**

CCTS requires participating KL2 scholars to:

- Commit to a minimum of 75% FTE (9 person months) (for surgeons, 50% FTE – 6 person months) for research and training during the award period.
- Meet at least twice yearly with the KL2 Program Co-Directors and Manager to evaluate progress.
- 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 CCTS K-Club and present at least once during the award period.
- Identify and acknowledge CCTS KL2 grant on all related publications and presentations (e.g., oral, poster, etc.). To learn more about how to cite the training grant, click here.
- Attend quarterly meetings with KL2 Program Manager to review financial status, gain mentorship on accountability of funds, and confer on study progress.
- 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 mentors and CCTS 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 during the two years of the program.
  - Submit and present research abstract(s) at a professional society meeting each year.
  - Present at CCTS K-Club at least once each year; attend regularly.
  - Adhere to all University research regulatory and compliance policies.

**Section IV. Award Information**

<table>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>Application Types Allowed</td>
<td>New and Resubmissions</td>
</tr>
<tr>
<td>Anticipated # of Award(s)</td>
<td>One award</td>
</tr>
<tr>
<td>Award Budget</td>
<td>Award budgets, $112,500 per year, are composed of salary, benefits, and other program-related expenses, as described below.</td>
</tr>
<tr>
<td>Award Project Period</td>
<td>Individuals may receive up to 2 years of CCTS KL2 support. The 2nd year of funds is contingent upon satisfactory review of progress report.</td>
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</table>

**Other Award Budget Information**

| Salary | The KL2 Program will provide salary and fringe benefits up to a total maximum of $97,500 for the award recipient. The total salary/benefits requested must be based on a fulltime, 12-month faculty appointment. The KL2 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 other research, clinical, and teaching activities consistent with the objectives of the award. The total salary and benefits requested, up to $97,500/year, must be based on a fulltime faculty appointment. Fringe benefits, based on the department/college’s rate and the percent of effort, are included in the $97,500/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 staff members of equivalent qualifications, rank, and responsibilities in the department/college concerned. If fulltime, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately |

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related to the existing salary structure. Confirmation of salary may be required prior to the issuance of an award.

The department/college must agree to provide mandatory departmental matching support when the 75% FTE (50% FTE for surgeons) of actual salary base or NIH Cap and benefits is greater than the $97,500 award. The departmental match must be completed through appropriate University of Utah accounting procedures. The supplementation may not be from Federal funds unless specifically authorized by the CCTS KL2 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:

| Other Program-Related Expenses | The CCTS KL2 Program will provide research development support for the award recipient up to a total minimum of $15,000 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 KL2 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. |

| KL2 Travel and Mentor Support | In addition to the annual $112,500, each year the CCTS KL2 Program will provide a maximum of $1,500 for one domestic professional meeting/conference (foreign travel expense is unallowable). The program will also support 5% FTE salary, up to the current NIH Salary Cap, and benefits for the primary mentor. |

### Section V. Application and Submission Information

#### General Instructions

The Utah CCTS KL2 Program requires all applicants to adhere to the following instructions when preparing their application. Not adhering 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 KL2 Application does not require prior consideration by the University of Utah Office of Sponsored Projects (OSP). An eProposal should not be created for this application. The application should not be sent to OSP five days prior to the due date.

2. **Recommended Supplemental Instructions:** As appropriate, the CCTS 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.

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**Program Application**

**1. Utah CCTS KL2 Competition Space Application**

Applicants must log into the University of Utah’s [Competition Space](#) and select the *University of Utah Center for Clinical and Translational Science (CCTS)/Program in Personalized Health (PPH) KL2 Career Development Scholar Program* option and, following the directions, complete the online application.

**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. For Early Stage Investigators (ESIs), 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 JAMA](#).
3. Biographical Sketches

A. Candidate NIH Biographical Sketch (5 page limit)

The candidate must submit a NIH Biographical Sketch utilizing the NIH General Forms Version D format. Please follow the NIH SF424 (R&R) Application Packages Career Development Instructions for NIH and Other PHS Agencies provided in Section K.240 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 NIH General Forms Version D 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 provided in Section K.240 when preparing the biosketch.

4. Introduction to Application (for RESUBMISSION only - maximum of 1 page)

You must include an introduction for all resubmissions that summarizes substantial additions, deletions, and changes to the application. Individual changes do not need to be identified within other application attachments (e.g., do not need to bold or italicize changes in Research Strategy). The Introduction should respond to the issues and criticism raised in the summary statement.

5. 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 Child Health 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 objectives and long-term career plans of the candidate.
- Describe the candidate’s research efforts to this point in his/her research career, including any publications, prior research interests, and experience.
- Provide evidence of the candidate’s potential to develop into an independent investigator.
- Include a statement that you will commit at least 9 person months (75% FTE) (for surgeons, 6 person months - 50% FTE) to the KL2 Scholars 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.
  - They have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects.
  - 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 Center for Clinical and Translational Science (http://medicine.utah.edu/ccts/).
- 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.

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 precision medicine?
- Briefly describe the significance of your proposed project.
- Will it solve an important problem or address a critical barrier to progress in the field of precision medicine?
- Will it improve scientific knowledge, technical capability, and/or clinical practice in the field?
- Describe what makes your project innovative in precision medicine. Describe your commitment to research.

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 precision medicine 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 in precision medicine.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions in precision medicine 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 in precision medicine.
  - 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 Supplemental Instructions, Part III Section 1.16 for information on the NIH Policy on Training in the RCR. Documentation of candidate’s CITI Certification 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 four-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 four years. See also NOT-OD-10-019.

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 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. CCTS 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 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.

**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 Supplemental Instructions Grant Application Instructions.

1. **Risks to Human Subjects**: explain who the subjects are, sampling plan, rationale for involvement of vulnerable population, study group assignment, and procedures.
2. **Sources of Materials**: describe exactly what you are collecting and how.
3. **Potential Risks**: what are all potential the risks to subjects, physical, psychological, financial, legal, etc., include likelihood and seriousness.
4. **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.
5. **Potential Benefits of Proposed Research to Human Subjects and Others**: what are benefits relative to risks.
6. Importance of Knowledge to be Gained: include how any risks are reasonable given importance of this new knowledge.

7. Data and Safety Monitoring Board Plan (DSMP): Please include your DSMP. If a DSMP is not required/not applicable, explicitly state this.

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 Supplemental Instructions Grant Application Instructions, Section 4.2.

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 when preparing the form.

H. Inclusion of Children
If the proposed research uses human research subjects, specimens, and/or data, candidate MUST address, at a minimum, the following five points. For further guidance, see the Supplemental Instructions Grant Application Instructions, Section 4.4.

1. Describe the age(s) or age range of all individuals to be included in the proposed study.

2. Specifically discuss whether children under the age of 18 (as a whole or a subset of individuals under18) will be included or excluded.

3. Description of the plan should include a rationale for selecting a specific age range of children.

4. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

5. When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR part 46 Subpart D) apply and must be addressed under the Protections against Risk subheading.

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 KL2 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 Supplemental Instructions, Part III 1.5.

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-15-095 and NOT-OD-16-012).

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 CCTS KL2 Guidelines and Instructions, CCTS KL2 Salary/Benefit Determination Sheet, and CCTS KL2 Detailed Budget Sheet. Include the Budget Justification in the KL2 Application (see Checklist) and the detailed budget sheet in the online application.

17. Appendix (*if applicable*)

The CCTS KL2 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

Via Competition Space online application system, the applicants should submit their KL2 program 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 KL2 Program Manager (see Part 3, Section IV).

PART 3. APPLICATION REVIEW AND AWARD INFORMATION

Section I. Criteria Review


The Utah CCTS 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 **Precision Medicine**?
- 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?
- 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, and Children. 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-10-019).

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 KL2 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).

If approved, the manager will contact the applicant to schedule a face-to-face meeting to review the formal Notice of Award (NoA). The manager will also assist the applicant with scheduling their first meeting with the Program Co-Directors to begin discussion of the applicant’s career plan and mentoring team. Awardees must comply with terms and conditions of the NoA and NIH Grants Policy Statement. Awardees must comply with the trainee responsibilities as is outlined in Part 2, Section III.

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 CCTS KL2 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
Co-Director, Utah CCTS KL2 Scholar Program
Associate Professor of Epidemiology, University of Utah
Phone: 801-585-9216; Email: maureen.murtaugh@hsc.utah.edu

David Turok, MD, MPH
Co-Director, Utah CCTS KL2 Scholar Program
Associate Professor of Obstetrics and Gynecology, University of Utah
Phone: 801-581-6170; Email: david.turok@hsc.utah.edu

KL2 Program Manager

Erin Wachs
Funding and Program Development Manager, Utah CCTS
26 South 2000 East, HSEB 5725A; Salt Lake City, UT 84112-5750
Phone: (801) 213-3756; Email: erin.wachs@hsc.utah.edu
## Part 4. Application Checklist

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<td>• Other Project Information</td>
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<td>• Candidate NIH Biographical Sketch</td>
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<td>• Introduction to Application (for RESUBMISSIONS only)</td>
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<td>• Career Goals and Objectives</td>
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<td>• Candidate’s Plan for Career Development/Training Activities During Award Period</td>
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**Center for Clinical and Translational Science**

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- IRB Approved via Amendment/Ancillary Study Document(s)
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- Clinical Trial Document(s)
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- Protection of Human Subjects
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- Inclusion of Women and Minorities
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- Inclusion of Children
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- Good Clinical Practice (GCP) Training Assurance *(Candidate and Mentor(s))*
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