
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 **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, 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.