UTAH CCTS KL2 APPLICATION SPECIFIC REVIEW CRITERIA


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?
- 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.** All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (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 on-line 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 also: 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.
The peer review of grant applications is at the heart of the NIH grants process. As you enter the review panel meeting, recognize that you are playing a very important role in NIH’s mission of ‘making important discoveries that improve health and save lives.’ You are tasked with evaluating the scientific merit of NIH grant applications in a fair, independent, expert and timely fashion that is free of inappropriate influence. Your assessment — coupled with that of other esteemed peer reviewers — will determine the most promising basic or applied research that NIH can fund and provide the lifeblood for biomedical research in the US and worldwide.

To orient you to the peer review process, this guide walks you through your pre-meeting responsibilities, activities at the meeting, and post-meeting responsibilities. All eligible Scientific Review Group (SRG) members, who have no conflict of interest, participate in the evaluation of an application. Members are designated as primary, secondary, or tertiary reviewers, and additional reviewers, as needed; mail reviewers; and discussants.

This guide orients you to the review process, providing information about reviewer tasks and responsibilities.

Contents

Pre-meeting Activities
- Summary
- Reviewing the Applications
  - Written Critique
  - Scoring
  - Review Criteria and Considerations
    - Overall Impact
    - Scored Review Criteria
    - Additional Review Criteria
    - Additional Review Considerations
    - Additional Comments to the Applicant

Meeting Activities
- Summary
- Presentation and Discussion
- Final Score and Voting

Post-Meeting Activities

Ethical Conduct
- Conflict of Interest
- Confidentiality
- Research Misconduct
PRE-MEETING ACTIVITIES

Summary

- Examine your review assignments, review materials (including Funding Opportunity Announcements and applications), and instructions.
- Review all applications pending review in the meeting for conflict of interest or the appearance of conflict of interest. If you perceive a conflict or have questions regarding a conflict, contact the Scientific Review Officer (SRO) immediately.
- Review your application assignments for match with your expertise. If you have questions regarding your assignment to an application, contact the SRO immediately.
- Review the “NIH Conflict of Interest Rules: Information for Reviewers of NIH Applications and R&D Contract Proposals” and complete the NIH pre-review Certification.
- Make sure that you have signed a Confidentiality Certification (usually in the Internet Assisted Review module).
- Read, evaluate and write a critique for each of your assigned applications (discussants may be asked to provide an ‘Overall Impact’ critique).
- Gain access to and upload critiques, preliminary overall impact scores and individual criterion scores to the Internet Assisted Review (IAR) site for the applications assigned to you; a deadline will be provided by the SRO.
- Read posted critiques for your assigned applications and other applications (you will be denied access to applications where you have a Conflict of Interest).
- Prepare for discussions at the meeting.

Reviewing the Applications

Written Critique

- Reviewers will use bullets to note strengths and weaknesses for each of the scored review criteria, and should provide context and an explanation for their comments based on the project (e.g., refer to a Specific Aim). While brevity is acceptable, bullets should express complete thoughts and be sufficient to inform the reader.
- Reviewers will write a paragraph summarizing the factors that informed their Overall Impact score (See Overall Impact below).
- Download the critique templates and enter bulleted comments directly into the document (if you prefer to compose your critique in a separate document, you may wish to “paste special” – as plain text - to retain the bulleted format).
- When finished, upload the document to IAR.
- Please see the Critique Template Instructions for more information on working with the critique templates.

Scoring

- The NIH scoring system uses a 9-point scale for the overall impact score and individual scores for (at least) five scored criteria.
- For both types of score, ratings are in whole numbers only (no decimal ratings).
- NIH expects that scores of 1 or 9 to be used less frequently than the other scores.
- 5 is considered an average score.
No formula is used to derive the overall impact score from the individual criterion scores, and reviewers are instructed to weigh the different criteria as they see fit in deriving their overall scores.

- Ratings are in whole numbers only (no decimal ratings).
- Reviewers enter scores into IAR (not on the template).
- Please see the Scoring System and Procedure for more information on scoring.
- Reviewers will score an application as presented in its entirety, and may not modify their scores on the assumption that a portion of the work proposed will be deleted or modified according to the SRG’s recommendations.

**Review Criteria and Considerations**

- Each application is evaluated for scientific and technical merit according to the Scored Review Criteria, Additional Review Criteria, and Additional Review Considerations stated in the Funding Opportunity Announcement.
- More details about the Review Criteria for common award mechanisms are found in Review Criteria at a Glance.

1. **Overall Impact**
   - In reviewing Research Projects, reviewers will provide an overall impact score and critique to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five (or more) scored review criteria, and additional review criteria (as applicable for the project proposed). For other activity codes (such as fellowships, career awards, training programs, and others), overall impact may be defined differently.
   - Reviewers will provide a paragraph summarizing the factors that informed their Overall Impact score. This paragraph should be a stand-alone assessment of the strengths and weaknesses outlined for each of the five scored criteria below. It is not intended to be a restatement or summary of the specific aims or the bulleted comments outlined in the critique. Rather, this paragraph should succinctly inform the reader (e.g., the applicant, program staff, members of council) of the underlying rationale for the Overall Impact score in consideration with the scored review criteria.
   - In reviewing Research Projects, reviewers should assume that basic and applied research are equally relevant to the mission of NIH and must evaluate overall impact in the context of the application.
   - Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a good impact score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.
   - The Overall Impact score is not necessarily the average of the individual criterion scores.
   - Overall Impact and Significance are different entities. The distinction between Overall Impact and Significance is described here.

2. **Scored Review Criteria**
   - Reviewers will consider each of the scored review criteria in the determination of scientific and technical merit, and give a separate score for each.
   - Most Funding Opportunity Announcements have the following five scored review criteria:
Significance, Investigator(s), Innovation, Approach, and Environment.

- In evaluating the Investigator(s) review criterion, reviewers are encouraged to focus on the qualifications and expertise of the members of the research team for the work proposed, including the Personal Statement in each Biosketch. Unless the application is for a fellowship or career development award, remarks about career tracks, titles, or salaries should be reserved for the Additional Comments to the Applicant box, or the Budget section.

Resources
- See Review Criteria at a Glance.

3. Additional Review Criteria
- When applicable, reviewers will consider the additional review criteria in the determination of scientific and technical merit and an overall impact score.
- Reviewers will not give separate scores for these items.

Resources
Here are guidelines for:
- The review of the Vertebrate Animals section (PDF - 43 KB) — March 21, 2016
- The Review of the Human Subjects Section (PDF - 146 KB) — March 21, 2016
- The Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research (PDF - 81 KB) — March 21, 2016
- The review of use of Human Embryonic Stem Cells (PDF-69 KB) — March 21, 2016
- The review of Revision Applications (formerly Competing Supplements) (PDF – 47 KB) — Dec. 18, 2015
- Revised Definition of Clinical Trials and Clinical Trial Decision Tree (from the Office of Science Policy website)

4. Additional Review Considerations
- When applicable, reviewers will comment on each of the additional review considerations, but will not assign scores and should not consider these items when determining an overall impact score.
- Program staff will administratively handle any concerns on these items following the review.

Resources
Here are guidelines for:
- The review of the Budget Information (PDF - 284 KB) — March 5, 2012
- Considering Information on Select Agents

5. Additional Comments to the Applicant
- Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.
- These comments need not relate directly to the scientific or technical merit of the application, do not factor into the final impact score, are not binding, and do not represent a consensus of the review panel.
• Other reviewers may not agree with these comments.
• Applicants are not obligated to address these comments when writing an introduction to a resubmission application.

MEETING ACTIVITIES

Summary

• The SRO will begin the meeting by reviewing policies and describing meeting procedures.
• In some SRGs, applications are reviewed based on the preliminary overall impact score (beginning with the best scores).
• Applications will be grouped together when feasible (e.g., same mechanisms, new investigators, or clinical applications).
• In most cases, only the more meritorious applications (based on preliminary scores) will be discussed at the meeting. All fully participating members of the SRG must concur on the recommendation to not discuss an application.
  o Applications that are discussed at the meeting will receive a final impact score, individually assigned reviewer criterion scores, a summary statement with critiques, and a resume and summary of the discussion.
  o Applications that are not discussed will receive summary statements containing written critiques and individual criterion scores from assigned reviewers and in some cases discussants.

Presentation and Discussion

• Applications will be introduced by the Chair of the SRG.
• Assigned reviewers will share their initial overall impact score and should be prepared to explain the significance of the proposed research and the overall impact the research will have on the field.
• Group discussion follows assigned reviewer presentations.
• Open discussion of scientific merit may result in disparate levels of enthusiasm.
  o The reasons for any disparities should be made clear to allow for both an informed vote by all panel members, and also a high quality summary statement.
• Because consideration of human subject protections, inclusion plans, vertebrate animals or biohazards can affect scientific and technical merit, these elements are discussed before final scoring.

Final Score and Voting

Based on the presentation and discussion, and the preliminary critique and overall impact scores from each assigned reviewer, each discussed application is given a score by all reviewers who are eligible to vote on that application. Mail Reviewers do not attend the review meeting and their preliminary overall impact scores are not averaged in to determine the average preliminary score. Mail Reviewers’ critiques and scores are considered by the review panel.

• Both regularly appointed and temporary members vote on each application for which they do not have a conflict of interest.
• Mail reviewers do not provide final, overall impact scores.
  ▪ Reviewers may use non-numeric impact scores, as appropriate:
    o AB – abstain from voting
    o CF – conflict of interest; did not participate in the discussion and scoring
    o NP – not present during discussion
• The following scenarios require a committee decision
  ▪ ND - not discussed
  ▪ NR - not recommended for further consideration (may reflect a lack of substantial merit or serious ethical problems in use of human subjects, vertebrate animals, or the environment)
  ▪ DF – deferred
• If a particular score is considered an outlier, the reviewer must have stated his/her concerns during the discussion so that they can be reflected in the final summary statement.
• The scores from all eligible reviewers for a given application are averaged (calculated to one decimal point) and multiplied by 10 to determine the final overall impact score.
• A final overall impact score and summary of the discussion will be included in the summary statement.

POST-MEETING ACTIVITIES

• After the meeting, the SRO sets an “Edit Phase” in IAR.
• Reviewers should edit their criterion scores and critiques to reflect any changes to their preliminary assessment.
• Reviewers must sign their post-meeting Conflict of Interest (COI) certification.

ETHICAL CONDUCT OF REVIEWERS

Conflict of Interest

• Check for potential conflicts of interest (or appearances of conflicts) and alert the SRO immediately of any conflicts of which you are aware.
• During the meeting, if a reviewer has a conflict of interest with any application or proposal, the reviewer must leave the room during evaluation and scoring of that application or proposal.
• In signing the post-review certification, each reviewer certifies that he/she did not participate in an evaluation of any application or proposal with which he/she knowingly had a conflict of interest.

Confidentiality

• Respect for the privacy of the investigators' ideas and reviewers' opinions is important; all applications and related materials are privileged communications that cannot be shown to or discussed with unauthorized individuals. (See Confidentiality in NIH Peer Review.) This means that you are prohibited from:
  ▪ Sharing applications, proposals, or meeting materials with anyone who has not been officially designated to participate in the peer review process.
  ▪ Granting access to any NIH secure computer system or advisory committee meeting to
anyone who has not been officially designated to participate in the peer review process.

- Disclosing, in any manner, information about the committee deliberations, discussions, evaluations, or documents to anyone who has not been designated to participate in the peer review process or who has a declared conflict of interest.
- Using information contained in an application or proposal for his/her personal benefit or making such information available for the personal benefit of any other individual or organization.

- In signing the confidentiality certification, each reviewer certifies that he/she fully understands the confidential nature of the review process and agrees to confidentiality and non-disclosure.
- Reviewers are required to leave all review materials (that are not in the public domain) with the SRO at the conclusion of the review meeting.

Research Misconduct

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, but not honest error or differences of opinion.
- It is vital that you do not make allegations of potential misconduct in the critique; instead, such concerns must be brought to the attention of the SRO in a confidential manner, preferably before the study section meets.

Resources

- More guidance on [Additional Comments to the Applicant](#).
Managing Conflict of Interest in NIH Peer Review of Grants and Contracts

If John is a paid employee of Science University, which has submitted a research application to NIH, can he serve on the panel that reviews the application? Since John has a conflict of interest with the application, he may not review that particular application and will have to be out of the room during the discussion and evaluation of that application, but may serve on the panel to review other applications.

The core values of impartiality, fairness, and integrity are fundamental to the NIH peer review process. NIH Scientific Review Officers (SROs) spend considerable time and energy identifying appropriate reviewers and managing reviewer conflicts of interest (COI).

Application of the Rules

The rules for managing COI addressed on this page apply to peer reviewers participating in:

- initial peer review for all types of grant programs, with the exception of construction grants, and
- peer review of proposals for Research and Development (R & D) contracts.

When does COI arise?

What are the types of conflicts that must be managed? Check out the many types below. Note that COI is handled differently for reviewers of grants and R&D contracts.

Grants Reviews
### Situation: Grant Reviews

**Proposed reviewer may not be on the study section if:**
- The reviewer is named on the application in a major professional role.
- The reviewer is a member of an NIH Advisory Council.
- The reviewer (or close family member) would receive a direct financial benefit if the application is funded.

**Proposed reviewer may be on the study section but may not review certain applications and must leave the room when:**
- The PI or others on the application with a major role are from the reviewer’s institution or institutional component (e.g., department).
- Within the past three years, the reviewer has been a collaborator or has had any other professional relationship (e.g., served as a mentor) with any person on the application who has a major role.
- The application includes a letter of support or reference letter from the reviewer.
- The reviewer serves as a member of the advisory board for the project under review.
- The reviewer has an indirect financial interest from the applicant institution or PD/PI of over $10,000 in honoraria, stocks, and fees during the course of the last year or during the project period.

**Proposed reviewer may be on the study section and may review specific applications without a waiver if: (not considered COIs)**
- An application originates from an institution where the reviewer has collaborators, but the reviewer’s collaborators are not listed on the application.
- The reviewer has an indirect financial interest of less than $10,000.
- The reviewer freely donates reagents or other materials to the proposed project, and these reagents or materials would also be available to other researchers.
- The reviewer, as well as a person with a major role on the proposed project, contributes data, reagents, specimens, etc., to the same repository or database.
- The reviewer is a member of a research network that involves a person with a major role on the proposed project.
- The reviewer is a co-author of a non-research publication (e.g., review, commentary) or a mega-multi-authored publication with a person with a major role on the proposed project.

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**Note:** A Federal employee serving as an NIH peer reviewer is responsible for obtaining any clearance required by his employing institute, agency, or office.

### Situation: Contract Reviews

**Proposed reviewer may not be on the technical evaluation panel if:**
- The reviewer is named on the proposal in a major professional role.
- The reviewer (or close family member) would receive a direct financial interest if the proposal is funded.
- The reviewer is employed by the offerer institution.

**Proposed reviewer may not be on the technical evaluation panel if:**
- The reviewer is from an institution that is included as a subcomponent of the proposal.
- Within the past three years, the reviewer has been a collaborator or has had any other professional relationship (e.g., served as a mentor) with any person on the proposal who has a major role.
- The proposal includes a letter of support or reference letter from the reviewer.
- The reviewer serves as a member of the advisory board for the project under review.
- The reviewer has an indirect financial interest from the offerer institution or person with a major professional role of over $10,000 in honoraria, stocks, and fees during the course of the last year or during the contract period.

**Proposed reviewer may be on the technical evaluation panel and may review the proposal if: (not considered a conflict)**
- A proposal originates from an institution where the reviewer has collaborators, but the reviewer’s collaborators are not listed on the proposal.
- The reviewer has an indirect financial interest of less than $10,000.
- The reviewer freely donates reagents or other materials to the proposed project, and these reagents or materials would also be available to other researchers.
- The reviewer, as well as a person with a major role on the proposed project, contributes data, reagents, specimens, etc., to the same repository or database.
- The reviewer is a member of a research network that involves a person with a major role on the proposed project.
- The reviewer is a co-author of a non-research publication (e.g., review, commentary) or a mega-multi-authored publication with a person with a major role on the proposed project.

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**Note:** A Federal employee serving as an NIH peer reviewer is responsible for obtaining any clearance required by his employing institute, agency, or office.
• **Appearance of a COI:** Any situation that could cause a reasonable person with all the relevant facts to question the impartiality of the reviewer or that leads a reviewer to question his or her objectivity means that the reviewer:
  - May not participate in the evaluation of that grant application.
  - May not serve on the study section where that R&D contract proposal is evaluated.

• **Study section membership:** An application from a member of a study section that meets regularly may not be reviewed by that member’s study section.

• **Applications in response to a Request for Applications (RFA):** An individual who is listed on an application submitted to an RFA with a major professional role may not serve on a study section evaluating any applications from that same RFA.

Certifying COI

Each NIH peer reviewer must certify, under penalty of perjury (US Code Title 18 chapter 47 section 1001), that to the best of his or her knowledge he/she has disclosed all conflicts of interest that he or she may have with the applications or R&D contract proposals; he or she fully understands the confidential nature of the review process and agrees:

(1) to destroy or return all materials related to it;

(2) not to disclose or discuss the materials associated with the review, the evaluation, or the review meeting with any other individual except as authorized by the Scientific Review Officer (SRO) or other designated NIH official;

(3) not to disclose procurement information prior to the award of a contract; and

(4) to refer all inquiries concerning the review to the SRO or other designated NIH official.

Want more policy details?
Scoring System and Procedure

The NIH scoring system was designed to encourage reliable scoring of applications. Reviewers or study sections who assign high ratings to all applications diminish their ability to communicate the scientific impact of an individual application. Therefore, reviewers who carefully consider the rating guidance below can improve the reliability of their scores as well as their ability to communicate the scientific impact of the applications reviewed.

Contents

Scoring
- Summary
- Preliminary Scores
- Criterion Scoring
- Impact/Priority Score
- Non-Numeric Scores
- Reviewer Guidance and Chart

**SCORING**

Summary

- The NIH grant application scoring system uses a 9-point scale for both overall impact scores and scores for individual review criteria.
  - For both types of score, ratings are in whole numbers only (no decimal ratings).
  - NIH expects that scores of 1 or 9 to be used less frequently than the other scores.
- For the overall impact score,
  - the scale is used by all eligible (without conflict of interest) SRG (Scientific Review Group) members
  - 5 is considered an average score.
- For criterion scores,
  - the scale is used by the assigned reviewers to evaluate (at least) five individual criteria (e.g., Significance, Investigator(s), Innovation, Approach, Environment).
  - reviewers should consider the strengths and weaknesses within each criterion. For example, a major strength may outweigh many minor and correctable weaknesses.
- For information about using the critique template, see [Critique Template Instructions](#)

Preliminary Scores

- Before the review meeting, assigned reviewers determine preliminary scores for each of the scored review criteria and a preliminary score for the overall impact
- The impact score should reflect the reviewer’s overall evaluation, not a numerical average of individual criterion scores
- Reviewers should consider the full range of the rating scale and the scoring descriptors in assigning preliminary and final scores
  - However, a reviewer should not assume that the applications assigned to him/her necessarily cover that entire range of scores, and should assign scores as appropriate for the work or science proposed
- An application does not need to be strong in all categories to be judged likely to have major impact
For example, a project that by its nature is not innovative may be essential to advance a field.

- Reviewers must enter the criterion scores into the Internet Assisted Review (IAR) site in the NIH Commons for them to appear in the summary statement.
  - If entered in IAR, the scores will be transferred to a table at the beginning of the reviewer’s critique.
- Assigned reviewers may submit criterion scores only after their critiques have been uploaded.
  - At the SRO’s discretion, SRG members assigned as discussants may submit criterion scores without critiques.
- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them.
- Final scores are given by private scoring and are based on the outcome of the deliberations at the peer review meeting.

**Criterion Scoring**

- In most cases, five individual criteria are scored, but certain Funding Opportunity Announcements may include more than five scored criteria.
- Criterion scores are provided for all applications.
- Criterion scores are intended to convey how each assigned reviewer weighed the strengths and weaknesses of each section.
- Providing scores without providing comments in the review critique is discouraged.
- The impact score for the application is not intended to be an average of criterion scores.
- Criterion scores are entered into the Internet Assisted Review site for the meeting; the same screen also allows uploading of the written critique at the same time.
- If the reviewer’s opinion changed as a result of discussion at the meeting, the reviewer should change his/her criterion scores to match his/her critiques and overall impact score as part of the EDIT phase.
- The criterion scores appear in a table at the beginning of each critique in the summary statement.

**Impact Score**

- Discussed applications receive numerical impact scores from all eligible reviewers (e.g., without conflicts of interest).
- The impact score for an application is based on each individual reviewer’s assessment of the scored criteria plus additional criteria regarding the protection and inclusion of human subjects; vertebrate animal care and welfare; biohazards, and criteria specific to the funding opportunity.
- Reviewers are guided to use the full range of the rating scale and spread their scores to better discriminate among applications.
- Reviewers whose evaluations or opinions of an application fall outside the range of those presented by the assigned reviewers and discussant(s) should ensure that their opinions are brought to the attention of the entire committee.
- In addition, the SRO and Chairperson should ensure that all opinions are voiced before final scoring is conducted.
- Reviewers should feel free to assign the score that they believe best represents the impact of the application, and not feel constrained to limit their scores to the upper half of the score range if they do not feel such a score is warranted.
• Reviewers will score an application as presented in its entirety, and may not modify their scores on the assumption that a portion of the work proposed will be deleted or modified according to the SRG’s recommendations
• After the meeting, individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact score
• The range of the final application scores is 10 through 90

Non-Numeric Scores

• Not Discussed (ND)
  o Applications unanimously judged by the peer review committee to be less competitive are not discussed at the peer review meeting
  o These applications do not receive a numerical impact score
  o These applications do receive individual criterion scores
  o Not all meetings use the “Not Discussed” option
• Not Recommended for Further Consideration (NRFC)
  o NR for an application occurs by majority vote of the SRG members
  o NR occurs in the following scenarios:
    ▪ Application lacks significant and substantial merit
    ▪ Application presents serious ethical problems in the protection of human subjects from research risks
    ▪ Application presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents
  o NR-scored applications do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded
  o The NR is a serious committee recommendation that is substantially different from Not Discussed (ND)
• Other Non-numeric Scores
  o DF: Deferred (usually due to lack of sufficient information or quorum, allegations of research misconduct)
  o AB: Abstention (used rarely)
  o CF: Conflict (score put in by a reviewer who is in conflict with the application)
  o NP: Not Present

Reviewer Guidance

• The table below provides a guide for reviewers in assigning overall impact scores and individual criterion scores.
• Overall impact, for a research project, is the project’s likelihood to have a sustained, powerful influence on the research field(s) involved, but may be defined differently for different types of applications.
• Each review criterion should be assessed based on the strength of that criterion in the context of the work being proposed
  o As a result, a reviewer may give only moderate scores to some of the review criteria but still give a high overall impact score because the one review criterion critically important to the research is rated highly; or a reviewer could give mostly high criterion ratings but rate the overall impact score lower because the one criterion critically important to the research being proposed is not highly rated.
• An application does not need to be strong in all categories to be judged likely to have major impact, e.g., a project that by its nature is not innovative may be essential to advance a field.
• A score of 5 is a good, medium-impact application.
• The entire scale (1-9) should always be considered.
<table>
<thead>
<tr>
<th>Overall Impact or Criterion Strength</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>

Other Designations for Final Outcome

<table>
<thead>
<tr>
<th>Designation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB</td>
<td>Abstention</td>
</tr>
<tr>
<td>CF</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>DF</td>
<td>Deferred</td>
</tr>
<tr>
<td>ND</td>
<td>Not Discussed</td>
</tr>
<tr>
<td>NP</td>
<td>Not Present</td>
</tr>
<tr>
<td>NR</td>
<td>Not Recommended for Further Consideration</td>
</tr>
</tbody>
</table>

See specific guidance for [Research Applications](#) and [Training Applications](#).
Review Criteria at a Glance

CONTENTS

Review Criteria at a Glance - Research......................................................................................... 2

Review Criteria at a Glance - Training ............................................................................................. 3

Review Criteria at a Glance - Other................................................................................................ 4
# REVIEW CRITERIA AT A GLANCE - RESEARCH

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>Research and Research Center (R, DP, RC, P, etc.)</th>
<th>Institutional R25</th>
<th>Conferences and Scientific Meetings R13/U13</th>
<th>SBIR/STTR (R41, R42, R43, R44)</th>
<th>Academic Research Enhancement Award (AREA) (R15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scored Review Criteria</td>
<td>✓ Significance ✓ Investigator(s) ✓ Innovation ✓ Approach ✓ Environment</td>
<td>✓ Significance ✓ Investigator(s) ✓ Innovation ✓ Approach ✓ Environment</td>
<td>✓ Significance ✓ Investigator(s) ✓ Innovation ✓ Approach ✓ Environment</td>
<td>✓ Significance ✓ Investigator(s) ✓ Innovation ✓ Approach ✓ Environment</td>
<td>✓ Significance ✓ Investigator(s) ✓ Innovation ✓ Approach ✓ Environment</td>
</tr>
<tr>
<td>(Scored individually and considered in overall impact score)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAR &amp; RFA: May add questions to each scored criterion or additional criteria</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>(Not scored individually, but considered in overall impact score)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAR &amp; RFA: May add new criteria or questions to each additional criterion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Review Considerations</td>
<td>R01-BRP only: • Technology Transfer</td>
<td>• Recruitment &amp; Retention Plan to Enhance Diversity • Training in the Responsible Conduct of Research • Select Agents • Resource Sharing Plans • Authentication of Key Biological and/or Chemical Resources • Budget &amp; Period of Support</td>
<td>• Provision of Family Care Facilities • Applications from Foreign Organizations • Select Agents • Resource Sharing Plans • Budget and Period of Support</td>
<td>• Select Agents • Resource Sharing Plans • Authentication of Key Biological and/or Chemical Resources • Budget &amp; Period of Support</td>
<td>• Select Agents • Resource Sharing Plans • Authentication of Key Biological and/or Chemical Resources • Budget &amp; Period of Support</td>
</tr>
<tr>
<td>(Not scored individually and not considered in overall score)</td>
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<tr>
<td>Additional Comments to Applicant</td>
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</tr>
</tbody>
</table>

Responses for items with emphasis (✓ italics) are required.  

Last updated June 1, 2016
## REVIEW CRITERIA AT A GLANCE - TRAINING

<table>
<thead>
<tr>
<th>Scored Review Criteria</th>
<th>Overall Impact</th>
<th>Overall Impact</th>
<th>Overall Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fellowship</strong> <em>(F30, F31, F32, F33)</em></td>
<td>Overall Impact/Merit</td>
<td>Overall Impact</td>
<td>Overall Impact</td>
</tr>
<tr>
<td><strong>Career Development</strong> <em>(K01, K02, K07, K08, K23, K24, K25, K99)</em></td>
<td>Overall Impact</td>
<td>Overall Impact</td>
<td>Overall Impact</td>
</tr>
<tr>
<td><strong>Institutional Training</strong> <em>(T32, T35, K12)</em></td>
<td>Overall Impact</td>
<td>Overall Impact</td>
<td>Overall Impact</td>
</tr>
</tbody>
</table>

### Scored Review Criteria

(Scored individually and considered in overall impact score)

- **Fellowship Applicant**
- **Sponsors, Collaborators, and Consultants**
- **Research Training Plan**
- **Training Potential**
- **Institutional Environment & Commitment to Training**

- **Candidate**
- **Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring**
- **Research Plan**
- **Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)**
- **Environment & Institutional Commitment to the Candidate**

- **Training Program and Environment**
- **Training PD/PI**
- **Preceptors /Mentors**
- **Trainees**
- **Training Record**

Other T programs use other criteria

### Additional Review Criteria

(Not scored individually, but considered in overall impact score)

- **Protections for Human Subjects**
- **Inclusion of Women, Minorities, & Children**
- **Vertebrate Animals**
- **Biohazards**
- **Resubmission**
- **Renewal**

- **Protections for Human Subjects**
- **Inclusion of Women, Minorities, & Children**
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- **Resubmission**
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- **Revision**

- **Protections for Human Subjects**
- **Inclusion of Women, Minorities, & Children**
- **Vertebrate Animals**
- **Biohazards**
- **Resubmission**
- **Renewal**
- **Revision**

### Additional Review Considerations

(Not scored individually and not considered in overall score)

- **Training in the Responsible Conduct of Research**
- **Applications from Foreign Organizations**
- **Select Agents**
- **Resource Sharing Plans**
- **Budget & Period of Support**

- **Training in the Responsible Conduct of Research**
- **Select Agents**
- **Resource Sharing Plans**
- **Authentication of Key Biological and/or Chemical Resources**
- **Budget & Period of Support**

- **Training in the Responsible Conduct of Research**
- **Select Agents**
- **Resource Sharing Plans**
- **Authentication of Key Biological and/or Chemical Resources**
- **Budget & Period of Support**

### Additional Comments to Applicant

- Additional Comments to Applicant
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- Additional Comments to Applicant

Responses for items with emphasis (✓ italics) are required.

*Last updated June 1, 2016*
### REVIEW CRITERIA AT A GLANCE – OTHER

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>Shared Instrumentation (S10)</th>
<th>Construction and Modernization Grants (C06, UC6, G20)</th>
<th>Administrative Centers (P30, P40, P41, P2C, R24, R28, U24, U41, U42, U2C)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall Impact/Benefit</td>
<td>Overall Impact</td>
<td>Overall Impact</td>
</tr>
</tbody>
</table>

#### Scored Review Criteria
(Scored individually and considered in overall impact score)

- Justification of Need
- Technical Expertise
- Research Projects
- Administration
- Institutional Commitment
- Scientific Merit and Organization of the Total Program and Its Component Parts to be Carried out in the Facility
- Administrative and Leadership Capabilities of the Applicant’s Officers and Staff
- Anticipated Effect of the Project on Other Relevant Research Programs and Facilities in the Geographic Area and Nationwide
- Need for the Project/Additional Space
- Project Design
- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

#### Additional Review Criteria
(Not scored individually, but considered in overall impact score)

- Biohazards
  - Resubmission
- Protections for Human Subjects
- Inclusion of Women, Minorities, & Children
- Vertebrate Animals
- Biohazards
  - Resubmission
  - Revision
- Protections for Human Subjects
- Inclusion of Women, Minorities, & Children
- Vertebrate Animals
- Biohazards
  - Resubmission
  - Renewal
  - Revision

#### Additional Review Considerations
(Not scored individually and not considered in overall score)

- Select Agents
  - Budget & Period of Support
- Applications from Foreign Organizations
  - Select Agents
  - Resource Sharing Plans
  - Budget & Period of Support
- Applications from Foreign Organizations
  - Select Agents
  - Resource Sharing Plans
  - Authentication of Key Biological and/or Chemical Resources
  - Budget & Period of Support

#### Additional Comments to Applicant

- Additional Comments to Applicant
- Additional Comments to Applicant
- Additional Comments to Applicant

Responses for items with emphasis (✓ italics) are required. **Last updated June 1, 2016**
Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

Notice Number: NOT-OD-16-011

Key Dates
Release Date: October 9, 2015

Related Announcements
NOT-OD-16-012
NOT-OD-16-005
NOT-OD-16-004
NOT-OD-15-103
NOT-OD-15-102

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)

Purpose
This notice informs the biomedical research community of updates to application instructions and review language intended to enhance the reproducibility of research findings through increased scientific rigor and transparency. These updates will take effect for most* research grant applications (including small business and complex research grant applications) submitted for due dates on or after January 25, 2016. For research contracts, this policy will be effective for proposals received on/after January 25, 2016 and expected to result in contract awards in Fiscal Year 2017 and beyond.

Updates include:

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.

The basic principles of rigor and transparency and the four areas of focus apply to the full spectrum of research, from basic to clinical. Investigators will need to consider how all four areas apply to their proposed research. Likewise, reviewers will assess whether these areas have been appropriately addressed by the applicant through revised language defining the peer review criteria.

*Notes & Exceptions:

- Research grant activity codes excluded from this policy include C06, G08, G11, G12, G13, G20, R13, S06, S10, S21, SB1, U13, U55, UB1, UC6, UC7, UG4, UH4, X02, and 333.
- Research Resource and Related grants or components (P30, P40, P41, P2C, R24, R28, U24, U41,
U42, and U2C) may have slightly revised review language; please refer to the Funding Opportunity Announcement.

- Refer to NOT-OD-16-012 for updates to Career Development Award application instructions and review language.
- Fellowship and Training grant applications submitted for the May 25, 2016 due date and beyond will include new instructions and review criteria to address this policy. Details on these changes will be available by December 2015.

Implementation for Grant Applications

**Updates to Research Strategy Guidance**

By November 25, 2015 application guide instructions will be updated to include the following additional guidance for the Significance and Approach sections of the Research Strategy, in addition to the existing instructions.

**Significance**
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.

**Approach**
Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

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. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

**New Authentication of Key Biological and/or Chemical Resources Attachment**

Grant applications for the activity codes covered by the policy must include a new PDF attachment related to the authentication of key biological and/or chemical resources.

**Authentication of Key Biological and/or Chemical Resources**
Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

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.

Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095).

Applications submitted for due dates between January 25, 2016 and May 24, 2016 will use the FORMS-C forms and application guide. The general application guide will be updated by November 25, 2015 with instructions for this new attachment and guidance to upload your PDF document (titled "Authentication of Key Resources Plan") in the "Other Attachments" section of the "Other Project Information" form.

Applications submitted for due dates on or after May 25, 2016, will use updated FORMS-D forms. The PHS 398 Research Plan form will include a new "Authentication of Key Biological and/or Chemical Resources" attachment field. FORMS-D application forms and instructions will be available for all active Funding Opportunity Announcements at least 60 days prior to due dates that fall on or after May 25, 2016.

Application Review Information

Unless stated otherwise in the Funding Opportunity Announcement, reviewers will be asked to consider additional review questions in order to assess rigor and transparency in research grant applications. By November 25, 2015, all active Funding Opportunity Announcements will be updated to reference these additional review questions.

Scored Review Criteria

Significance
Is there a strong scientific premise for the project

Approach
Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Additional Review Considerations

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.

Research Performance Progress Reports

Research Performance Progress Reports (RPPR) submitted January 25, 2016 or later will be expected to emphasize rigorous approaches taken to ensure robust and unbiased results. Rigor should be addressed in the RPPR for any grant that funds research or training in research; grants that support other activities do not need to address rigor. This includes non-competing continuation reports (Type 5) for grants
reviewed and awarded before implementation of the policy. The RPPR instructions will be updated by January 25, 2016. Reporting on rigor in RPPR will help NIH implement and evaluate the policy for both current and new awards, as well as prepare non-competing renewals for the next competitive renewal.

**Resources**

- Website describing reproducibility efforts for NIH applicants and grantees
- Frequently Asked Questions

**Background**

NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Key to the successful application of that knowledge toward health outcomes is scientific rigor in conducting biomedical research. One of NIH’s four stated goals is to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science (see [http://www.nih.gov/about/mission.htm](http://www.nih.gov/about/mission.htm)).

These rigor and transparency updates:

- clarify long-standing expectations to ensure that NIH is funding the best and most rigorous science,
- highlight the need for applicants to describe details that may have been previously overlooked,
- highlight the need for reviewers to consider such details in their reviews through updated review language, and
- minimize additional burden.

These are not new expectations, but NIH is formalizing these expectations in grant applications and reviews. Some investigators already address some of the four areas of rigor in their applications, while other investigators are doing so in their research but not providing details in applications and/or publications. All biomedical science will benefit from increased attention to rigor and transparency in research grant applications and reviews.

**Inquiries**

Please direct all inquiries to:

reproducibility@nih.gov

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Weekly TOC for this Announcement  
NIH Funding Opportunities and Notices

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Office of Extramural Research  
Department of Health and Human Services (HHS)