Reviewer Manual
For Contract Reviews

NIAID Scientific Review Program
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Rockville, MD 20852
301-496-2550

Scientific Review Program, Division of Extramural Activities
Fostering the best biomedical and behavioral research through leadership in NIH peer review quality, innovation, and professionalism.
Dear Reviewer,

On behalf of NIAID's Scientific Review Program (SRP), I welcome you to the NIH's Peer Review process. The mission of the SRP is to foster the best biomedical and behavioral research through leadership in NIH peer review, quality, innovation, and professionalism. The scientific expertise, technical knowledge, and valuable time that you contribute to the peer review process are instrumental in helping us achieve our mission. Last year more than 2,700 reviewers participated in over 120 NIAID Special Emphasis Panels and Standing Review Committees to review approximately 1,700 grant applications and contract proposals requesting over $10.5 billion. We would not have been able to achieve this outcome without your support, and I thank you for your efforts.

The SRP manages and conducts scientific peer review meetings for applications and proposals focused on basic, clinical, and translational research along with developing and supporting research infrastructure. Again, your contributions to the peer review of these applications and proposals play an important role in providing the scientific basis for understanding, diagnosing, treating, and preventing infectious, immune-mediated, and allergic diseases that afflict people throughout the world.

The accompanying internet-based Reviewer Manual is our latest effort to provide simplified and chronological guidance for the peer review process. Each of the steps and encompassing chapters describes an important aspect of the overall process. Please familiarize yourself with the accompanying manual; it will help you to accomplish your review tasks step-by-step. As always, your Scientific Review Officer (SRO) is your point of contact for addressing any questions and concerns you may have about this peer review meeting. Thank you for your participation in this review.

Sincerely,

Hortencia Hornbeak
Hortencia Hornbeak, PhD
Director, Scientific Review Program
Division of Extramural Activities, NIAID
# TABLE OF CONTENTS

**STEP 1** ....................................................................................................................................... 1  
INTRODUCTION TO THE NIH CONTRACTING PROCESS ........................................................... 1  
THE CONTRACT SOLICITATION (RFP/BAA) ........................................................................... 5  
MAINTAINING CONFIDENTIALITY ........................................................................................ 8  
AVOIDING CONFLICTS OF INTEREST .................................................................................... 9  
PROTECTING THE SECURITY OF CONTRACT PROPOSALS ................................................... 10  
MISCONDUCT IN SCIENCE ................................................................................................... 12  
GLOSSARY AND ACRONYMS ................................................................................................. 13  

**STEP 2** ..................................................................................................................................... 16  
REGISTRATION FOR RECEIVING HONORARIUM AND REIMBURSEMENT ....................... 16  
HONORARIUM AND REIMBURSEMENTS FOR NON-FEDERAL REVIEWERS ......................... 20  
TRAVEL INFORMATION FOR NON-FEDERAL REVIEWERS ................................................... 22  
TRAVEL AND REIMBURSEMENT INSTRUCTIONS FOR FEDERAL REVIEWERS ..................... 25  
HOTEL RESERVATIONS ........................................................................................................ 28  

**STEP 3** ..................................................................................................................................... 29  
PRE-MEETING PREPARATIONS ............................................................................................ 29  
ACCESSING YOUR REVIEW ASSIGNMENTS IN REVIEWER SUPPORT SITE (RSS) .............. 31  
WRITING AND SUBMITTING REVIEWER CRITIQUES .......................................................... 32  
VIEWING CRITIQUES FROM OTHER REVIEWERS ............................................................... 36  
SCORING CONTRACT PROPOSALS ....................................................................................... 37  
SPECIAL REVIEW ISSUES: ................................................................................................... 39  
HUMAN SUBJECTS PROTECTION AND INCLUSION ........................................................... 39  
VERTEBRATE ANIMALS ....................................................................................................... 47  
BIOSHAKARDS ...................................................................................................................... 49  
SELECT AGENTS ................................................................................................................ 50  
DATA SHARING PLAN ........................................................................................................ 52  
NIH GENOMIC DATA SHARING (GDS) POLICY ............................................................... 54  
BUDGET ASSESSMENT ......................................................................................................... 60  
PRE-REVIEW ORIENTATION TELECONFERENCE ................................................................. 61  

**STEP 4** ..................................................................................................................................... 62  
GENERAL CONTRACT REVIEW ............................................................................................. 62  
MEETING PROCEDURES ....................................................................................................... 62  
TELECONFERENCE REVIEWERS ........................................................................................... 65  
EVALUATION OF AN INITIATIVE ......................................................................................... 67  

**STEP 5** ..................................................................................................................................... 69  
POST-REVIEW CHECKLIST ................................................................................................... 69
INTRODUCTION TO THE NIH CONTRACTING PROCESS

THE NIH MISSION

The National Institutes of Health (NIH) is the principal medical research component of the United States Government and one of the health agencies of the Public Health Service (PHS), a component of the Department of Health and Human Services (DHHS). Included within the NIH are 27 Institutes and Centers (IC).

The mission of the NIH is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by:

- conducting research in its own laboratories;
- supporting the research of non-Federal scientists in universities, medical schools, hospitals, research institutions, and companies throughout the country and abroad;
- helping in the training of research investigators; and
- fostering communication of medical information.

The goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability from the rarest genetic disorder to the common cold.

Approximately 84 percent of tax dollars provided to NIH is invested in the Extramural Research Program, funding grants and contracts that support research and training conducted by about 50,000 program directors/principal investigators (PD/PI) at more than 2,000 research institutions throughout the United States and abroad. Approximately ten percent of the budget goes to the Intramural Research Programs, with more than 2,000 projects conducted mainly in NIH’s own laboratories. About eight percent of the budget is for both intramural and extramural research support costs.

THE NIAID MISSION

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 60 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world. The scope of the NIAID research portfolio has expanded considerably in recent years in response to new challenges such as bioterrorism; emerging and re-emerging infectious diseases including acquired immunodeficiency syndrome (AIDS); severe acute respiratory syndrome (SARS); West Nile virus, malaria, and tuberculosis; and an increase in asthma prevalence among children in this country.

The growth of NIAID programs also has been driven by unprecedented scientific opportunities in the core NIAID scientific disciplines of microbiology, immunology, and infectious diseases. Advances in these key fields have led to a better understanding of the human immune system and the mechanisms of infectious and immune-mediated diseases.

Research and Development Contracts

Updated October 11, 2016
The NIAID Office of Acquisitions (OA) supports the Institute’s mission through planning, soliciting, negotiating, awarding, and administering biomedical and behavioral Research and Development (R&D) contracts, contracts for the direct support of R&D, station support contracts, and simplified acquisitions.

The NIAID OA uses R&D contracts to address critical needs such as the acquisition of clinical trials, vaccines and vaccine development, statistical and data coordinating centers, animal models of human diseases, establishment of research centers of excellence for many diseases, and maintenance of reagent and specimen repositories.

**Contract Solicitation Mechanisms:**

**Requests for Proposals**

A Request for Proposals (RFP) is the primary contract solicitation mechanism used by NIAID. In addition to required solicitation elements, the RFP provides a detailed Statement of Work (SOW) that defines in specific language what goods or services the Government wants to purchase (e.g. a Phase I Clinical Trial Unit to assess safety of new therapeutics or a vaccine stable at 35°C and efficacious in 1-2 doses). Proposals are evaluated objectively for scientific and technical merit against a standard set of Technical Evaluation Criteria/Criterion (TEC) published in the RFP (see Review Process below).

**Broad Agency Announcements**

A Broad Agency Announcement (BAA) is a general contract solicitation that identifies areas of scientific interest or aims, including products or services, to advance science. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government. It differs from an RFP in that there is no defined Statement of Work (SOW), but a deliverable is defined that specifies a service or product that the Government wishes to acquire. Proposals in response to a BAA are not evaluated against a specific, common SOW, as for RFPs. Instead, the BAA provides research and technical objectives describing the areas in which the Government is interested, and the offeror develops and defines their own SOW. Like an RFP, a BAA solicitation also includes standard TEC by which all proposals are evaluated.

**Noncompeting Proposals**

The following types of contract proposals are, for review purposes, synonymous: noncompeting, sole-source, and JOFOC (Justification for Other than Full and Open Competition). For the review of these types of contract proposals, evaluation criteria are usually provided but without assigned points. These proposals may be judged on their uniqueness and determined to be acceptable or unacceptable solely on their strengths and weaknesses.

**Technical vs. Business Proposals**

All proposals must be submitted in two parts: a technical proposal and a business proposal. Each part is to be separate and complete in itself so that each may be evaluated independently of the other. Reviewers receive and evaluate only the technical proposal. The business proposal goes to the Office of Acquisitions; cost and price information is not disclosed to the peer reviewers.
OVERVIEW OF THE R&D CONTRACTING PROCESS

Concept Review: NIH Scientific Peer Review regulations require peer review and approval of all biomedical and behavioral R&D project Concepts prior to solicitation. Peer review of R&D project concepts evaluates the basic purpose, scope, and objectives of the projects and establishes relevance, priority, and the need to accomplish the NIH objectives. After the peer review and approval of a project concept, the OA works with NIH program staff to create a solicitation.

Solicitation: The solicitation contains all the elements necessary for prospective offerors to submit a proposal: schedule; contract clauses; lists of documents, exhibits, and other attachments; representations and instructions; and evaluation factors for award. Prospective offerors should carefully review each element of the solicitation to ensure that they understand the requirements and are able to fully respond. Solicitations are advertised in FedBizOpps. See NIAID-specific solicitations at Requests for Proposals list.

Peer Review: Technical proposals submitted to NIH in response to a solicitation are peer-reviewed for scientific and technical merit by a Technical Evaluation Panel (TEP). The peer reviewers on the TEP are recruited by the Scientific Review Officer (SRO) and screened for potential conflicts of interest. During the peer review meeting, reviewers discuss each technical proposal and score each one independently against the TEC stated in the solicitation. After scoring a proposal, the TEP then judges the proposal to be either “Acceptable” or “Unacceptable” based on definitions in the NIH Policy Manual Chapter 6315-1 (See chapter “Scoring Contract Proposals” for additional details).

Office of Acquisitions and the Competitive Range: After peer review is complete, the OA determines the Competitive Range (or Order of Merit for a BAA) of the most highly rated proposals based on the score from the TEP and other evaluation factors from the solicitation. Offerors in the Competitive Range are notified, and oral and/or written negotiations are then conducted. When negotiations are conducted in a competitive acquisition, they are called discussions.

Discussions: Discussions are tailored to each offeror's proposal, and they must be conducted by the Contracting Officer with each offeror within the competitive range. The primary objective of discussions is to maximize the government’s ability to obtain best value, based on the requirements and the evaluation factors set forth in the solicitation. During discussions, the Contracting Officer may request or allow written responses to business and technical questions and proposal revisions to clarify and document understandings reached during discussions. At the conclusion of discussions, each offeror still in the competitive range will be given an opportunity to submit a final proposal revision (previously Best and Final Offer or BAFO).
**Funding Decisions:** Final proposal revisions are reviewed by a Source Selection Group, which includes several NIH staff members and may include members of the original TEP. Based on the offerors' responses to questions raised during negotiations, the Source Selection Group may adjust the scores for each Technical Evaluation Criterion upward or downward. Awards are usually made to the highest technically ranked offeror(s); when two or more offerors are technically equivalent, cost may become the determining factor.

For further information on the NIAID contracting process, please see:

*About NIAID Research and Development Contracts:*

*Contracting portal for NIAID's Office of Acquisitions:*
http://www.niaid.nih.gov/RESEARCHFUNDING/CONTRACT/Pages/default.aspx
THE CONTRACT SOLICITATION (RFP/ BAA)

NIH mainly uses two contract mechanisms—the Request for Proposals (RFP) or the Broad Agency Announcement (BAA) to solicit basic and applied research. The RFP/BAA contains information that prospective offerors need in order to prepare a complete proposal. For members of Technical Evaluation Panel (TEP), the most important sections of the RFP/BAA are 1) Statement of Work (SOW) for the RFP or Research and Technical Objectives (RTO) for the BAA, 2) Technical Review Criteria/ Criterion (TEC) and 3) Additional Technical Proposal Instructions to the offeror.

Amendments to the RFP/ BAA

Amendments to the RFP/BAA are sometimes issued by the Government during the solicitation period, before the proposals are received by the NIH. This could be necessary for a variety of reasons (e.g., material changes or clarifications can be made, usually in response to questions by the offerors, regarding the specifications, terms, or conditions contained in the original solicitation). When an amendment is needed, contracting personnel prepare a response and post it on FedBizOpps. Any amendment to an RFP/BAA must provide a reasonable amount of time for potential offerors to respond to the change.

Technical Evaluation Criteria

TEC permit an objective assessment of the merits of individual proposals against standards, rather than against other proposals. Each RFP/BAA identifies the specific TEC and the relative importance (weight) of each. Prospective offerors use the TEC to judge the basis by which their proposals are to be evaluated and how they may best devote their efforts in preparing their proposals. Members of the TEP evaluate and score the offerors’ proposals according to each of the TEC. The TEC set forth in the RFP/ BAA are the only standards that may be used in evaluating proposals. The TEC must only be applied to elements within the scope (i.e., Reviewers cannot evaluate or assign weight to activities that are not part of the scope).

Statement of Work (RFP)

The RFP provides a detailed SOW to communicate and define the Government’s requirements to prospective offerors. The SOW guides the offerors on the content of their technical proposals by defining the scope of work, including: tasks the contractor must undertake, types of stages of work, number and type of personnel, sequence of effort, and reporting requirements. The SOW also defines the respective responsibilities of the Government and the offeror and provides an objective measure so that both parties will know when the work is complete and payment is justified. The SOW will usually contain most or all of the following sections:

- **Background**: Describes the Government’s requirements in general and non-technical terms as well as explains why the acquisition is being pursued and how it relates to past, current, or future projects.
• **Project Objectives**: Provides a succinct statement of the purpose of the acquisition. This section outlines the results that the Government expects and may also identify the desired benefit to the Institute/Center’s (IC) Extramural Research Program.

• **Scope of Work**: Provides an overall, description of the work to be performed. It expands on the project’s objectives but does not attempt to list all of the work required in detail.

• **Detailed Technical Requirements**: States most precisely what is expected of the contractor in the performance of the work. This section describes the specific tasks and phases of the work and specifies the total labor each task or phase is to receive. Considerations that may guide the contractor in its analysis, design, or experimentation on the designated problems are also included.

• **Reporting Schedule**: Defines the method by which the contractor can demonstrate progress and compliance with the contract’s requirements as well as present any problems it may have encountered by regular submission of technical progress reports.

• **Special Considerations**: Includes any relevant additional information. For example, this section might explain any special relationships between the contractor working under this specific contract and other contractors working for the Government.

• **References**: Provides a detailed list and description of any studies, reports, and other data referred to elsewhere in the SOW.

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**Research and Technical Objectives (BAA)**

Since the BAA is a more general solicitation that aims to encourage creative and innovative approaches to specific research areas identified by the Government, there is not a defined, common SOW by which to evaluate the proposals. Instead, the BAA contains a section entitled “Research and Technical Objectives” (RTO) that describes the technical objectives that the Government seeks to achieve. The offeror (not the Government) then develops and defines their own SOW showing how they will achieve the Government’s objectives, including specific work requirements, performance specifications and deliverables. The approaches can vary, since the proposals do not adhere to a common SOW. The RTO may contain many of the sections noted in the SOW section above.

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**Electives**

In addition to the required RTO, there may be electives that offerors may choose to address. Response to an elective requires a response to the RTO. Electives are treated as independent parts of proposals that will be evaluated and scored on their own merit. Scores of Electives and RTOs are treated separately in funding decisions.

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**Additional Technical Proposal Instructions**

This section (often seen in Attachment 4 of the RFP/BAA) includes specific formatting instructions as well as additional details about how the SOW or RTO should be presented.
Options

“Option” sections include services the Government may choose to fund, depending on a variety of issues. Offerors must address all Options so that they can receive the points associated with them. Thus, the Options are not optional for the offeror; the Government has the choice to exercise the work specified under that Option. Some examples of options include increase in level of support, additional performance periods, conduct of a clinical trial on a particular topic or inclusion of a specimen repository.

Sample Task Orders

In addition to the SOW or RTO, some solicitations will request Sample Task Orders on a topic so the Government can see how an offeror would respond to their requests. For example, the solicitation may direct offerors to provide administrative and technical support, maintenance activities and infrastructure building activities.

Mandatory Qualification Criteria

The RFP/BAA also may include Mandatory Qualification Criteria that define conditions that the offeror must meet in order for the proposal to be considered for an award. For example, an RFP for a vaccine production facility might specify that the offeror must provide documentation that they meet FDA certification requirements for an establishment engaged in the preparation of vaccines licensed for human use and must also be certified as meeting cGMP standards.

Web Links

Web links in proposals are not permitted unless otherwise specified in an NIH solicitation. For peer review purposes, proposals must be self-contained within the page limits stated in the solicitation. If reviewers encounter a web link during the reading of a proposal, they should not view or use the information on the webpage during the evaluation of the proposal.

Additional Information


MAINTAINING CONFIDENTIALITY

Privileged information shared with reviewers during the contract review process (e.g. contract proposals or meeting discussions) must not be shared with anyone not associated with the review or used for personal benefit, as there are potential legal ramifications for such actions.

All materials and discussions that are pertinent to the proposals being reviewed are privileged communications to be shared only with reviewers and NIH staff who are directly involved in the review. Reviewers must not solicit opinions or reviews on particular proposals or parts thereof from anyone who is not officially on the review panel. However, reviewers may suggest scientists from whom the Scientific Review Officer (SRO) may subsequently obtain advice regarding this review. Reviewers must leave all review materials with the SRO or agree to destroy all the review-related material themselves at the conclusion of the review meeting.

Under no circumstances should the reviewers inform offerors, their organizations, or anyone else of recommendations or discussions from the review proceedings. Offerors may make unwise decisions or actions on the basis of premature or erroneous information. Such disclosure also represents an unfair intrusion into the privileged nature of the review and invades the privacy of fellow reviewers who are serving on review committees. A breach of confidentiality could deter qualified reviewers from serving on future review committees and inhibit those who do serve from engaging in a free and full discussion of recommendations.

There must be no communications between the reviewers and offerors. Any requests or correspondence from offerors must be directed to the SRO who will direct them to the Contracting Officer.
AVOIDING CONFLICTS OF INTEREST

Before a reviewer is placed on a Technical Evaluation Panel (TEP), the Scientific Review Officer (SRO) discusses the conflict of interest rules with the potential reviewer. Then, the reviewer completes a certification of Conflict of Interest and Confidentiality after examining a list of investigators and institutions associated with the proposals to be reviewed.

For the review of contract proposals, no reviewer with a conflict or an appearance of a conflict may be present during deliberations unless a waiver has been obtained prior to the meeting by the SRO. If such a waiver has been obtained, then a reviewer with an appearance of a conflict of interest may be allowed to be part of the deliberations, but a reviewer with a real conflict will be required to leave the room. In either case, at the beginning of the review meeting, the SRO will orient the panel members by explaining the NIH conflict-of-interest policy and declaring whether the NIH’s Office of Extramural Research has granted any waivers.

Reviewers must immediately notify the SRO of any new potential conflicts of interest should any develop prior to the meeting, either through reading the proposals or other unforeseen circumstances.

At the end of the review meeting, the SRO will obtain written certification from all reviewers that they have not, in fact, participated in the review of any proposals in which their presence would have constituted a real or apparent conflict of interest and that the confidentiality of actions will be maintained.
PROTECTING THE SECURITY OF CONTRACT PROPOSALS

Contract proposals, critiques, assignment lists, and scores are considered highly confidential information. By following the best practices below, you can protect the information entrusted to your care.

THINK ELECTRONIC SECURITY

- Download proposals to a secure computer and not to unsecured network drives or servers. Make sure these files are never exposed to the Internet. Proposals should never be posted on a peer reviewer’s (or institution’s) website because the files can be “discovered” by internet search engines.
- Have a strong password for computer access and never share it.
- If you leave your office, secure all the documents (paper and electronic) associated with the review. You should also lock your computer.
- Refrain from discussing proposal-related information in an email—it is not secure, and it can be intercepted. If you must send information related to a proposal, carefully review the message content and double check the accuracy of the recipients before sending the message.
- Most operating systems have the ability to natively run an encrypted file system (Windows = EFS and Mac OSX = File Vault). Consider running this type of system—especially for laptops, which can be stolen or misplaced.

THINK PHYSICAL SECURITY

- If the proposal and/or related data are in hard copy format or reside on portable media (e.g. on a CD, flash drive, or laptop), treat it as though it were cash:
  - Do not leave it unattended or in an unlocked room.
  - Exercise caution when traveling with portable media, i.e. take extra precautions to avoid the possibility of loss or theft (especially flash drives, which are small and can easily be misplaced).
- If you lose any material related to the review, immediately notify your Scientific Review Officer (SRO).
- Refrain from discussing review information in public—you never know who is listening.

WHEN THE REVIEW MEETING IS OVER—DESTROY ALL REVIEW-RELATED MATERIALS

- Shred hard copies—preferably using a cross-cut shredder.
- Delete electronic files securely:
  - At a minimum, delete the files and then empty the recycle bin on your computer.
Optimally, use a secure method, e.g. an electronic “shredder” program that performs a permanent delete and overwrite.

CDs can be broken or crushed, incinerated, shredded, melted, or returned to the SRO.

FOR MORE INFORMATION:

“Misconduct” or “misconduct in science” is defined in the Code of Federal Regulations (42 CFR 50.102) as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in the interpretation or judgment of data.

Reviewers who suspect misconduct must contact the Scientific Review Officer (SRO) immediately to ensure that the concerns can be addressed prior to the review. Do not share this information with anyone except the SRO. It is critical that a reviewer does not wait until the review meeting or until the review meeting is over to bring this to the SRO’s attention, as this could jeopardize the entire review.

It is important that reviewers appreciate the seriousness of such allegations and the potential harm that may result, particularly if confidentiality is not strictly maintained. In no instance shall a reviewer communicate these concerns to anyone but the SRO. Any concerns of misconduct will subsequently be forwarded by the SRO through the management and the agency-level Misconduct Policy Officer to the DHHS Office of Research Integrity (ORI) (http://ori.hhs.gov/) for resolution.
GLOSSARY AND ACRONYMS

GLOSSARY

Acceptable Proposal: A proposal that contains no major deficiencies, is complete in itself, and for which no additional information is required for the reviewers to determine that the offeror can fulfill the minimum requirements of the RFP; although, additional information may be required for clarification.

Broad Agency Announcement (BAA): A general contract solicitation that identifies (an) area(s) of scientific interest or aims which the government (e.g. NIH) wants to advance. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government. It differs from an RFP in that there is no defined Statement of Work (SOW), but there is a deliverable defined that specifies a service or product the Government wishes to acquire. Proposals in response to a BAA are not evaluated against a specific, common SOW, as for RFPs. Instead, the BAA provides research and technical objectives (RTOs) describing the areas in which the government is interested, and the offeror develops and defines their own SOW. BAAs do include standard TEC by which to evaluate the proposal.

Competitive Range: For a RFP, a range of offerors whose proposals are found acceptable by the Technical Evaluation Panel (TEP) and who have a real possibility of improving their proposals to the point where they might receive an award.

Deficiency: A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level, as defined by Federal Acquisition Regulations Subpart 15.001 Definitions.

Final Proposal Revision (FPR): This document is in response to the negotiation letter sent to all offerors in the competitive range who responded to a specific solicitation. The negotiation letter contains the questions to offerors developed by the Office of Acquisitions, in part, from the questions provided by reviewers on their TESS documents.

Mandatory Qualification Criterion/ Criteria: The RFP/BAA may include Mandatory Qualification Criteria that define conditions that the offeror must meet in order for the proposal to be considered for an award.

Offeror: The institution/organization that sponsors the proposal. Terminology used in the contracting process that can be equated to the “applicant” institution/organization that sponsors a grant application.

Order of Merit: For a BAA, the group of offerors whose proposals are found acceptable by the TEP and who have a real possibility of improving their proposals to the point that they might receive an award.
Proposal: The document submitted by an offeror in response to an RFP/BAA. A proposal can be equated to the application submitted to a grant or cooperative agreement solicitation.

Request for Proposals (RFP): A solicitation used to obtain responses (proposals) from potential contractors (offerors) in response to a governmental (e.g. NIH) need for a specific product or service. The RFP provides a detailed Statement of Work (SOW) that defines what goods or services the Government wants to purchase.

Research and Technical Objectives (RTO): Contained within a Broad Agency Announcement (BAA), the RTO describes the scientific and technical objectives that the Government seeks to achieve from the offeror.

Scientific Review Group: A committee/panel of technical and scientific experts recruited by the NIH to perform the initial peer review of contract proposals submitted to a contract solicitation (RFP/BAA).

Significant Weakness: A flaw in the proposal that appreciably increases the risk of unsuccessful contract performance, as defined by Federal Acquisition Regulations Subpart 15.001 Definitions.

Source Selection: A process that occurs following the scientific/technical review of proposals and receipt of Final Proposal Revisions (FPR). A Source Selection Group or Committee is assembled and is responsible for reviewing the FPRs and determining to what degree they provide new information in response to the questions to offerors posed in the negotiation letter. Based on these determinations, the Source Selection Group/Committee has the opportunity to adjust the original proposal scores for each of the offerors in the competitive range. The scores may be adjusted up or down. These adjusted scores then become the basis for the decision to award a contract. Generally, the Source Selection Group/Committee includes: Chief, Contracts Management Branch; Director, Division of Extramural Activities; and the Project Officer(s). It may also include two or more representatives of the original TEP.

Statement of Work (SOW): Part of the RFP, the SOW describes in detail the scope of the work to be completed by the contractor.

Technical Evaluation Criteria/ Criterion (TEC): Contained in the RFP/BAA, the Technical Evaluation Criteria are the only criteria that can be used in the evaluation of each proposal received in response to that RFP.

Technical Evaluation Score Sheet (TESS): The document, provided in your meeting material (one for each proposal), on which you will record your preliminary and final critique on how a proposal responds to each of the Technical Evaluation Criteria (TEC)—both by your comments recorded on the TESS and the numerical score you provide for each of the TEC. The TESS is confidential, becomes part of the official review file, and takes precedence over any other written comments you may have prepared.

Unacceptable Proposal: A proposal that contains deficiencies which are so substantive as to preclude any possibility of it being upgraded to a level that meets the minimum requirements of
the RFP, except through major revisions and additions that would be tantamount to the submission of a new proposal.

**Weakness:** A flaw in the proposal that increases the risk of unsuccessful contract performance, as defined by Federal Acquisition Regulations Subpart 15.001 Definitions.

**ACRONYMS**

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>BAA</td>
<td>Broad Agency Announcement</td>
</tr>
<tr>
<td>CMO</td>
<td>Committee Management Office</td>
</tr>
<tr>
<td>CO</td>
<td>Contracting Officer</td>
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<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>COTR</td>
<td>Contracting Officer Technical Representative</td>
</tr>
<tr>
<td>CR</td>
<td>Competitive Range</td>
</tr>
<tr>
<td>CS</td>
<td>Contract Specialist</td>
</tr>
<tr>
<td>eRSS</td>
<td>Electronic Reviewer Support Site</td>
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<tr>
<td>eRA</td>
<td>Electronic Research Administration</td>
</tr>
<tr>
<td>ESA</td>
<td>Extramural Staff Assistant</td>
</tr>
<tr>
<td>F&amp;A</td>
<td>Facilities and Administrative costs</td>
</tr>
<tr>
<td>FACA</td>
<td>Federal Advisory Committee Act</td>
</tr>
<tr>
<td>FAR</td>
<td>Federal Acquisition Regulations</td>
</tr>
<tr>
<td>FOA</td>
<td>Funding Opportunity Announcement</td>
</tr>
<tr>
<td>FOC</td>
<td>Full and Open Competition</td>
</tr>
<tr>
<td>GWAS</td>
<td>Genome-Wide Association Studies</td>
</tr>
<tr>
<td>HHS</td>
<td>Department of Health and Human Services</td>
</tr>
<tr>
<td>HHSAR</td>
<td>Department of Health and Human Services Acquisition Regulations</td>
</tr>
<tr>
<td>IAR</td>
<td>Internet Assisted Review</td>
</tr>
<tr>
<td>IDIQ</td>
<td>Indefinite Delivery/Indefinite Quantity</td>
</tr>
<tr>
<td>IRG</td>
<td>Integrated Review Group</td>
</tr>
<tr>
<td>JOFOC</td>
<td>Justification for Other than Full and Open Competition</td>
</tr>
<tr>
<td>MQC</td>
<td>Mandatory Qualification Criteria</td>
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<td>OA</td>
<td>Office of Acquisitions</td>
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<tr>
<td>OFOC</td>
<td>Other than Full and Open Competition</td>
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<tr>
<td>PO</td>
<td>Project Officer</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>RFP</td>
<td>Request for Proposals</td>
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<tr>
<td>SEP</td>
<td>Special Emphasis Panel</td>
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<tr>
<td>SOW</td>
<td>Statement of Work</td>
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<tr>
<td>SPRS</td>
<td>Secure Payee Reimbursement System</td>
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<td>SRO</td>
<td>Scientific Review Officer</td>
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<td>SSG</td>
<td>Source Selection Group</td>
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<td>TEC</td>
<td>Technical Evaluation Criteria/Criterion</td>
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<td>TEP</td>
<td>Technical Evaluation Panel</td>
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<tr>
<td>TER</td>
<td>Technical Evaluation Report</td>
</tr>
<tr>
<td>TESS</td>
<td>Technical Evaluation Score Sheet(s)</td>
</tr>
</tbody>
</table>
REGISTRATION FOR RECEIVING HONORARIUM AND REIMBURSEMENT

The NIH has implemented a simplified and secure registration system - the Secure Payee Registration System (SPRS) - for reviewers to provide the information required to receive honoraria and reimbursement for their valued participation in NIH peer review meetings.

**Note:** No review materials will be made available through eRA Commons/IAR and reviewers cannot use eRA Commons/IAR for Technical Evaluation Score Sheet (TESS) submission. eRA Commons/IAR will only be used for reimbursement purposes.

If a reviewer is not registered in SPRS, the NIH will be unable to disburse honoraria and reimbursable expenses.

Reviewers who are already registered in SPRS are urged to log into Commons to update/verify residential address and bank information.

The NIH Office of Financial Management (OFM) has control over this secure payment site. *Only the reviewer can access the page containing their information using their eRA Commons username and password.*

**To complete the registration process, reviewers will need the following:**

- A NIH eRA Commons account username and password
- A U.S. financial institution account and routing number
- A Social Security Number (for domestic reviewers only)
- **Note:** For help with an eRA Commons account username, reviewers should contact their SRO.
- **Note:** Reviewers should click on “Forgot Password?” for help with lost or forgotten passwords.
- **Note:** Requirements for Foreign Reviewers are described below.

**HOW TO REGISTER**

**STEP 1: UPDATE RESIDENTIAL ADDRESS**

- Log into eRA Commons at [https://commons.era.nih.gov/commons/](https://commons.era.nih.gov/commons/).

Once logged in, reviewers will see the page shown below. If this page is not visible, reviewers may need to get to it by clicking the “Personal Profile” link, followed by clicking on
Enter and make sure your residential address is correct and all boxes with an asterisk (*) are filled in. Click on the Submit button.

- **Foreign reviewers:** Please do not use the ZIP Code box for the city code or postal code; put it on the line with the city. If the foreign city or postal code is entered in the ZIP Code box, the system will reject the address.
- For foreign reviewers, this is the address where the check will be sent.
- For US reviewers, this is the address where tax documentation from NIH will be sent.

- Click the Submit button at the bottom of the screen.
- Once you have submitted your residential address, click on the words Secure Payee Registration System.

**STEP 2: UPDATE SECURE PAYEE REGISTRATION SYSTEM**

- The Secure Payee Registration System screen below will appear.
In box 1, enter your US Social Security Number (no dashes, just nine digits). If a reviewer does not have a Social Security Number (i.e., a foreign reviewer), he or she should check the box that states “I do not have a US Social Security Number.”

If the reviewer has a US bank account, they should enter their account number, routing number and account type (even if they do not live in the US) and they will be reimbursed via direct deposit.

  - When entering bank account information in SPRS, reviewers are cautioned to enter a routing number for direct deposits and not a routing number for wire transfers. Reviewers may want to verify this information with their financial institution, especially if their account is with Bank of America or a Credit Union.

If a reviewer’s permanent residence is outside the US and he or she does not have a US bank account, they should click the “My permanent residence is outside the US” button and the registration will be reviewed by the NIH Office of Financial Management. Reviewers may be contacted directly for more information if needed. If approved, a check will be mailed.

Reviewers need to remember to click the “Submit” button to finalize the registration.

Click on “Log Out” next to the reviewer name near the right hand top of the screen.

For questions, please click on the ? icon for a list of Frequently Asked Questions.
SPRS registration is now complete! Once approved, the honorarium and reimbursement will be sent electronically via direct deposit for reviewers with a US bank account or by check for reviewers living outside the US.
HONORARIUM \ AND REIMBURSEMENTS FOR NON-FEDERAL REVIEWERS

This information pertains to non-federal reviewers only. Federal employees do not receive an honorarium for participation in any NIAID peer-review related activity.

HONORARIUM

Review Meeting Honorarium is paid to non-federal reviewers at the rate of $200 per day for each day of participation in a scheduled meeting. If the reviewer takes part in more than one meeting on a specific day, the reviewer can receive only $200 in honorarium. Honorarium is not paid for a day that is solely for travel.

REIMBURSEMENT

Transportation, Meals and Incidental Expenses

For a face-to-face review, participants are paid a flat rate for each meeting which is determined by the length of the meeting; see the chart below. The rates include honorarium (hon), ground transportation (trans = $235 non-local or $75 local), and meals and incidental expenses (M&I = $80 per day non-local or $45 per day local). If the reviewer lives outside the “local” Washington, DC area and drives to the meeting instead of flying, the reviewer must let the Scientific Review Officer (SRO) and the Committee Management Officer know (see below for contact information) so that the reimbursement for mileage can be calculated. Reviewers participating via a teleconference system do not receive any reimbursement for transportation, meals, or incidental expenses.

<table>
<thead>
<tr>
<th>Type of Reviewer</th>
<th>1 day meeting Total (hon+meals+misc)</th>
<th>2 day meeting Total (hon+meals+misc)</th>
<th>3 day meeting Total (hon+meals+misc)</th>
<th>4 day meeting Total (hon+meals+misc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-local (&gt; 50 miles) plane, train or car</td>
<td>$515 (200+80+235)</td>
<td>$795 (400+160+235)</td>
<td>$1075 (600+240+235)</td>
<td>$1355 (800+320+235)</td>
</tr>
<tr>
<td>Local (&lt; 50 miles) commutes</td>
<td>$345 (200+45+100)</td>
<td>$690 (400+90+200)</td>
<td>$1035 (600+135+300)</td>
<td>$1380 (800+180+400)</td>
</tr>
<tr>
<td>Local (&lt; 50 miles) stays at hotel</td>
<td>$380 (200+100+80)</td>
<td>$700 (400+140+160)</td>
<td>$1020 (600+180+240)</td>
<td>$1340 (800+220+320)</td>
</tr>
</tbody>
</table>

(hon = honorarium, trans = ground transportation, M&I = meals and incidental expenses)
Method of payment
Payment for United States residents will be by direct deposit. Foreign reviewers will receive payment by check. Foreign reviewers who have a US bank account may have their payment made to that account by direct deposit. Please see the “Registration for Reimbursement” chapter for more information.

Income Tax Information
For a reviewer (who is considered to be a consultant to the US government) with a US social security number, honoraria, per diem (M&I), and ground transportation reimbursements exceeding $600 within a given year will be reported by the Office of Financial Management (OFM), NIH, to the Internal Revenue Service. If a reviewer purchases his/her own airline ticket and the NIH reimburses the expense, or if the NIH pays out any additional costs to a reviewer (excessive mileage, etc.), these items will also be reported if the total reimbursement exceeds the $600 in a given year. Reviewers meeting these criteria will receive a 1099 form for reporting/including these payments/reimbursements on their income tax returns. Reviewers who receive less than $600 in honorarium, per diem (M&I), and ground transportation reimbursements, etc. in a given year will NOT receive a 1099 form. For more information and/or questions regarding this topic, please call the OFM at 301-496-1418.

For questions concerning the reimbursement process, please contact either the SRO or the Committee Management Officer at committeemanagement@niaid.nih.gov.
TRAVEL INFORMATION FOR NON-FEDERAL REVIEWERS

World Travel Service (WTS) directly bills ticket costs to NIH. WTS is authorized to make roundtrip reservations at the lowest restricted fare. Any variations from the roundtrip itinerary must be cleared through the Institute’s Committee Management Office (WTS will contact them). Travel reservations should be made as soon as possible for maximum availability and minimal cost. Additional fees are charged every time reservations are changed, so flights should be scheduled with care.

Making a reservation will require the meeting code: the code should look something like this: ZAI1-XXX-X-X. The code will be provided by the Scientific Review Officer (SRO).

CONTACT INFORMATION: WORLD TRAVEL SERVICE

- **WTS website (links to making reservations):** [www.nihreviewers.com](http://www.nihreviewers.com)
- **To cancel reservations:** cancel@worldtravelservice.com
- **Toll free number:** 1-800-638-8500
- **Local number:** 301-816-8991
- **After Hours number:** 1-877-853-3648, Use Access Code: WAS 1S2115
- **Corporate ID:** “NIH”

METHODS TO SET UP TRAVEL RESERVATIONS

Reservations can be made one of two ways:

**NOTE:** Online booking Option 1A is the most cost-effective travel reservations method. WTS charges $20 more for using any other option.

1. **Online Booking:** There are two options for making online reservations; both begin with going to the WTS NIH travel website, [www.nihreviewers.com](http://www.nihreviewers.com), to get started:
   - **Option 1A: Online Self-Booking**
     Once at the WTS NIH Reviewer Resource site, click on the “Book Travel Online” link. This method requires the set-up of a WTS account. This account will remain active after the meeting, so this is a good option for individuals who regularly participate in NIH peer review. This option allows reviewers to directly book air/train reservations themselves. WTS will provide the tickets once reviewers have made travel plans.
   - **Option 1B: Online WTS-assisted Booking**
     Once at the WTS NIH Reviewer Resource site, click on the “Submit Request Online” link. Reviewers need to fill in their information and travel preferences and then click on the “Submit FastRes Form.” A WTS representative will contact reviewers with
several travel options based on the information provided on the form. Reviewers then choose the travel itinerary that best fits their needs.

2. **Direct Call:** Reviewers may also call and talk directly to a WTS travel representative to set up travel arrangements (see number above).

### Response Time from WTS
- Response to reviewers’ inquiries will be within one business day.
- Arrangements by email, fax, or online booking will be processed within one business day; and
- Technical problems with email connections or fax will be reported within four business hours.

### Airline/Train Reservations
- Non-refundable tickets are issued for NIH Peer Review Meetings.
- Reviewers will be informed of the most cost- and time-efficient routing and scheduling options based on the reviewer’s preferred itinerary.
- An alternate departure/return location may be approved by the Institute’s Committee Management Officer. Reviewers will be responsible for fees that result from changes that they make to their alternate departure/return flights after their tickets have been issued.
- The cost of airfare to return to the reviewer’s home base from the alternate location is to be paid by the reviewer.

### REQUEST TO CHANGE TICKETS
Non-refundable tickets are capacity-controlled by each airline. The number of allocated seats varies for each airline. Therefore, any change to the original reservations, either before departure or involving the return flight, will result in a change penalty fee of $150 per change and also possible fare increases. Therefore, the following guidelines will apply:

- Requests to change a non-refundable ticket will be processed by WTS **without prior NIH approval for**:
  1. **Unusual circumstances** (e.g. inclement weather conditions, a personal emergency, or a change in the peer review meeting from a two-day meeting to a one-day meeting after the ticket has been issued); Any additional costs that may be incurred by the reviewer as a result of these unusual circumstances will be reimbursed; and
  2. **One change per ticket issued will be allowed if the change in fare does not exceed $500.00.**
- If the change is **greater than $500**, or the departing flight is less than three hours from the original scheduled departing time, or the request is for multiple changes, the request to change a non-refundable ticket **will require prior approval by NIH**. If the request is **not approved** by NIH, the reviewer is **liable for** additional costs and **will not** be reimbursed by NIH.
Ticket Delivery
- Electronic tickets will be the default and a confirmation number will be sent via phone, email, or fax.
- If absolutely necessary, a reviewer may request tickets to be sent via first-class mail. If the trip is scheduled to occur within ten days and a hard copy ticket is requested, the ticket will be sent via Federal Express.
- The airlines listed at http://www.worldtravelservice.com/boarding_pass.html will allow check-in and printing of the boarding pass before going to the airport. Simply click on the name of the airline to be taken to that airline's appropriate site. The instructions/restrictions on the airline site should be read carefully. The instructions below are a general guide; airline policies change, and this information should be verified on the airline's website.

Lost Tickets
- WTS will issue a second ticket only if authorized by an authorized NIAID ordering official.

Travel Insurance
- There is a minimum of $200,000 in travel insurance provided with each issued ticket at no additional cost.

TRAVEL BY CAR
- Reviewers may travel to the review meeting by car. Reviewers participating in a face-to-face meeting will receive reimbursement for ground transportation of $75 for local reviewers (if the meeting site is within 50 miles of their home) or $235 for non-local reviewers. These are flat rates. If the cost for non-local reviewers driving—tolls plus $0.56 per mile round trip—adds up to more than the previously stated dollar amount of $235, reviewers will be reimbursed for the overage.
- Reviewers should alert their SRO if they choose this option, so that the SRO knows that WTS will not send the travel arrangement information.

If reviewers make reservations and pay for tickets themselves, they must contact the Committee Management Officer at committeemanagement@niaid.nih.gov. Reviewers will need to provide a receipt for the airfare no later than two business days after the review meeting. The following form will need to be completed and submitted to the Office of Committee Management.
TRAVEL AND REIMBURSEMENT INSTRUCTIONS FOR FEDERAL REVIEWERS

Federal government employees are required to travel under the Federal Travel Regulations that govern all regular Federal employees. Travel to and from the review meeting is authorized via issuance of a Standard Form HHS-1 (government travel order) that is prepared in advance of each meeting by NIH staff.

Reimbursement may be made for the following travel expenses incurred while on official NIH business (please save all receipts):

TRANSPORTATION

Air/Train
Initially, an NIH staff member will contact the reviewer and serve as the Federal reviewer’s travel planner. All air and train travel will be set up using the NIH travel system GovTrip. If the reviewer is not in the GovTrip system, a staff member will provide the reviewer an ACH form and the Non-NIH Affiliated Traveler Addition form. Once these forms are filled out and sent back, the reviewer’s information will be entered into the system and a staff member will contact and help with the reviewer to book their flight or train reservations. Then, Omega World Travel will issue the reviewer a round-trip government contract airfare/train ticket to be used for traveling directly to and from the review meeting.

If the reviewer needs to alter travel plans at any point after the initial plans are made, the reviewer must contact Omega World Travel. Omega staff can be reached by phone at 1-800-419-2312. They can also be contacted by fax (1-866-657-0070) and email nihmd@owt.net. For after-hours emergencies, reviewers should call 1-866-651-0076.

Automobile
Reimbursement will be made at the rate of 56 cents per mile. This rate is subject to change by GSA. Tolls and parking fees are also reimbursable. Reviewers may be reimbursed for the round-trip mileage to the airport if someone else has driven them or for the parking fee plus round trip mileage if the reviewer is the driver and parks at the airport.

OTHER REIMBURSABLE EXPENSES

Limousine and Taxi Fares
Trips to and from airports and review meetings are reimbursable. Rental cars are not authorized.

Telephone Calls
Reviewers are authorized up to $5 per day reimbursement for telephone calls to their family. Special Government Employees (SGE) in extended travel of two or more days can batch their allowance for telephone reimbursement. In lieu of making one call per day not to exceed $5, an SGE can batch two days together and make one call amounting to $10 or batch three days together and make one call amount to $15.
Taxes
State and local taxes on hotel rooms are reimbursable.

Per Diem/ Lodging Reimbursement
The current per diem rate for the metropolitan Washington, DC area varies by time of year.

Lodging
The current rate of reimbursement for overnight lodging/hotel expense, not including taxes, in metropolitan Washington, D.C. area for FY2014 are October - $219, November through February - $184, March through June - $224, July and August - $167, and September - $219. These rates may change at any time.

Meals and Incidental Expense (M&IE)
The Washington DC rate is currently $71.00 per day, $53.25 for ¾ day reimbursement on travel days.

Travel without Lodging:
If an SGE is in travel status from 12 to 24 hours, travel is completed within this timeframe, and no lodging is required, then the per diem allowance will be ¾ of the applicable M&IE allowance for the temporary duty assignment location.

Travel with Lodging:
If lodging is required, the per diem allowance shall include the applicable maximum lodging allowance for the temporary duty assignment location (unless the hotel charges less) plus ¾ of the M&IE allowance.

EXAMPLES:
1. SGE travels to metropolitan DC area on May 28, attends a meeting on May 29, and returns home on May 29. This individual will receive the following reimbursement:

   May 28: ¾ M&IE ($53.25) plus lodging
   May 29: ¾ M&IE ($53.25)

2. SGE travels to metropolitan DC area on May 28, attends a meeting on May 29 and 30, and returns home on May 30. This individual will receive the following reimbursement:

   May 28: ¾ M&IE ($53.25) plus lodging
   May 29: full M&IE ($71.00) plus lodging
   May 30: ¾ M&IE ($53.25) -- day of meeting and return home

REQUIRED RECEIPTS
- airline tickets
- hotel receipts
- receipts for taxis charging $75 or more
- express mailing or fax charges (reimbursable up to $25)

HONORARIUM
Honorarium is not paid to federal employees.
**MISCELLANEOUS**
Dual compensation must not be claimed. When service is provided for another sponsor during the same trip, charges should be prorated between sponsors.

**PAYMENT OF CLAIMS**
Every effort is made to audit and prepare travel vouchers in a timely manner. Questions regarding reimbursement should be directed to SRP at 301-496-2550. Vouchers are processed more quickly when all required receipts are submitted as requested.
HOTEL RESERVATIONS

Hotel reservations for reviewers requiring a hotel room are made by NIH staff. The reviewers will receive information from them regarding the reservation. **Please promptly respond to any queries from the NIH staff about this process.** If a reviewer needs to stay additional nights either before or after the meeting, NIH staff will be able to take care of those reservations.

**Non-Federal Reviewers**

Lodging costs for the nights that the reviewer is staying for NIH business will be billed directly to the NIH. The reviewer will be responsible for any incidental costs incurred during the stay (room service, movies, long-distance calls, etc.).

**Federal Reviewers**

Lodging costs for the nights that the reviewer is staying for NIH business will be billed to the reviewer, who will need to pay at checkout. The hotel receipt(s) should be saved, as the reviewer will be reimbursed for cost of the hotel room. The reviewer will be responsible for any incidental costs incurred during the stay (room service, movies, long-distance calls, etc.).

**Extended Stay**

Extra nights that are not for NIH business will be billed to the reviewer, who will need to pay at checkout. In this case, the reviewer should check with the Scientific Review Officer (SRO) to determine whether they can receive the government rate for the extra night(s).
PRE-MEETING PREPARATIONS

A Scientific Review Officer will provide pertinent review materials for evaluating the proposals. These include the:

- Proposals
- Technical Evaluation Score Sheet(s) (TESS) forms on which the critiques will be written
- Copy of the Request for Proposals (RFP) or Broad Agency Announcement (BAA)
- Proposal scoring scale
- Review assignment list
- Reviewer Manual

To prepare for the review meeting, reviewers should:

- Complete the pre-review process on eRSS.
- Become familiar with the proposals, materials, and the RFP or BAA requirements.
- Critique the assigned proposals (see assignment list) on the TESS forms provided.
- For primary assignments, reviewers should prepare a brief oral description (maximum of two to three minutes) of the overall proposal used for orienting the committee prior to the evaluation. This should be descriptive (non-evaluative) only and should not comment on the offeror’s qualifications, the quality of the facilities, or the work/science proposed.

Some general considerations:

- Several individuals are assigned as reviewers on each proposal. Each assigned reviewer will prepare written TESS for use in discussion during the review meeting and for anonymous inclusion in the final review documentation, the Technical Evaluation Report (TER).

- Reviewers also should be familiar with the content of the proposals to which they are not specifically assigned. This will prepare them to participate in the discussion at the meeting. Each reviewer will be asked to score the proposal and complete a TESS at the meeting whether or not they have been assigned to prepare a written critique prior to the meeting.

- While an individual reviewer may not have the necessary expertise to evaluate all aspects of each proposal, the combined efforts of all assigned reviewers will address all aspects. Thus, reviewers should evaluate the scientific merit of each assigned proposal from the perspective of their own expertise and experience.

- Each proposal must be reviewed in strict accordance with the Technical Evaluation Criteria/Criterion (TEC) and any additional criteria specified in the RFP/BAA. In addition, special review issues are evaluated that may affect the overall score for a proposal if they are specifically addressed in the TEC. These include human subject protection and representation, vertebrate animal welfare and biohazard and select agent handling. If these issues are not addressed in the TEC, they do not affect the score of the proposal and will be voted Acceptable/Unacceptable after scoring is complete. The budget is assessed, as are select agents and resource sharing plans (data, model organisms, and genome-wide association studies), but these do not contribute to the score or the acceptability of the proposal.
• Offerors may refer to the URLs of their co-authored, freely available publications, patents and/or NIH policy. However, per NIH Guide Notice OD-00-004, all proposals for NIH funding are to be self-contained within specified page limitations. Therefore, unless otherwise specified in an NIH solicitation, offerors should not use other URLs to provide information that is necessary to the review, and reviewers should not view websites that are referenced in a particular proposal. Reviewers are cautioned that their anonymity may be compromised when they directly access such a website.
ACCESSING YOUR REVIEW ASSIGNMENTS IN REVIEWER SUPPORT SITE (RSS)

- Reviewer assignments will be electronically available under the eRSS website *Meeting Documents* Tab:
  - You will need Adobe Reader and the FileOpen plug-in; an IT person with administrative rights may be needed to install FileOpen on your computer
  - If the SRO makes an Assignment List available, reviewers may access it under the Meeting Documents tab in eRSS.

- To download meeting documents individually *(after downloading Adobe Reader and the File Open plug-in)*
  - Click the *document icon* next to the document name.
  - Save the document to your computer.

- Reviewers should review assignments immediately and call the SRO at once for any questions, concerns, or additional conflict(s) not previously disclosed.

- Note: The SRO assigns reviewers with complementary expertise; thus the collective expertise of the panel will allow for a full assessment of the scientific and technical merits of the proposal.
WRITING AND SUBMITTING REVIEWER CRITIQUES

Official reviewers will be asked to evaluate certain proposals and to look over others without providing a written evaluation prior to the review meeting. If reviewers are required to provide a written evaluation prior to the meeting, the word **Required** will appear after the Fill Form link for a proposal. If reviewers are NOT required to provide a written evaluation PRIOR to the meeting, the word **Optional** will appear after the Fill Form link.

Reviewers who are marked “Required” (assigned) should conduct a full technical and scientific review. Federal contracting law dictates that every reviewer should review and score every proposal; however, for large reviews this is impractical. **Reviewers who are marked as “Optional”** will complete the technical evaluation score sheet form with strengths and weaknesses for all proposals AT the review meeting.

WRITING THE CRITIQUE

- Write a critique using the proposal-specific Technical Evaluation Score Sheet (TESS) form for **every** proposal that will be reviewed at the meeting. If a reviewer is assigned to a proposal, that reviewer will complete the eRSS web Technical Evaluation Score Sheet (TESS) form or upload a completed Word TESS form to eRSS, determine the proposal’s Acceptability or Unacceptability, sign the web TESS by typing in their name in the Reviewer’s Signature box and pressing the ‘Submit to SRO’ button to submit the TESS to the SRO. If a reviewer is not assigned to a proposal, that reviewer will fill in the TESS for that proposal at the meeting while listening to/participating in the discussion of the review panel.

- Evaluate each proposal individually against the Technical Review Criteria/Criterion (TEC) provided in the Funding Opportunity Announcement (FOA).

- Be consistent with the scoring calibration across all proposals being reviewed and hold all proposals to the same standards, but do not compare them to each other.

- Write in a bulleted format using full sentences.

- Fully explain what the perceived strengths or weaknesses are, what element (i.e., aim, experiment or strategy) they refer to, and why they are strengths and weaknesses, e.g., a sentence or two sets the context, three or four sentences describe the strength or weakness, and a few sentences justify why it is a strength or weakness. Thus, one bullet could be ten lines or more.

- Provide points under each TEC prior to the meeting for proposals to which you are assigned.

- The scores assigned to a particular TEC must be reflected accurately in the written comments. If a reviewer does not give the maximum points, there must be at least one weakness listed. Likewise, if a reviewer does not give the minimum (0) points, there should be at least one strength.
• List strengths and weaknesses for the subcriteria in the order they are listed in the TEC and RFP/BAA.
• Subcriteria (or subcriteria of the subcriteria) within an individual TEC are weighted equally when determining the overall TEC score unless the RFP/BAA states that the subcriteria are listed in descending order of importance.
• If there are individually scored subcriteria, strengths and weaknesses must be noted for each subcriterion.
• If there are no weaknesses to list for a TEC, state “No significant weaknesses are noted.” The preliminary score would be the maximum points allowed.
• No section or subsection listed in the TESS is to be assigned more than the maximum number of points allowed for that section. **NOTE:** No “extra credit” should be given for proposed work that is not part of or not allowed by the statement of work (SOW) or research and technical objectives (RTO) (please see Glossary and Acronyms chapter for more information).
• Do not deduct points for the same weaknesses under more than one TEC. Similarly, do not give credit for the same strength under more than one TEC.
• Only information provided in the proposal should guide the evaluation. The assessment should not assume that the offeror has experience, expertise, or access to a particular facility. It must be stated in the proposal to receive credit.
• Do not repeat descriptive information from the proposal unless it is needed to describe a strength or weakness.
• Do not include any information on the TESS that might be personally identifying (e.g., a reviewer attributing his or her own work).

**TO EVALUATE A PROPOSAL**

When writing a TESS, reviewers can choose to fill in their TESSs directly in eRSS (Option 1) or export the web TESS as a Word document to save on their computers or laptops to be completed and uploaded later to eRSS (Option 2).

**Option 1: Using a Web TESS Form**

Log into eRSS at [http://erss.nih.gov](http://erss.nih.gov)

*From the “MyMeetings” Screen*

1. Select **Applications/ Proposals** Tab.
2. Click on the **Fill Form** link under the Evaluation Form column for a proposal.
   a. The web TESS opens for that proposal.
   b. Complete the evaluation using web TESS form provided.
3. Enter strengths, weaknesses, and a score for each of the technical evaluation criteria on the TESS.
4. Choose **Acceptable** or **Unacceptable** for technical acceptability. For **Acceptable** proposals, complete the Special Issues Section. Write comments for any item that is determined to be **Unacceptable** in the Comments box provided.
5. Type your name in the **Reviewer’s Signature** field.
6. Click **Submit to SRO** to officially submit the TESS.

**NOTE:** All entries on the web TESS form are auto saved in eRSS; however, if you do intend to save your work and come back to it, it might also be a good idea to save what you have written elsewhere.

Option 2: Exporting a Web TESS Form to a Word TESS Document *(recommended option)*

Reviewers can also export a web TESS form as a Microsoft Word document, complete their evaluation on their computer or laptop and then upload it later to eRSS.

**From the Applications/Proposals Tab**
1. Select the proposal’s **Fill Form** link *(The web TESS Form opens in eRSS).*
2. Click **Export TESS Form** button.
3. File Download Query Appears. Select **Open** *(File Opens in MS Word as read-only).*
4. Select **Enable-Editing** on top of document.
5. **Save the file** to a computer.
6. Complete the evaluation *(then upload the completed document to eRSS).*

**TO UPLOAD A COMPLETED TESS (WORD DOCUMENT) TO eRSS**

**From the Applications/Proposal Tab**
1. Select the proposal’s **Fill Form** link.
2. Select **Import TESS Form** button.
3. Click **Browse**… button.
4. Locate the completed Word TESS form on your computer.
5. Select **Upload file** button.

**TO CREATE A NEW OR EDIT A PREVIOUSLY SUBMITTED TESS FORM AT THE MEETING**

**After logging into eRSS**
1. Select the meeting on your My Meetings page.
2. Select the **Applications/Proposals** tab.
3. Click **Fill Form** link next to the proposal to be edited.
4. Edit any response.
5. Click **Submit to SRO**.

**TO SIGN CONFLICT OF INTEREST (COI) FORMS**

**NOTE:** In the event a reviewer has identified a conflict but is permitted to participate on the review panel, the reviewer must add the name of the offeror for the conflicted proposal on the pre- and post-meeting COI forms in eRSS.
FACE-TO-FACE REVIEW MEETING

- Before the review meeting, reviewers will sign a pre-meeting COI form (available in the pre-review process in eRSS) to confirm no additional COIs were identified during the initial review of assigned contract proposals and submit the document to the SRO by pressing the Confirm button at the end of the pre-review process. Alternatively, the SRO may distribute a paper copy of the pre-meeting COI form for reviewers to complete and submit at the beginning of the review meeting.

- Reviewers will also be asked to electronically sign a post-meeting COI form (available on the Post-Review COI Certification tab in eRSS) at the end of the review meeting to confirm that no additional COIs were identified during the review. Alternatively, the SRO may distribute a paper copy of the post-meeting COI form for reviewers to complete and submit at the end of the review meeting.

TELECONFERENCE REVIEW MEETING

- Before the review meeting, reviewers will sign a pre-meeting COI form (available in the pre-review process in eRSS) to confirm no additional COIs were identified during the initial review of assigned contract proposals and submit the document to the SRO in eRSS.

- Reviewers will also be asked to electronically sign a post-meeting COI form (available on Post-Review COI Certification tab in eRSS) at the end of the review meeting to confirm that no additional COIs were identified during the review meeting. This is submitted to the SRO when the reviewer presses the ‘Save and Continue’ button on the Post-Review Certification tab.
VIEWING CRITIQUES FROM OTHER REVIEWERS

TO REVIEW THE CRITIQUES FROM OTHER REVIEWERS:

Once a reviewer submits his/her Technical Evaluation Score Sheet (TESS; also known as “critique”), access to view critiques from other reviewers is permitted. Reviewers will not be able to see other reviewers’ critiques until they submit their own.

1. Log into eRSS at http://erss.nih.gov/
2. Select the Applications/Proposals tab.
3. Click Fill Form link for any Proposal.
4. Click on an active Export Responses or Export Spec Issues button next to any proposal.

Note: Once the critique is submitted to the SRO via eRSS, reviewers will be able to edit only their own critiques AT the review meeting (or via the SRO after initial critique submission but before the review meeting).
SCORING CONTRACT PROPOSALS

When scoring contract proposals, reviewers score a number of individual Technical Evaluation Criteria/Criterion (TEC). For contract proposals, the overall final score is simply the sum of all of the scores of the individual TEC. Each TEC may have a varying number of points, i.e., some may be worth more than others due to the relative importance of that TEC to the Statement of Work (SOW) in the solicitation. Reviewers should refer to Section M, Technical Evaluation Factors, of the RFP/BAA for specific guidance regarding proposal evaluation.

When scoring a contract proposal, reviewers should keep in mind the following Federal Acquisition Regulations (FAR) definitions of a weakness, significant weakness, and deficiency. The FAR is the primary legal authority used by all federal agencies when acquiring supplies or services with appropriated funds.

**Federal Acquisitions Regulations Subpart 15.001 definitions:**

**Weakness:** A flaw in the proposal that increases the risk of unsuccessful contract performance.

**Significant Weakness:** A flaw in the proposal that appreciably increases the risk of unsuccessful contract performance.

**Deficiency:** A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

**SPECIAL ISSUES**

Unlike the review of grant applications, Special Issues such as Human Subject Protections, Vertebrate Animal Welfare, and Biohazards are evaluated after the proposal is deemed ‘Acceptable’. The various Special Issues (e.g., concerns related to the use of Human Subjects or Vertebrate Animals) do not influence the score of any TEC unless it is identified as a review criterion in the TEC.

**ADDITIONAL GUIDELINES**

- Please use the assigned maximum points when evaluating each TEC.
- Be consistent with the scoring calibration across all proposals being reviewed; hold all proposals to the same standards.
- Reviewers should not compare one proposal to another to help calibrate scores. Evaluate each proposal individually against the TEC provided in the RFP/BAA.
- Comments for a TEC should be based only on the review criteria under that particular TEC.
- The scores assigned to a particular TEC must be reflected accurately in the written comments. If the maximum points are not given, at least one weakness must be given. Likewise, if the minimum points are not given, there should be at least one strength.
• No section or subsection listed in the Technical Evaluation Score Sheet (TESS) is to be assigned more than the maximum number of points allowed for that section. **NOTE:** No “extra credit” or deductions should be given for proposed work that is not part of the Technical and Research Objectives or SOW.

• Reviewers should not deduct twice for the same weakness (i.e., points cannot be taken off for the same weakness in multiple sections). Although multiple weaknesses can arise from one significant weakness, the wording of the weaknesses must reflect the TEC. Thus, if a significant weakness does cause multiple weaknesses and is, for example, “no technical expertise”, under Personnel, it would read “lack of vaccine formulation expertise,” but under Technical Approach it could read “offeror fails to demonstrate a clear understanding of vaccine formulation.”

• List strengths and weaknesses for each individually scored subcriteria (if applicable) in the order they are listed in the TEC and RFP/BAA. Identify major strengths and/or major weaknesses that contribute to the TEC score.

• Subcriterias (or subcriterias of the subcriterias) within an individual TEC are weighted equally when determining the overall TEC score unless the RFP/BAA states the subcriterias are in the descending order of importance.

• Only information included in the proposal can be used during the evaluation process. Reviewers should not consider any information that is not in the proposal when scoring the TEC; this includes a reviewer’s personal knowledge of the offeror(s), named personnel, facilities, technical abilities, etc.

• Non-peer reviewed information or knowledge should not be used in the evaluation of a proposal (e.g., newspaper articles).

• Only links to websites that cite laws/regulations are allowed to be used in the review of proposals. Reviewers should not view any other website referenced in the proposal since this may compromise their identities. The reviewer should notify the SRO of any non-regulatory websites that are included in the proposal.

• The SRO will provide reviewers with a chart to track their individual scores at the review meeting to facilitate calibrating their individual scoring stringency (i.e., evaluating the proposals consistently throughout the meeting).
HUMAN SUBJECTS PROTECTION AND INCLUSION

WHAT REVIEWERS NEED TO EVALUATE

Reviewers of research and development contract proposals are asked to:

1. Determine whether human subjects are involved in the research.
2. If human subjects are involved, determine whether they are adequately protected from research risks.
3. Determine whether the research is a Phase III clinical trial, and if so, determine the adequacy of the Data and Safety Monitoring Board.
4. Evaluate whether or not the gender and minority representation in the sample and the inclusion of children are scientifically acceptable given the aims of the research, and why the inclusion plans for gender, minorities, and children are scientifically acceptable or not. Children are defined as individuals under the age of 18 years, as specified in NOT-OD-16-010: Inclusion of Children in Clinical Research: Change in NIH Definition. Also, for a Phase III clinical trial, determine whether this inclusion plan is adequate to conduct a valid analysis for detecting significant differences among minorities and gender. Determine if a planned enrollment table(s) with the proposed sample distributed on the basis of sex/gender, race, and ethnicity (or a cumulative inclusion enrollment report if working with an existing dataset) is provided.
5. Determine whether the special issue is acceptable or unacceptable.

Note: Evaluation of the human subject issues does not affect the proposal's score or the Acceptable/Unacceptable rating unless human subject issues are specifically defined in the Technical Review Criteria/Criterion (TEC). Normally, they will be addressed administratively. The offeror must ensure that all subcontractors and collaborators (both US and non-US) provide the required information for this special issue, and this information is provided for each performance site listed in the contract proposal.

GUIDANCE FOR MAKING THESE EVALUATIONS

1. Are Human Subjects involved in the research?

A Yes/No code will be used to decide if there are human subjects involved and if the research proposed is a Phase III clinical trial.

Human subject research is comprised of all research involving the use of human organs, tissues, and body fluids from living individuals or graphic, written, or recorded information derived from living individuals.

Human subjects are not considered to be involved if the research uses only coded private information or specimens AND
• The private information or specimens are not collected specifically for the proposed research, AND

• Any of the involved investigator(s) cannot identify the individual(s) providing the coded private information or specimens, because the key to decipher the code has either been destroyed or a formal agreement exists that prohibits the release of that key to the investigators during the lifetime of the subjects.


NIH defines clinical research as comprising three areas:

• **Patient-oriented research.** Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects (excluded from this definition are *in vitro* studies utilizing human tissues that cannot be linked to a living individual, as described above). This research includes:
  o Mechanisms of human disease
  o Therapeutic interventions
  o Clinical trials
  o Development of new technologies

• **Epidemiologic and behavioral studies.** By NIH policy, all human behavioral research is clinical research, whether it is large or small scale, observational, survey, focus group, or other types of behavioral research.

• **Outcomes research and health services research.**

2. **Are human subjects adequately protected from research risks?**

To assess the adequate protection of human subjects, four requirements must be considered:

• **Requirement 1:** Risks to subjects, including:
  o Characteristics of the study population such as anticipated number, age range, and health status; inclusion and exclusion criteria; and the rationale for the involvement of any vulnerable populations.
  o The source and type of research data or specimens, how this will be collected, who will have access to identifiable private information, and whether or not materials will be collected specifically for the proposed project.
  o Potential risks (physical, psychological, financial, legal, or other).

• **Requirement 2:** Adequacy of protection against risks, including:
o Plans for the recruitment and informed consent process.
o Protections against risk, including procedures for protecting against risks to privacy and confidentiality of data as well as plans for medical intervention and the reporting of adverse events.

- **Requirement 3**: Potential benefit of the proposed research to the subjects and others as well as why risks are reasonable in relation to the anticipated benefits.

- **Requirement 4**: Importance of the knowledge to be gained in relation to the risks to subjects. If a clinical trial is proposed, a data and safety monitoring plan must be included.

### 3. Is the research a Phase III Clinical Trial?

NIH definition: Phase III clinical trials are broadly based, prospective clinical investigations for the purpose of investigating the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand). These trials compare the intervention to other standard or experimental interventions, monitor adverse effects, and collect information that will allow the intervention to be used safely. Phase III clinical research trials may include pharmacologic, non-pharmacologic, and behavioral interventions that are given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

In the case of an NIH-defined Phase III clinical trial, a data and safety monitoring board must be in place.

### 4. Use of a Single Institutional Review Board for Multi-Site Research

The new policy enhances and streamlines the IRB review process, setting the expectation that a single IRB of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.

Please see [NOT-OD-16-094](#) for additional information.

### 5. Are the gender and minority characteristics of the study subjects and the inclusion of children scientifically acceptable given the aims of the research?

The judgment of scientific acceptability requires that reviewers first evaluate the human subjects protection plans in terms of the scientific questions posed.

**Note:** The judgment of scientific acceptability for Phase III clinical trials research requires the consideration of additional criteria. These criteria include the assessment of sample retention plans, sample recruitment plans, and plans (or the reason that plans are not needed) to conduct a valid analysis to detect significant differences among minorities and genders in the intervention effect (see section below entitled “Gender and Minority Representation Requirements for Phase III Clinical Trials”).
It is not anticipated that every study will include both genders, all minority groups and subgroups, and children. Inclusion should be determined by the scientific questions under examination. Proposals should describe and justify fully the human subject composition that will be included in the research.

In some cases, sample representation is unknown because sample composition cannot be accurately determined (e.g., pooled blood samples or stored specimens without gender designation). This may or may not be scientifically acceptable, depending on the research questions.

In foreign research projects involving human subjects, the definition of minority groups may be different from those in the US. If there are scientific reasons for examining minority groups/subgroup differences in such settings, the studies should be designed accordingly.

For foreign proposals as well as foreign components, the policy on the inclusion of both genders applies fully.

The inclusion plan is scientifically unacceptable if it fails to conform to NIH policy guidelines in relation to the scientific purpose and type of study, it fails to provide sufficient information, it does not adequately justify the limited or lack of representation of one gender or minority persons or children, or for Phase III clinical trials, it does not realistically address recruitment/retention.

**GENDER AND MINORITY REPRESENTATION REQUIREMENTS FOR PHASE III CLINICAL TRIALS**

A Phase III clinical trial must include plans (or the reason that plans are not needed) to conduct a valid analysis to detect significant differences among minorities and genders in the intervention effect. Offerors should provide one or more of the following rationales that may apply for a scientifically acceptable project:

- Available evidence strongly indicates significant gender differences of clinical or public health importance in intervention effect and the study design is appropriate to answer separate primary questions (one for males and one for females) with an adequate sample size for each gender.

- Available evidence strongly indicates significant racial/ethnic differences of clinical or public health importance, and the study design is appropriate to answer separate primary questions for each of the relevant racial/ethnic subgroups with an adequate sample size for each group.

- Available evidence strongly indicates that there are no significant differences of clinical or public health importance among racial/ethnic groups or subgroups and/or between genders in relation to the effects of study variables (minority representation and representation of both genders are not required as subject selection criteria; however, the inclusion of both genders and minority group/subgroup members is encouraged).

- There is no clear-cut scientific evidence to rule out significant differences of clinical or public health importance between males and females and/or among racial/ethnic groups or subgroups in relation to study variables, and the study design includes a sufficient and appropriate representation of both genders and/or minority groups to permit the valid analysis of a differential intervention effect (high statistical power is not required to
determine differential effects).

- One gender and/or some minority groups or subgroups are excluded from the study because the inclusion of these individuals would be inappropriate with respect to their health or because the inclusion of these individuals would be inappropriate with respect to the purposes of the research, e.g., the research question that is addressed is relevant only to one gender or ethnic/racial group or subgroup.

“Information on NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research” was published the NIH Guide in October, 2001. Among these provisions for all clinical research are special requirements for Phase III clinical trials. The amended policy "Inclusion of Women and Minorities Policy Implementation" may be found at the website http://grants.nih.gov/grants/funding/women_min/women_min.htm.

“Inclusion of Children Policy Implementation” may be found at the web site: http://grants.nih.gov/grants/funding/children/children.htm

Expanded guidance on protection of human subjects criteria can be found in Part II, Section 4.11 of the PHS 398 instructions http://grants.nih.gov/grants/funding/phs398/phs398.doc#_Toc224516045.

5. Assigning codes summarizing the inclusion and acceptability status.

**Human Subject Protection Codes:**

- 10: No human subjects involved
- 30: Human subjects are involved and protections are adequate
- 35: For institutional training mechanisms only: trainees may be assigned to projects in which human subjects are involved.
- 44: Human subjects are involved and there is a concern about human subjects that must be resolved before the proposal can be funded.
- E4: Research involving the use of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. “Existing” means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt (per http://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c5)

Rarely used (for NIAID) additional exemption codes you may see can be found here: https://humansubjects.nih.gov/walkthrough-investigator#pre-submission
Specific examples regarding NIH’s most used exemptions (E1, E2, and E4) can be found here: https://humansubjects.nih.gov/sites/hs/public_files/exemption_infographic_v6_hs_internet.pdf

**Inclusion and Acceptability Codes:**
A three-digit alphanumeric coding system is used (e.g. G1A):

- G, M, or C indicates Gender, Minority or Children.
- A number 1-5 indicates inclusion status.
- An A or U indicates scientific Acceptability or Unacceptability.

**Gender**: The classification of humans as either female or male.

**Gender Inclusion Codes**:
- G1 = Both genders
- G2 = Females only
- G3 = Males only
- G4 = Unknown (cannot be known)

**Minority group**: A readily identifiable subset of the US population that is distinguished by racial, ethnic, and/or cultural heritage. In accordance with OMB Directive No. 15, the currently defined groups are American Indian or Alaskan Native; Asian or Pacific Islander; Black, not of Hispanic origin; and Hispanic.

**Minority Inclusion Codes**:
- M1 = Both minorities and non-minorities
- M2 = Minorities only
- M3 = Non-minorities only
- M4 = Unknown (cannot be known)
- M5 = Only foreign (non-US) subjects

**Children**: Individuals under the age of 18 years. Starting with applications/proposals submitted for due dates on or after January 25, 2016, for the purposes of inclusion policy, the age of a child will be defined as individuals under 18 years old as specified in [NOT-OD-16-010: Inclusion of Children in Clinical Research: Change in NIH Definition](http://grants.nih.gov/grants/funding/children/children.htm).

**Children Inclusion Code**:
- C1 = Both children and adults
- C2 = Children only
- C3 = Adults only
- C4 = Unknown (cannot be known)


**Scientific Acceptability Code** (third character):

- A = Scientifically Acceptable
- U = Scientifically Unacceptable
Thus, for example:

G1A indicates that both genders are represented in the research; the research is scientifically acceptable.

M3U indicates that only non-minorities are represented in the research; the research is scientifically unacceptable, given the stated aims of the research.

For more information, please read:
http://www.hhs.gov/ohrp/policy/checklists决策charts.html

Use of Human Fetal Tissue

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines.

Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B) Human Subjects Research (45 CFR 46) | HHS.gov. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Guidance for recipients conducting research on human fetal tissue and other information on the governing Federal statute is found in sections 498A and 498B of the PHS Act, 42 U.S.C. 298g-2 Office for Human Research Protections (OHRP) | HHS.gov.


For legal requirements regarding the acquisition and use of human fetal tissue for research purposes see Guide Notice NOT-OD-15-143.

Proposed Use of Newborn Dried Blood Spots

A new provision of the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240) requires federally funded research using newborn dried blood spots collected on or after March 18, 2015 to be considered non-exempt human subjects research.

- NIH funded research using newborn dried blood spots collected on or after March 18, 2015, will be considered to be non-exempt human subjects research, and therefore, must follow the HHS protection of human subjects regulations at 45 CFR part 46.
- Grant applications and R&D contract proposals submitted to NIH that will use such materials in research should be designated as non-exempt human subjects research and include a complete human subjects section per relevant NIH instructions including plans
for inclusion on the basis of sex/gender, race, ethnicity, and age per the NIH Policies on the Inclusion of Women, Minorities, and Children.

- Parental permission must have been obtained in order to use newborn dried blood spots **collected on or after March 18, 2015**, in NIH-funded research. Waiver of parental permission for such research is not permitted under this legislation.
- Non-identifiable newborn dried blood spots collected prior to March 18, 2015, may continue to be used in NIH-funded research without parental permission, and this activity would continue to be considered research that does not involve human subjects under the current human subjects regulations.
- NIH recognizes that there is no universal agreement on the optimal timing for collection of parental permission for research purposes.

For more information, please read [NOT-OD-15-127](#).

### Proposed Use of Humanized Animals

Proposals that include the development and/or use of humanized animals must address any applicable aspects of human subjects protection. If the proposed activities are claimed to be exempt, the proposal should include a justification for claiming exemption from human subjects regulations.

### Human Embryonic Stem Cells


For additional guidance on Protection of Human Subjects see [45 CFR Part 46](#).
VERTEBRATE ANIMALS

WHAT THE REVIEWER NEEDS TO EVALUATE

For contract proposals, any FOA instructions regarding the assessment of the involvement of vertebrate animals supersedes the instructions here. If no specific FOA instructions exist, offerors should follow the recently simplified Vertebrate Animal Section instructions found in NOT-OD-16-006 as stated below.

Reviewers of extramural research contract proposals are asked to

- Determine if vertebrate animals are involved in the proposed research.
- If vertebrate animals are involved, determine if their care and use is acceptable based on the four required points noted below.
  1. Description of 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 the euthanasia method if not consistent with the AVMA Guidelines for the Euthanasia of Animals. Offerors should state if the method(s) is consistent with the guidelines.
- Reviewers will assess the use of chimpanzees as they would any other proposed use of vertebrate animals.

**Note:** Evaluation of vertebrate animal welfare issues does not affect the contract proposal’s score or the Acceptable/Unacceptable rating unless vertebrate animal issues are specifically defined in the Technical Review Criteria/Criterion (TEC). Normally, they will be addressed administratively. The offeror must ensure that all subcontractors and collaborators (both US and non-US) provide the required information for this special issue and that this information is provided for each performance site listed in the contract proposal.

Summary of Changes

The Vertebrate Animal Section (VAS) criteria are simplified by the following changes:

- A description of veterinary care is no longer required.
- Justification for the number of animals has been eliminated.
- A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines.

Updated VAS Requirements
If live vertebrate animals are to be used, federal policy requires offerors to address the following four criteria:

1. **Description of Procedures.** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the proposal. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

2. **Justifications.** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

3. **Minimization of Pain and Distress.** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

4. **Euthanasia.** State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

**USE OF HUMANIZED ANIMALS**

Proposals that generate/utilize humanized animals must address the use of human subjects in research. Please refer to the Human Subjects Protection and Inclusion section for more details.

**VERTEBRATE ANIMALS ARE NOT INVOLVED**

For proposals not involving any vertebrate animals, the relevant section in the special issues can be marked as “Not Applicable.”

**REFERENCES**

Guidance in this document is based on PHS Policy and federal requirements. The PHS Policy incorporates the standards in the Guide for the Care and Use of Laboratory Animals and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, and it requires that euthanasia be conducted according to the AVMA Guidelines on Euthanasia.

Additional background information and references are available on the Office of Laboratory Animal Welfare website (http://olaw.nih.gov).

BI OHAZARDS

WHAT REVIEWERS NEED TO EVALUATE

If infectious agents or other biohazardous substances are described in the proposal, reviewers should apply the collective standards of the professions that are represented within the Technical Evaluation Panel (TEP) to identify potential hazards. These hazards include the inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

Reviewers must specifically evaluate:

- Which infectious agent(s)/pathogens will be used?
- Are the proposed facilities appropriate and adequate for handling, storage, and biocontainment?

Issues relating to biohazards are not scored, but they can be noted as Acceptable or Unacceptable after scoring is completed.

If serious hazards are described in the proposal, these hazards should be identified by the TEP, and any concerns about the adequacy of safety procedures will be highlighted at the end of the Technical Evaluation Report (TER) in the Biohazards section.

**Note:** Offerors from foreign countries are required to follow the biohazard regulations stipulated by the NIH.
SELECT AGENTS

WHAT THE REVIEWER NEEDS TO EVALUATE

If a contract proposal indicates the involvement of select agents, it must specifically address:

- Which select agent(s)/pathogens will be used?
- Is the offeror or subcontractor registered (the offeror may state that registration is complete or pending without providing documentation)?
- Is the offeror compliant or exempt from the regulations? If it is exempt, why?
- Are the proposed facilities appropriate for handling, storage, and biocontainment?
- What procedures are in place to monitor biosafety and biocontainment?
- What security precautions (including physical security) are in place? Are security risk assessments complete/pending for all involved personnel?
- How does the offeror manage/enforce compliance with the select agent rule? Has a Responsible Official(s) (RO) been designated? How often does the RO conduct inspections? Is there a biosafety committee?

Evaluation of the use of select agent section does not affect the contract proposal’s score or the Acceptable/Unacceptable rating unless select agent issues are specifically defined in the TEC. Normally, they will be addressed administratively. **Note:** The Offeror must ensure that all subcontractors and collaborators (both US and non-US) provide the required information for this special issue, and that this information is provided for each performance site listed in the contract proposal. Offerors from foreign countries are also required to follow these select agent and biohazard regulations.

BACKGROUND

As part of regulations enacted by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (PL 107-188), researchers are now required to register with the federal government and get approval to possess or use any pathogen or toxin that is defined as a “select agent.” By February 7, 2002, most NIAID-supported investigators who own or use a select agent that is listed in 42 CFR 73 should have notified the CDC (published on December 13, 2002, this rule supersedes 42 CFR 72). All researchers who were previously registered must reregister in accordance with the regulation, and all newcomers must register. Certain specified attenuated strains derived from select agents are excluded from the need to register. The excluded strains are posted and regularly updated at [http://www.cdc.gov/od/sap](http://www.cdc.gov/od/sap)

**Requirements for Facilities Transferring or Receiving Select Agents (Title 42 CFR Part 72.6).** Under the *Antiterrorism and Effective Death Penalty Act of 1996*, the Secretary of the Department of Health and Human Services regulates the transfer of certain biological agents that are harmful to humans. These regulations are designed to ensure that these infectious agents and toxins are shipped only to institutions or individuals that are equipped to handle them appropriately and have legitimate reasons to use them.

The CDC is responsible for the implementation of this regulation. The CDC’s Select Agent Program (SAP) currently requires the registration of facilities, including government agencies,
universities, research institutions, and commercial entities. Helpful information may be online via the SAP web site at http://www.cdc.gov/od/sap.

Note that the HHS and USDA Select Agent List and the NIAID List of Priority Pathogens have incomplete overlap. However, reviewers should assess any potential biohazard issues that apply to organisms on either list. In addition, NIAID has a List of NIAID Emerging and Re-emerging Diseases, which includes a link to the priority pathogens noted above.

GENOMIC MATERIAL FROM SELECT AGENTS

The following additional guidance regards genomic material from select agents that is subject to 42 CFR 73 is from 42 CFR 73.4(e) and 73.5(e) and specifies genetic elements, recombinant nucleic acids, and recombinant organisms that are subject to the requirements of Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73):

1. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

2. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in the Select Agent List if the nucleic acids:
   - Are in a vector or host chromosome; or
   - Can be expressed in vivo or in vitro; or
   - Are in a vector or host chromosome and can be expressed in vivo or in vitro.

3. Viruses, bacteria, fungi, and toxins listed in the Select Agent List that have been genetically modified.

Additional clarifications

- **Non-viable select agent organisms** (including agents in fixed tissues). Select agent organisms that have been treated in such a manner (e.g. gamma irradiation) that they are no longer able to replicate (i.e. non-viable, inactivated, killed, or dead) are not select agents. See 42 Parts 73.4(f)(2) and 73.5 (f)(2).

- **Purified genomic material or genetic elements from select agent viruses.** Genetic elements (nucleic acids) from select agent viruses are regulated if they are in host chromosomes or expression vectors and if they encode for infectious or replication competent forms of any of the select agent viruses. See 42 Parts 73.4(e)(1) and 73.5 (e)(1).

- **Purified genomic material or genetic elements from select agent bacteria** are select agents if the nucleic acid encodes for a functional form of a listed toxin in a vector or host chromosome and/or can be expressed in vivo or in vitro. See 42 Parts 73.4(e)(2) and 73.5 (e)(2).
DATA SHARING PLAN

WHAT THE REVIEWER NEEDS TO EVALUATE

If applicable, the reviewer will address whether the proposal’s data sharing plan is “Acceptable” or “Unacceptable.” The evaluation should not affect the scoring or the acceptability rating of the proposal. If the data sharing plan is deemed “Unacceptable,” a brief explanation of why it was unacceptable should be provided.

However, some Requests for Proposals or Broad Agency Announcements may contain special requirements related to data sharing; in these cases, the adequacy of the data sharing plan may be factored into the score of the respective Technical Evaluation Criteria and into whether the proposal is “Acceptable” or “Unacceptable.”

BACKGROUND

Scientific research depends on the free flow of information and ideas. To ensure that future research can build on previous efforts and discoveries, the NIH has a data sharing policy for all contract proposals. The policy expects that offerors will make final research data, especially unique data, from NIH-supported research efforts available to other investigators. It includes data from:

- Basic research
- Clinical studies
- Surveys
- Other types of research

Data sharing applies to human subjects and laboratory research. In some instances, it may include data that was used in an NIH-supported activity but not produced with NIH funding.

DATA SHARING PLAN REQUIREMENTS

Offerors submitting contract proposals must provide a data sharing plan as requested in the RFP or BAA, regardless of the proposal’s direct costs. If the data cannot be shared, the offeror must state why data sharing is restricted or not possible. The precise content of the data sharing plan will vary, depending on the data being collected. The sharing plan may include the:

- Schedule for data sharing
- Format of the final dataset
- Documentation to be provided
- Analytical tools to be provided, if any
- Need for a data sharing agreement
- Mode of data sharing
TIMEFRAME FOR DATA SHARING

Data sharing should be timely and occur no later than the acceptance for publication of the main findings from the final dataset. Data from large studies can be released in waves as data become available or as they are published.

For more information, see the following NIH website:
http://grants.nih.gov/grants/policy/data_sharing/
NIH GENOMIC DATA SHARING (GDS) POLICY

The NIH GDS Policy replaces the Genome-Wide Association Studies (GWAS) policy and became effective with NIH grant applications submitted on or after the January 25, 2015 due date and thereafter. The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research (see examples).

WHAT THE REVIEWER NEEDS TO EVALUATE

NIH expects investigators and their institutions to provide basic plans for following this policy in the “Genomic Data Sharing Plan” located in the Resource Sharing Plan section of funding applications. Any resources that may be needed to support a proposed genomic data sharing plan (e.g., preparation of data for submission) should be included in the project’s budget. A more detailed genomic data sharing plan should be provided to the funding IC prior to award. Note: Current guidance is that applicants who generate GDS data must include a GDS plan; those using human genomic data from NIH-designated data repositories need not submit a GDS plan.

Until the implementation of this policy (see “NIH GDS Policy” below) is finalized, the role of the reviewer is as follows:

- If GDS is applicable to the application, the reviewer should provide comments regarding the proposed GDS plan or indicate the need for a GDS plan if not included in the application.
- The reviewer should not include an assessment of the plan in the determination of the application’s Overall Impact/Priority score.
- However, some special initiatives may contain additional requirements related to GDS; in these cases, the adequacy of the GDS sharing plan may be an additional review criterion, and the reviewers would then factor an evaluation of the plan into the overall evaluation of scientific merit, i.e., the Overall Impact/Priority score.

At a minimum, the Resource Sharing Plan section of the grant application should include:

- Type of data that will be shared (i.e., the type of genomic data, relevant associated data, and information necessary to interpret the data);
- The data repository to which the data will be submitted;
- The timeline for the data to be shared;
- Any limitations on the secondary research uses of the data, if the study involved human data; and
- Acknowledgement that the Institutional Certification will be submitted and assurance by the Institutional Review Board (IRB) that the data can be shared through NIH-designated data repositories, consistent with data sharing under the NIH GDS Policy.

Investigators should provide a justification for an exception to the data sharing expectation in the grant application, prior to the grant award.
NIH GDS POLICY

The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support). The Supplemental Information to the GDS Policy provides examples of genomic research projects that are subject to the Policy.

The GDS Policy has no direct cost threshold associated with it and applies only to grant activities requesting support for research, such as:

- Research project grants (Rs);
- Program projects (Ps) and SCORs (Ss);
- Cooperative agreements for research (Us);
- Individual career development awards (Ks) that include a research component;
- S activities that include a research component; and
- All other activities that include a research component.

The GDS Policy does not apply to:

- Institutional training grants (T32s, T34s, T35s, and TL2s);
- K12 career development awards (KL2s);
- Individual fellowships (Fs);
- Resource grants and contracts (Ss);
- Linked awards derived from previously reviewed applications (KL1, KL2, RL1, RL2, RL5, RL9, TL1, UL1);
- Facilities or coordinating centers funded through related initiatives to provide genotyping, sequencing, or other core services in support of GDS.

Examples of such research include, but are not limited to, projects involving:

- Sequence data from more than one gene or region of comparable size in the genomes of more than 1,000 human research participants.
- Sequence data from more than 100 genes or region of comparable size in the genomes of more than 100 human research participants.
- Data from 300,000 or more variant sites in more than 1,000 human research participants.
- Sequence data from more than 100 isolates from infectious organisms.
- Sequence data from more than 100 metagenomes of human or model organism microbiomes.
- Sequence data from more than 100 metatranscriptomes of human or model organism microbiomes.
- Whole genome or exome sequence data of more than one model organism species or strain.
- Comprehensive catalog of transcripts and non-coding RNA from one or more model organism species or strains.
- Catalog of more than 100,000 SNPs from one or more model organism species or strains.
• Comparisons of genome-wide methylated sites across more than 10 cell types.
• Comparisons of differentially methylated sites genome-wide at single-base resolution within a given sample.

GDS SHARING PLAN REQUIREMENTS

Applicants preparing grant applications that include GDS research are expected to state in the cover letter that the studies proposed will generate large-scale human and/or non-human genomic data, and they should include a GDS plan. When the applicant is unable to submit GDS data (due to informed consent issues, local laws and limitations, concerns about harms to individuals and groups, or other limitations), the applicant must describe why sharing (in part or in full) is not possible.

Exceptions to NIH expectations for data submission to an NIH-designated data repository will be considered on a case-by-case basis by the NIH funding Institute or Center (IC).

The sharing plan should contain details about the submission of relevant data to the NIH GDS data repository including:

For Non-human Genomic Data Sharing Plans, information should include:

1. DATA SUBMISSION EXPECTATIONS AND TIMELINE

Large-scale non-human genomic data, including data from microbes, microbiomes, and model organisms, as well as relevant associated data (e.g., phenotype and exposure data), are to be shared in a timely manner. Genomic data undergo different levels of data processing, which provides the basis for NIH’s expectations for data submission. These expectations are provided in the Supplemental Information (see “Supplemental Information” link at the end of this chapter). In general, investigators should make non-human genomic data publicly available no later than the date of initial publication.

2. Data Repositories

Non-human data may be made available through any widely used data repository, whether NIH-funded or not, such as the Gene Expression Omnibus (GEO), Sequence Read Archive (SRA), Trace Archive, Array Express, Mouse Genome Informatics (MGI), WormBase, the Zebrafish Model Organism Database (ZFIN), GenBank, European Nucleotide Archive (ENA), or DNA Data Bank of Japan (DDBJ) (see GDS policy link for more repository information). NIH expects investigators to continue submitting data types to the same repositories that they submitted the data to before the effective date of the GDS Policy (e.g., DNA sequence data to GenBank/ENA/DDBJ, expression data to GEO or Array Express). Data types not previously submitted to any repositories may be submitted to these or other widely used repositories as agreed to by the funding IC.

For Human Genomic Data Sharing Plans, information should include:

1. DATA SUBMISSION EXPECTATIONS AND TIMELINE

Updated October 11, 2016
Investigators should submit large-scale human genomic data as well as relevant associated data (e.g., phenotype and exposure data) to an NIH-designated data repository in a timely manner. Investigators should also submit any information necessary to interpret the submitted genomic data, such as study protocols, data instruments, and survey tools.

Genomic data undergo different levels of data processing, which provides the basis for NIH's expectations for data submission and timelines for the release of the data for access by investigators. These expectations and timelines are provided in the Supplemental Information (see "Supplemental Information" link at the end of this chapter). In general, NIH will release data submitted to NIH-designated data repositories no later than six months after the initial data submission begins or at the time of acceptance of the first publication, whichever occurs first, without restrictions on publication or other dissemination.

2. Data Repositories

Investigators should register all studies with human genomic data that fall within the scope of the GDS Policy in dbGaP by the time that data cleaning and quality control measures begin, regardless of which NIH-designated data repository will receive the data. After registration in dbGaP, investigators should submit the data to the relevant NIH-designated data repository (e.g., dbGaP, GEO, SRA, the Cancer Genomics Hub). NIH-designated data repositories need not be the exclusive source for facilitating the sharing of genomic data, i.e., investigators may also elect to submit data to a non-NIH-designated data repository in addition to an NIH-designated data repository. However, investigators should ensure that appropriate data security measures are in place, and that confidentiality, privacy, and data use measures are consistent with the GDS Policy.

3. Tiered System for the Distribution of Human Data

Respect for, and protection of the interests of, research participants are fundamental to NIH's stewardship of human genomic data. The informed consent under which the data or samples were collected is the basis for the submitting institution to determine the appropriateness of data submission to NIH-designated data repositories and whether the data should be available through unrestricted or controlled access. Controlled-access data in NIH-designated data repositories are made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data in unrestricted-access repositories are publicly available to anyone (e.g., The 1000 Genomes Project).

4. Informed Consent (see also Guidance on Informed Consent link below)

For research that falls within the scope of the GDS Policy, submitting institutions, through their Institutional Review Boards (IRBs), privacy boards, or equivalent bodies, are to review the informed consent materials to determine whether it is appropriate for data to be shared for secondary research use. Specific considerations may vary with the type of study and whether the data are obtained through prospective or retrospective data collections. NIH provides additional information on issues related to the respect for research participant interests in its Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications.24
For studies initiated after the effective date of the GDS Policy, NIH expects investigators to obtain participants’ consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent should include an explanation about whether participants’ individual-level data will be shared through unrestricted- or controlled-access repositories.

For studies proposing to use genomic data from cell lines or clinical specimens that were created or collected after the effective date of the Policy, NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified. If there are compelling scientific reasons that necessitate the use of genomic data from cell lines or clinical specimens that were created or collected after the effective date of this Policy and that lack consent for research use and data sharing, investigators should provide a justification in the funding request for their use. The funding IC will review the justification and decide whether to make an exception to the consent expectation.

5. Institutional Certification- Needs to be submitted just-in-time to the Program Officer

6. Justification for any Exceptions to Data Submission Expectations

7. Data Withdrawal

Submitting investigators and their institutions may request removal of data on individual participants from NIH-designated data repositories in the event that a research participant withdraws or changes his or her consent. However, some data that have been distributed for approved research use cannot be retrieved.

Additionally, the applicant must address any special requirements related to GDS data sharing and access that may be present in the Funding Opportunity Announcement.

International Collaborations and Foreign Grants

If the U.S. institution is the primary grantee, then the domestic institution is responsible for its sub-grantee or subcontract arrangements and is expected to ensure that this policy is adequately addressed in the application.

For more information, see the following NIH websites:


For the NIH GDS Policy (NOT-OD-14-124) see: [https://gds.nih.gov/PDF/NIH_GDS_Policy.pdf](https://gds.nih.gov/PDF/NIH_GDS_Policy.pdf)


For Supplemental Information to the NIH GDS Policy, see [http://gds.nih.gov/pdf/supplemental_info_GDS_Policy.pdf](http://gds.nih.gov/pdf/supplemental_info_GDS_Policy.pdf)
Guidance for Investigators in Developing Genomic Data Sharing Plans

Guidance for Consent for Use of Genomic Data

Guidance on Informed Consent
BUDGET ASSESSMENT

WHAT REVIEWERS NEED TO EVALUATE

The reviewers will, from the brief overview of the proposal’s budget (typically only one to two pages), determine if the offeror’s effort and stated direct costs are appropriate for the work proposed. The budget assessment will not affect the scoring of any of the Technical Evaluation Criteria/Criterion (TEC) or whether the overall proposal is “Acceptable” or “Unacceptable.” If the budget is not appropriate, a brief explanation of why it was not appropriate should be provided.

BACKGROUND

Contract proposals are submitted in two parts: a "Technical Proposal" and a "Business Proposal." Each component is separate and complete unto itself so that the evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. The Technical Proposal—the proposal that the review panel critiques—must include direct cost and resources information such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc. as well as associated costs so that the offeror's understanding of the project may be evaluated. However, the Technical Proposal does not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), or total costs. The Business Proposal, which contains the detailed budget, is evaluated separately by NIAID’s Office of Acquisition.
PRE-REVIEW ORIENTATION TELECONFERENCE

The Pre-Review Orientation Teleconference is an informational teleconference during which the Scientific Review Officer (SRO) will provide the review panel with important information concerning the Funding Opportunity Announcement (RFP or BAA) as well as the peer review and meeting process. Specific proposals are not discussed during this meeting.

The SRO will provide the review panel with all of the pertinent information required to participate in the teleconference. The SRO will also often send the panel a PowerPoint presentation that will be covered during the pre-review meeting. Additionally, a NIAID Program Officer and a Contract Officer/Specialist will be present to address any program/contract-related questions that reviewers may have.

The teleconference will be held two to three weeks before the actual review meeting; for large meetings, there may be more than one date to attend. The typical meeting lasts for approximately an hour, but times vary according to the complexity of the review and the number of questions from the panel.

Lastly, the pre-review teleconference is recorded, and a copy of the audio recording can be obtained from the SRO if a reviewer is unable to attend the meeting or wants the recording as a resource.
GENERAL CONTRACT REVIEW MEETING PROCEDURES

Before the review meeting, reviewers will sign a pre-meeting COI form (available in eRSS) to confirm that no additional COIs were identified during the initial review of assigned contract proposals. Reviewers will also be asked to electronically sign a post-meeting COI form (available in eRSS) at the end of the review meeting to confirm that no additional COIs were identified during the review meeting. **Note:** In the event that a reviewer has identified a conflict but is permitted to participate on the review panel, the reviewer should note the name of the offeror for the conflicted proposal on the pre- and post-meeting COI forms.

At the opening of the meeting, the Scientific Review Officer (SRO) will brief the review panel on review policy and procedures and address any questions. **Note:** All reviewers must be present for all discussions pertaining to all the proposals during the review meeting (i.e., leaving early, arriving late, or stepping outside the room is **NOT** allowed).

The Chair, following an agenda prepared by the SRO, will call the first proposal for discussion and ask Reviewer 1 (or the primary reviewer) to provide a brief, non-evaluative description of the proposal. The Chair will read the Technical Review Criteria/Criterion (TEC), beginning with the first review criterion, and ask the assigned reviewers to state their preliminary score for TEC 1. Reviewer 1 will then present his/her critique of the first criterion. Subsequently, all assigned reviewers will present areas of agreement or disagreement, limiting their comments to NEW insights or issues they feel are important. The Chair will then ask the panel to discuss the technical merits of the first criterion. **Note:** Reviewers must not compare proposals; each is to be judged independently based on the scientific and technical merit in relation to the TEC.

After the discussion reaches its productive limit, the Chair or Reviewer 1 will provide a brief summary of the major strengths, weaknesses, or concerns heard during the discussion and ask if any panel member wishes to add comments. The Chair will then ask the assigned reviewers to restate their recommended numerical scores based on the discussion. The Chair will direct all reviewers to provide a final numerical score on the Technical Evaluation Score sheet (TESS) form in eRSS. **Note:** Reviewers who plan to score significantly different from the stated scores should state this to the review panel and make sure that the reasons or issues influencing their score have been discussed and incorporated into the TESS. Additionally, reviewers should not deduct twice (under separate TEC) for the same weakness.

For contract reviews, **ALL panel members must provide written critiques and scores for ALL proposals at the meeting.** Reviewers who are not formally assigned to write a written evaluation of the proposal before the meeting are expected to listen to the discussion and list major strengths and weaknesses of the proposal on the appropriate proposal-specific TESS form that can be found in eRSS.
Reviewers that are asked to submit a written critique prior to the review meeting should update their scores and Strengths/Weaknesses comments following the discussion at the review meeting.

The process will be repeated for the remaining TEC and Options (if applicable) designed for this review.

After scoring all criteria and options, the final score for the proposal will be electronically calculated by eRSS.

The SRO will provide reviewers with a chart to track their individual scores throughout the review meeting to facilitate calibrating their individual scoring stringency (i.e., evaluating the proposals consistently throughout the meeting).

After final scoring, the panel will vote on the acceptability of the proposal. Each reviewer will choose either Acceptable or Unacceptable on the electronic TESS form in eRSS for each proposal.

The definition of an **Acceptable** or **Unacceptable** proposal is as follows:

**Acceptable proposal:** proposal contains no major deficiencies, is complete in itself, and no additional information is required for the reviewers to determine that the offeror can fulfill the minimum requirements of the RFP/BAA (although additional information may be required for clarification).

**Unacceptable proposal:** proposal contains deficiencies that are so substantive as to preclude any possibility of it being upgraded to a level that meets the minimum requirements of the RFP/BAA except through major revisions and additions which would be tantamount to the submission of a new proposal.

The following definitions from the Federal Acquisitions Regulations are provided in accordance with the law:

**Weakness:** a flaw in the proposal that increases the risk of unsuccessful contract performance.

**Significant Weakness:** a flaw in the proposal that appreciably increases the risk of unsuccessful contract performance.

**Deficiency:** a material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increase the risk of unsuccessful contract performance to an unacceptable level.

A proposal is deemed Acceptable if voted so by at least half the panel. In the event of a tie vote on a proposal’s Acceptability/Unacceptability, the SRO will ask for reconsideration. If the tie remains after reasonable further discussion, the proposal shall be considered Acceptable.
For Acceptable proposals, the panel will discuss the applicable special issues (e.g., Human Subjects, Animal Welfare, Biohazards, and Sharing Plans) and budget and make recommendations about their acceptability. Direct cost information (typically one page) provided in the Technical Proposal may describe Total Labor Hours/percent effort (labor hour base) for all personnel (or as specified in the RFP). It is appropriate for reviewers to comment on this information. The reviewers will not evaluate indirect cost information (facilities and administrative [F&A] costs) or salaries or wages linked to specific personnel. At the end of this discussion, the technical evaluation of the proposal will be complete. Reviewers will sign and date their electronic TESS forms and click “Submit to Scientific Review Officer” in eRSS.

If a proposal is deemed Unacceptable, the special issues and the budget are not discussed and the review of the proposal ends. Reviewers will sign and date their TESS forms and click “Submit to Scientific Review Officer” in eRSS. This process will be repeated for the remaining proposals that are part of the review meeting.

At any time prior to the conclusion of the meeting, reviewers can change their scores of a previously completed TESS if they feel that they have not been applying uniform stringency across proposals; individual stringency levels must be applied to the evaluation of each proposal. However, the proposals are not to be compared to each other. If a reviewer changes any score after the review of that proposal is complete, the reviewer must notify the SRO.

**Outside Information:** Reviewer assessments should be based only on the information presented in the proposal. Information from newspapers, internet websites, or personal knowledge cannot be used during the evaluation of the proposal. Likewise, Reviewers should not assume any information that is not presented in the proposal (e.g., management or technical support). Only information included in the proposal can be used during the evaluation process.

**Dissent and Consensus:** The technical evaluation panel (TEP) consists of individuals with a variety of expertise. It is important to note that a consensus among reviewers is not mandatory. However, it is expected that reviewers will learn from each other, especially those with expertise different from their own, and take all comments into consideration before recommending a score. Throughout the discussion, each reviewer should score each section as they see appropriate according to their own experience and comments from the other panel members.
TELECONFERENCE REVIEWERS

A teleconference review may be held in conjunction with a face-to-face review or as a stand-alone meeting.

BEFORE THE TELECONFERENCE

- Prepare for a teleconference review as if it were a face-to-face review meeting.
- Evaluate the proposals, prepare a written TESS for each proposal, and submit documents electronically as directed by the Scientific Review Officer (SRO). The Cover Letter provided with the Meeting Materials will have contact information for the SRO and the Extramural Support Assistant (ESA) associated with the review.
- The SRO will provide dial-in information and the time for the teleconference several days before the meeting.
- The SRO will request from reviewers a primary telephone number to be used for the teleconference and an emergency contact number in case there are problems connecting with the primary number provided.

THE TELECONFERENCE

- On the day and time indicated for the review meeting, use the telephone number and PIN provided by the SRO to dial-in for the meeting.
- If it has been decided that the SRO will call a reviewer, that reviewer should be available to take the call on the phone (primary number) indicated at the agreed upon time.
- If a reviewer is unable to connect to the teleconference, has not been contacted by the SRO or review representative at the agreed upon time, or wishes to change the telephone number from which he/she will call, the reviewer should contact the SRO immediately by phone or e-mail or contact the Extramural Support Assistant associated with the review.
- Each reviewer should have the Technical Evaluation Score Sheets (TESS) for all proposals available.
- During the review of contract proposals, the SRO may request reviewers to use electronic and internet resources for viewing the proposals and review materials.

TELECONFERENCE OPERATING GUIDELINES

- To maintain the confidentiality of the contract review process, reviewers should take the call in a quiet and private location.
• It is preferable and recommended to use a landline phone with good sound quality. Use of cell phones is not recommended due to the limitations of dropped calls, interference, and battery life. **Do not place the teleconference call on hold, since this may result in music being played that other reviewers will hear and disrupt the teleconference review.**

• Place your phone on mute when you are not speaking. Remember to unmute your phone when needed.

• Be familiar with certain features of the phone such as the speakerphone option, mute button, and volume adjustment.

• If disconnected during the call, simply call back immediately into the meeting using the telephone number provided by the SRO. The review meeting will be stopped and won't continue until all reviewers are present.

• Reviewers should always identify themselves when speaking and try not to interrupt someone who is already speaking.

• During the teleconference, limit activities to tasks associated with the review.

**AFTER THE TELECONFERENCE**

• To end the teleconference, simply hang up.

• All original, signed TESS forms and paper documents utilized at the meeting in the absence of electronic and internet resources must be sent via FedEx to the SRO. The SRO will provide a list of the specific materials to be returned prior to the conclusion of the review.
EVALUATION OF AN INITIATIVE

After the review, reviewers will be asked to comment about the solicitation using the questions below. NIAID staff will take reviewer comments into account when designing initiatives, so these comments and views are sincerely appreciated.

OVERALL ASSESSMENT FACTORS
What is the most important strength or weakness of this initiative?
Should anything have been done differently?

RESEARCH SCOPE AND DESIGN
Does the initiative clearly define the research areas that are covered and not covered?
Are the goals of the initiative well-matched to the work scope described?
Is the scope of the initiative realistic/feasible? Please consider the:
  • state of the science
  • availability of appropriate technologies and other research resources
  • adequacy of the pool of investigators
  • need for multi-institutional arrangements with the US and/or foreign institutions
  • duration of the award
If the scope is too broad or too narrow, what should be changed?
Is the initiative too direct in specifying how the work is to be carried out?

SUBMISSION INSTRUCTIONS & REQUIREMENTS
Are the instructions clearly stated and appropriate?
Are there specific materials not included in the application that would have helped the evaluation? What should be changed?
Please consider scientific, technical, administrative, and collaborative requirements.

FUNDS AVAILABLE
Are the funds available adequate to support this initiative?
How did this impact the number/type/quality of the applications/proposals submitted?

REVIEW CRITERIA
Do the Technical Review Criteria/Criterion (TEC) reflect the scope and requirements of the work requested in the initiative?
What would improve the criteria?

**QUALITY OF THE RESPONSE**

How should the quality of the applications/proposals submitted be rated?

How should the group of Program Directors/Principal Investigators who responded to the initiative be rated?

Are the people who could contribute to this effort represented in the pool of applicants?

Did the amount of time that investigators had to respond to the initiative affect the responses submitted?
POST-REVIEW CHECKLIST

After the review meeting is over, there are still a few tasks each reviewer must do in order to finish the review process. Listed below are steps to follow and/or reminders:

**Technical Evaluation Score Sheets (TESS)**

- **Teleconference Review Meeting** - Ensure all Technical Evaluation Score Sheets (TESS) are completed electronically in the eReviewer Support Site (eRSS). Electronic TESS forms require the following to be considered complete: comments are entered in the Strengths and Weaknesses sections of the Technical Review Criteria/Criterion (TEC), applicable Special Issues are addressed, acceptability/unacceptability of the overall proposal is determined, and the electronic form is signed and dated.

- **Face-to-Face Review Meeting** - Ensure all TESS forms are completed electronically in eRSS. Electronic TESS forms require the following to be considered complete: comments are entered in the Strengths and Weaknesses sections of each TEC, applicable Special Issues are addressed, acceptability/unacceptability of the overall proposal is determined, and the electronic form is signed and dated.

**Conflict of Interest (COI) Forms**

- **Face to Face Review Meetings**
  - Reviewers will be asked to electronically sign a post-meeting COI form (available under the Post-Review COI Certification tab in eRSS) immediately following the review meeting to confirm that no additional COIs were identified during the review meeting.

- **Teleconference Review Meetings**
  - Reviewers will be asked to electronically sign a post-meeting COI form (available under the Post-Review COI Certification tab in eRSS) immediately following the review meeting to confirm no additional COIs were identified during the review meeting.

**Post-Review Meeting Minutes**

The Chair of a meeting must enter the NIAID Division and total dollar amount in direct costs requested for all proposals as well as certify that the meeting minutes are accurate and complete. The Post-Review Meeting Minutes may be accessed in eRSS.

**Provide Post-Review Evaluation**

Reviewer comments regarding the initiative are highly valued by NIH staff and especially useful for preparing funding opportunity announcements in the future. Reviewers can email the comments to the SRO, who will compile the comments and suggestions of all reviewers. This document becomes a permanent part of the meeting record.
Register in SPRS for Reimbursement

Instructions for registering in the NIH's Secure Payee Registration System for reimbursement in eRA Commons can be found under Step 2 of the Contract Reviewer Manual. The NIH cannot disburse payment until the reviewer has provided the required information.

Destroy all Review Related Material

Any CDs/DVDs, paper copies of the review materials, and electronic versions of any review-related documents must be shredded or destroyed after the review meeting or mailed to the SRO for destruction.

Honor Confidentiality

All review-related discussions—whether taking place in person, via phone, or email—are to remain strictly confidential. Reviewers should not discuss anything before or after the review meeting pertaining to the review of proposals with anyone except NIH staff in the NIAID Scientific Review Program (e.g., SRO, Extramural Support Assistant, etc.). Only during the review meeting are reviewers permitted to discuss the review of proposals with other non-conflicted reviewers on the panel or NIH staff outside of the NIAID Scientific Review Program (e.g., Contract Officers, Program Officers, etc.). If any person affiliated with the offeror approaches a reviewer inquiring about any aspect of the review, please refer them to the SRO, who will then contact the Contracting Officer (CO).