PROGRAM PROJECT (P01)
REVIEW GUIDE

DEA, NCI, NIH, DHHS

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PROGRAM PROJECT (P01) REVIEW GUIDE

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PREFACE

Action Required: For Immediate Attention

Reviewers receive several items that require immediate attention. Reviewers should address those items before reading through this guide or evaluating the applications assigned for review.

Welcome to Peer Review

All research and development projects funded by the National Institutes of Health (NIH), including those supported by the National Cancer Institute (NCI), are required by legislation to undergo peer review. The NCI's Division of Extramural Activities developed this guide to help reviewers perform that important function.

The NCI P01 Review Guide

The sections and appendixes in this review guide are organized to make it easy to find instructions and information. They cover the following topics:

Section 1 – Procedures and Review Criteria for Review of Program Project Grant (P01) Applications

The NCI (P01) funding mechanism is designed to provide funding for multifaceted research focused on a single theme. Section 1 provides detailed information about the NCI review process for P01 applications.

Section 2 – Conflict of Interest, Confidentiality, and Misconduct

The review of an application must be free of conflicts of interest and remain confidential. Section 2 outlines what constitutes a conflict of interest in peer review and explains confidentiality requirements. It also defines misconduct and the process for reporting misconduct.

Section 3 – Federal Requirements

This section covers the Federal requirements reviewers must consider when evaluating grant applications, including the following topics: research involving human subjects; data and safety monitoring for clinical trials; sharing research data and model organisms; genome-wide association studies; standards for privacy of individually identifiable health information; NIH public access policy; and URLs in NIH grant applications or appendixes.

Section 4 – Travel, Consultant Fee, and Reimbursement Information

This section provides information about how to make travel arrangements, reviewer consultant fees, prepaid expenses, and the flat-rate reimbursements for reviewer travel expenses.

IMPORTANT: This section includes information about the **required** registration process that enables electronic transfer of travel expense reimbursements and consultant fees to the reviewer's checking account. Reviewers must complete this process before reimbursements can be made.

Additional Resources

Additional information is available in the appendices:

- Assessment of plans for protection of human subjects in research, inclusion of women, minorities, and children, and protection of vertebrate animals is an important part of reviewing an application for a research grant. Appendix A1, *Human Subjects Protection and Inclusion of Women, Minorities and Children: Guidelines for Review of NIH Grant Applications,* explains reviewer responsibilities in evaluating plans for use of human subjects in research projects. Appendix A2, *Worksheet for Comments on Vertebrate Animals,* explains reviewer responsibilities in evaluating plans for use of vertebrate animals in research projects;
- Appendix B provides detailed instructions for accessing and using the NIH Internet Assisted Review (IAR) system to post application critiques;
- Appendix C includes a list of useful Web sites;
- Appendix D is a glossary of peer review terms; and
- Appendix E contains a list of frequently used acronyms.

SECTION 1: PROGRAM PROJECT GRANT (P01) APPLICATIONS

Introduction

The National Cancer Institute (NCI) is committed to conducting impartial, high-quality peer review. The Research Programs Review Branch of NCI's Division of Extramural Activities manages the peer review of the NCI's P01 applications. The purpose of this section of the Review Guide is to inform reviewers of their part in that important process.

Distinguishing Features of a Program Project (P01) Grant

Refer to the NCI "Guidelines for the Program Project Grant" (P01 Guidelines) for detailed information about the scope and purpose of P01 grants and applicant eligibility. Information relevant to the review process is included throughout the P01 Guidelines. The P01 Guidelines are on the CD provided in the review package and at *http://deainfo.nci.nih.gov/awards/P01.htm.*

Briefly, the purpose of the P01 award mechanism is to support coordinated research programs that achieve research synergy through the sharing of personnel, facilities, equipment, data, ideas, and concepts. Program Projects should have a well-defined central research focus and theme involving several disciplines or several aspects of one discipline. At least three research projects are required. The individual Projects should be related to the central theme of the overall program. P01 applications also may include one or more Shared Resource Core(s), each with its own budget, for administrative or research support services required for—and shared solely within—that P01. Shared Resource Cores should be important to the overall success of the program, and each Shared Resource Core must serve at least two Projects.

Central to the quality of a P01 is the leadership of the Program Director/Principal Investigator (PD/PI) and the other senior participating investigators. The PD/PI of the P01 should be an established scientist with a strong record of accomplishment who is substantially committed to, and exercises the responsibility for, the scientific leadership, integration, and administration of the entire P01. More than one PD/PI (multiple PDs/PIs) may be appropriate for "team science" approaches (see *http://grants.nih.gov/grants/multi_pi/* and the NCI P01 Guidelines for more information). If applicants propose this option, they must designate one of the PD/PIs as the corresponding or "lead" PI and include a Multiple PI Leadership Plan after the Program Overview section in the application. The Multiple PI option is only available for the overall program. Each Project or Shared Resource Core still must have a single designated Project Leader or Core Director.

Interactions between Projects should be such that the acquisition of knowledge is accelerated or of a quality beyond that expected from the same Projects conducted separately.

Review Materials Requiring Immediate Attention

The **information requiring immediate action** may be sent to you in hard copy or by secure email. It includes several items that require immediate attention:

1. Scientific Review Officer's (SRO's) Letter to the Reviewers

Read the letter from the SRO carefully. It includes information about the date, time, and place of the review; instructions for making travel arrangements; and contact information for the NCI SRO and support staff involved in the review meeting. The letter also includes important information and guidance for reviewers about special and/or new procedures for the review and explanation of specific issues that pertain to the review. The letter will also contain a list of the items that should be in the review package. In some cases, these items are posted in the "Meeting Materials" folder on the IAR website for the review meeting. Contact the SRO if you cannot locate the listed materials.

2. Conflict of Interest/Confidentiality Certification

IMPORTANT: To maintain confidentiality and freedom from conflict of interest, there should be no communication between applicants and reviewers during the course of the review. From application submission through completion of the review, all contacts should through the NCI SRO.

It is critical that members of the review panel are free of conflicts of interest (COI) and understand the need to keep all review materials and review discussions confidential. The regulations guiding conflict of interest are detailed in **Section 2** of this Guide and at: *http://grants.nih.gov/grants/peer/COI_Information.pdf.*

Discuss with the SRO any potential Conflicts of Interest you may have with any of the P01 applications under review, and **then complete the pre-meeting COI certification through the Internet Assisted Review (IAR) website**. *You must complete this in IAR before you can access the applications and post your preliminary scores and critiques in IAR.*

Reviewers in conflict will be excused from the review of specific applications based on information provided on the certification. At the end of the review meeting, reviewers also will sign the NIH Post-Review Certification Form. (or certify through the IAR website). In addition, NCI review staff will keep a log during the review meeting, confirming that persons in conflict were not present during the discussion of each application.

3. Reviewer Assignment Sheets

Reviewer Assignment Sheets for each application (yellow paper) are usually included in the package sent to you. The Assignment Sheets will indicate review assignments and conflicts of interest. Alternatively, the Assignment Sheets may be included in a secure email file from the SRO, or you may be asked to go to the IAR website to see your specific review assignments. All review assignments are confidential and should not be shared with anyone. While an individual reviewer may not have the expertise to evaluate all aspects of a given application, the combined expertise of all assigned reviewers should address them.

4. Instructions for Making Arrangements for Hotel, Travel, and Reimbursement

The NIH will make lodging reservations for reviewers who must travel to the review meeting and will pay the hotel directly for their rooms. Reviewers should make their own travel arrangements through World Travel Services (WTS), the NIH travel contractor. Read **Section 4** of this review guide for full instructions regarding procedures for making NIH travel arrangements. Note that **non-refundable** tickets are mandatory for all reviewers.

If you have an emergency and will be unable to attend the meeting, notify the NCI SRO and WTS immediately so that all flight and hotel reservations can be cancelled and your review assignments can be reassigned.

The NIH has developed the Secure Payee Registration System (SPRS) to reimburse reviewers for their peer review meeting related expenses and honoraria through Electronic Funds Transfer (EFT). You **must** be registered in SPRS to be paid. See **Section 4** of this Review Guide for instructions on registering.

5. Instructions for Registering for Access to the Internet Assisted Review (IAR) System

Appendix B of this review guide contains detailed instructions for obtaining access to the IAR Web site. Refer to these instructions well in advance of the deadline for submitting critiques. Deadlines for submission of critiques to IAR are indicated in the cover letter from the SRO and on the "Review Meeting Fact Sheet."

Other Items in the Package of Review Materials and/or the "Meeting Materials" Folder in IAR

Fact Sheet

The **Fact Sheet** shows the meeting schedule, critique submission deadlines, and hotel and

travel information specific to the review meeting.

Consultant Information Form

A Consultant Information Form may be included in your review materials. Please read through the information, make corrections as necessary for accuracy (especially the Social Security number) and home address. Return the signed form immediately to the NCI SRO. This will ensure that the NCI has the most current information in its database and that your affiliation will be correctly entered on the review meeting Roster.

Advance Preparation for the Review Meeting—Overview of Activities

1. Read the NCI "Guidelines for the Program Project Grant"

The Guidelines contain more information about the purpose of the P01 mechanism and requirements for the application.

2. Study the NCI P01 Review Procedures and Review Criteria

The review criteria and review procedures for NCI P01s are outlined below. **Table 1** lists the roles and responsibilities of the review panel members and **Figure 1 and Tables 2 through 6** present the review criteria and scoring guidelines for Projects, Shared Resource Cores, Program as an Integrated Effort, Program Leadership, and the Overall Program.

It is extremely important that all reviewers strictly adhere to the scoring guidelines in Table 2 and Figure 1 in this Guide to determine the preliminary Project scores that they post in the IAR system before the review meeting. This will ensure that all NCI P01 applications are scored according to a consistent set of standards.

3. Read the Applications

Reviewers will generally receive paper copies of only their assigned applications. For some review meetings, you may receive PDF files with the applications through secure email or you may be asked to view and/or print applications and other review materials directly from the IAR website.

All reviewers assigned to an application should be sure to read the Program Overview section of the application, which explains the overall goals and structure of the program and the role of each proposed Project and Shared Resource Core in achieving the goals, as well as the Program Integration and Management section of the application.

There may also be PDF files with color illustrations and/or other important information in the Appendix material which is accessible through IAR.

NOTE: *If an application is missing such critical information that the review of the application cannot proceed and might have to be deferred, the reviewer should contact the SRO* ***immediately.*** *The SRO will contact the applicants and attempt to obtain the necessary information prior to the review.*

4. Prepare Critiques and Submit Them Using the IAR system

Refer to the detailed instructions for accessing and using the IAR system in **Appendix B**. There are separate structured Critique Templates for Projects, Shared Resource Cores, Program as an Integrated Effort, and Program Leadership. The templates are discussed in more detail later in this Section. Briefly, all reviewers will:

- Submit critiques and preliminary scores prior to the meeting
- Read critiques submitted by others (once they have posted their own critiques); and
- Modify their critiques after the meeting to reflect their final opinions after discussion.

Completion of these steps will facilitate discussion of the applications during the meeting and preparation of timely and accurate summary statements by the SRO after the review meeting.

Overview of P01 Review by Special Emphasis Panels (SEPs)

All NCI P01 applications are reviewed by SEPs specifically convened by SROs in NCI DEA for P01 review. The number of SEPS and their topic areas vary each review cycle based on the number of applications and their research subject matter. Applications are typically grouped in the following broad topic areas:

Molecular Biology
Cellular and Tissue Biology
Discovery and Development
Prevention, Control, and Population Biology
Clinical Studies

See **Appendix D** in the **NCI P01 Guidelines** for a summary of the topics usually included in each of these areas.

SROs recruit reviewers based on the scope of research of the applications to be reviewed. Applicants may not suggest names of prospective reviewers but may suggest expertise areas needed for review.

The reviewers will include senior investigators who can view the proposed science in a global perspective, specialists needed to assess work in specific scientific areas, scientists experienced in review of NCI P01 applications, and one or more patient advocates (for P01s involving clinical research). Resubmitted applications will have some reviewers from the previous review, for continuity, as well as reviewers newly assigned to the application.

The specific roles and responsibilities of reviewers are listed in **Table 1**. In brief, each review panel will have a Chairperson who will oversee the meeting; the Chairperson may also have specific review assignments. Each application will have a Discussion Leader, designated from among the assigned reviewers for the application, who will present a short, factual description of the application's goals and research scope, take notes of the discussion, and summarize the discussions. The Discussion Leader also will be assigned to review other applications. Generally, reviewers will have assignments in several applications and are responsible for preparing a complete critique for each assignment. The NCI SRO is the designated Federal official responsible for coordination of the review process. Observers can include NCI program staff, review staff, and/or other Government staff having an interest in the review meeting.

The review of each application will be based on the submitted application, Appendix materials, and any allowable supplemental materials submitted before the review. Reviewers will evaluate each component (Projects and Shared Resource Cores) of the application, the Program as an Integrated Effort, the Program Leadership, and progress in the current funding period (for renewal applications), and then assign an overall impact/priority score for the application. The review criteria and the NCI scoring standards for each element of a P01 and the Overall Program are discussed below and shown in **Figure 1 and Tables 2 - 6.**

Program Project Review Criteria

Reviewers must evaluate the application using the specific review criteria for Projects, Shared Resource Cores, Program as an Integrated Effort, and Overall Program as described in **Tables 2** through **6**.

Review Criteria for Projects

The review criteria for P01 projects are the same as the review criteria for traditional R01 research grant applications. They are shown in **Table 2**.

The Five "Core" Review Criteria

The five "core" review criteria for P01 projects are **Significance, Investigator(s), Innovation, Approach, and Environment**. All assigned reviewers should be prepared to discuss strengths and weaknesses of each project relative to each of these criteria. An application does not need to be strong in all criteria to be judged likely to have a high scientific impact. For example, a Project that by its nature is not innovative may, when completed, produce information essential to advance a field.

Each of these "core" review criteria will receive a separate score in IAR from each assigned reviewer; the criterion scores will not be

discussed during the review meeting but will be included in the Summary Statement prepared after the review along with each reviewer's critique.

Note that integration and thematic relatedness between Projects are rated under Program as an Integrated Effort, not in the individual Projects.

Additional Review Criteria

These review criteria do not receive individual scores, but are included in the score for the project.

Research Involving Human Subjects

Federal regulations require that for applications involving human subjects, reviewers evaluate the risks to the subjects, the adequacy of the plans for protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

For all projects that include human subjects, reviewers must evaluate the plans for:

- Protection of human subjects from research risks;
- Data and safety monitoring (for clinical trials); and
- Inclusion of women, minorities, and children (each evaluated separately) in clinical research.

There are separate sections in the Critique Template for these issues. Deficiencies in any of these elements should be included as weaknesses under the "Approach" review criterion and be factored into the score for the Project and the application as a whole. Detailed information about requirements and review criteria for research involving human subjects is provided in **Section 3** of this Review Guide and in **Appendix A1,** *Human Subjects Protection and Inclusion of Women, Minorities and Children: Guidelines for Review of NIH Grant Applications*.

Research Involving Vertebrate Animals

Federal regulations require that all applications involving vertebrate animals include specific information about the number and type of animals to be used, the procedures to be performed, and plans for protecting the animals. Reviewers must evaluate these plans. (See **Appendix A2**, *Worksheet for Review of the Vertebrate Animal Section)*. There is a separate section in the Critique Template for these issues. Deficiencies in any of these elements should be included as weaknesses under the "Approach" review criterion and be factored into the score for the Project and the application as a whole.

Resubmitted Project (if Applicable)

A resubmitted (amended) Project should be evaluated primarily on the application **as now presented**. Previous strengths (and new strengths resulting from the response to the previous critiques) should be considered. Previous weaknesses and the degree to which they were resolved by any changes to the research plan should be assessed, and any remaining weaknesses or new deficiencies identified. It is important to note that a resubmitted application may be better, the same as, or worse than the previous application.

Renewal Project (Progress in the Current Funding Period)

For renewal applications, reviewers should assess the following:

- The progress and achievements of the Project on the previously proposed aims since the previous competitive review;
- The extent to which new research goals are logical extensions of previous goals;
- If the research has been redirected from that proposed originally, the adequacy of the rationale for the redirection and the progress made in the new direction; and
- Publications and accepted manuscripts that resulted from the P01 grant.

Revision Project (Competing Supplement)

A request for additional funds for a new Project should be evaluated based on the need for the additional funds relative to changes in scope of the Program research. Review of Revision applications is described later in Section 1.

Biohazards

Assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and, if needed, determine whether adequate protection is proposed.

Additional Review Considerations

Reviewers also should consider a variety of administrative issues when evaluating P01 grant applications. However, these issues should not affect the impact/priority score.

Budget and Period of Support

The requested budget should not affect the impact/priority score. However, if the requested amounts are extremely out of the norm for a particular technical approach, this may reflect inadequate appreciation of what is required for the proposed approaches, and this should be included as a weakness under the "Approach" review criterion.

Note that reviewers cannot reduce budgets to improve the ratings of Projects, Shared Resource Cores, or the Overall Program.

Reviewers should evaluate the appropriateness of direct costs requested for each year of requested support, including future years. Reviewers should note any aspects that do not appear reasonable or realistic in terms of the work to be completed, level of effort, and methodology. Specific budget areas to examine include the following:

- **Personnel**—Are the time and effort requested for the PI/Project Leader/Core Director/ involved personnel sufficient and appropriate for the scope of work?
- **Equipment and Supplies**—Are the requested equipment and supplies appropriate in relation to the work proposed? Reviewers should pay particular attention to costly items and to the use of animals. Where applicable, reviewers should note how the requested costs compare to industry norms. Are special items requested in future years necessary and well justified? Are other institutional resources available to the Program?
- **Travel**—Are the requested funds necessary and appropriate?
- **Consultants (if applicable)**—Are proposed paid consultant services essential, and is the cost/level of effort appropriate?
- **Subcontracts (if applicable)**—Are proposed subcontracts necessary to complete the Project? Is the cost/level of effort appropriate for the work being done?
- **Other Expenses (if applicable)**—Are funds for other expenses (e.g., publication costs) necessary and appropriate?

Select Agent Research

Evaluate the information provided in this section of the application including: (1) the Select Agent(s) to be used in the proposed research; (2) the registration status of all entities where Select Agent(s) will be used; (3) the procedures that will be used to monitor possession and use and transfer for Select Agent(s); and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

For further information regarding select agents, see *http://www.selectagents.gov/*

Applications including Participation from Foreign Organizations

Reviewers should assess whether the proposed work presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

- **Data Sharing Plan** (*http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.html* ;
- **Sharing Model Organisms** (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html*;
- **Genome Wide Association Studies (GWAS)** (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html*)

Review Criteria for Shared Resource Cores

Reviewers should use the following criteria to evaluate each proposed Shared Resource Core:

- Is the proposed Shared Resource Core well matched to the needs of the Projects and the Overall Program? Does it provide essential facilities or services for two or more scored research Projects?

- Are there adequate quality control processes proposed for the facilities or services provided by the Shared Resource Cores (including procedures, techniques, and quality control)? What are the criteria for prioritization and use of Shared Resource Core products and/or services?

- Are the qualifications, experience, and commitment of the Shared Resource Core Director and other key personnel adequate and appropriate for providing the proposed facilities or services?

- Will the proposed Shared Resource Core(s) provide cost effective services to the Program? Are there adequate plans to augment and/or complement an existing shared resource supported by an NCI Cancer Center Support grant (P30), if applicable?

Additional Review Criteria for Administrative Core (if proposed in the P01)

- Do the administrative resources, decision-making process for allocation of resources and funds, and plans for the evaluation of progress meet the needs of the Program?

- If an Internal or External Advisory Board (optional) is proposed, are the plans for Board meetings and use of recommendations resulting from the meetings delineated? For renewal applications, is there evidence that the Board has been consulted and action taken?

Note: Information relating to Program management, decision-making, and coordination may also be provided in the "Program Overview" section of the application.

Additional Review Criteria

The Additional Review Criteria listed above and in **Table 2** for Projects also apply to Shared Resource Cores. Therefore, reviewers should evaluate the plans for Protection of Human Subjects; Inclusion of Women, Minorities, and Children; Vertebrate Animals; and Biohazards as necessary for each Shared Resource Core.

Resubmitted, Renewal, and Revision Shared Resource Cores should be evaluated according to their individual status and purpose. Strengths and weaknesses in these additional review criteria should be considered in determining the rating for the Shared Resource Core.

Resubmitted Shared Resource Core

The Shared Resource Core should be assessed primarily on the service/support plan as now presented, including the previous strengths, new strengths that may be present due to any changes made, and any new or remaining weaknesses.

Renewal Shared Resource Core

A renewal Shared Resource Core should be assessed for the level and quality of services provided during the current funding period. If the funded Shared Resource Core included aims to improve technology or other aspects of service, were the tasks completed?

Revision Shared Resource Core
A request for additional funds for a Shared Resource Core should be evaluated based on need for the additional funds relative to

changes in scope of the Program research. Review of revision applications is described later in **Section 1**.

Additional Review Considerations

Budget and period of support; select agent research; applications from foreign organizations and resource sharing plans as listed for Projects are also applicable to Shared Resource Cores.

Reviewers should address each of these items but not consider them in rating a Shared Resource Core.

Review Criteria for Program as an Integrated Effort

The scientific and administrative integration of the Overall Program should be evaluated based on the following review criteria (see also **Table 4)**:

- Evidence of coordination, interrelationships, and synergy among the Projects and Shared Resource Cores
- Relation of all Projects and Shared Resource Cores to the common theme of the P01;
- The advantages or value added that could be realized by conducting the proposed research as a Program rather than through separate research efforts;
- The presence and quality of mechanisms for regular communication and coordination among investigators;
- The mechanisms for quality control of the research; and
- For competing renewal applications, evidence of productive collaborations, such as joint publications, resulting from the P01 award.
-

Review Criteria for the Overall Program

As shown in **Table 5, r**eviewers should evaluate the **Overall Program** by the following criteria:

- Significance of the overall research
- Investigators and Program Leadership
- Overall innovation
- Overall approach
- Overall environment
- Integration
- Progress (for renewal applications)

NCI P01 Scoring Paradigms and Standards

The integrity of the peer review system is highly dependent on reviewers having fair and unbiased viewpoints. Each reviewer must evaluate the application based on the review criteria and the NCI P01 Scoring Guidelines and not allow discipline and personal biases or other extraneous factors to influence the review or scoring. It is important that reviewers use the full range of scores, as appropriate, to allow for clear differentiation of scientific impact between applications.

The scoring/rating paradigms in **Figure 1** and **Tables 3, 4, and 6** should be followed closely to assure that the same metrics are used for all applications and that each application receives a fair and equitable review. Figure 1 and Tables 2 through 6 should all be used “left to right” – that is, reviewers should find the characteristics of the Project, Shared Resource Core or overall Program on the LEFT side of the Table or Figure, and then use the scoring range associated with those characteristics on the RIGHT side of the Table or Figure.

Impact Score for Projects

Projects will be scored from 1 to 9 in whole numbers using the Scoring Guide for Projects shown in **Figure 1**. **The score should reflect the likelihood that the project will have a sustained powerful impact on the research field(s) involved.** Assigned reviewers will also assign a 1 – 9 score for each of the five “core” review criteria. The criterion score should reflect the balance of strengths and weaknesses of the application relative to that criterion.

Rating Shared Resource Cores

Shared Resource Cores are rated Superior, Satisfactory, Minimally Satisfactory, or Unsatisfactory according to the standards in

Table 3. It is expected that most Shared Resource Cores will be rated Satisfactory. Because the Satisfactory rating represents a broad range of quality, the strengths and weaknesses noted should clearly indicate whether the Shared Resource Core is managed very well or barely meets requirements.

Rating Program as an Integrated Effort

Use **Table 4** to rate the overall Program as Highly Integrated, Integrated, or Not Integrated. Programs rated Highly Integrated should demonstrate significant scientific integration and synergy.

Impact/Priority Score for the Overall Application

Use **Table 6** to determine the overall impact/priority score for the overall application. Find the "box" that has the most appropriate Overall Program Characteristics and Impact level on the left side of the Table and then use the associated score range on the right side of the Table. The "Overall Program Characteristics" shown in **Table 6** are idealized -- It is expected that most applications will actually have characteristics in more than one of the "boxes" on the left of **Table 6**. Therefore, it is very important that reviewers explain the overall characteristics of each application and how the decision to recommend a particular "box" or score range was reached.

Components Not Recommended for Further Consideration

If a Project lacks significant and substantial merit, or if extremely hazardous procedures are proposed, or if there are extremely serious deficiencies in protection of human subjects or animals, it may be Not Recommended for Further Consideration (NRFC). In this case, the Chairperson calls for a motion and a second to the motion to "not consider the Project further." The recommendation requires concurrence of a majority of the review panel members. A brief minority report is required if there are two or more panel members in opposition to the majority. **Note** that if any component of a P01 application is Not Recommended for Further Consideration, the entire application will also be Not Recommended for Further Consideration.

Very Weak Applications Not Discussed

The Discussion Leader and/or assigned reviewers of a very weak application may recommend that it be reviewed either with an expedited discussion or with essentially no discussion if the application falls in the bottom tier of all P01 applications normally seen by the NCI, as indicated in **Table 6**. The assigned reviewers will very briefly summarize the main reasons why the application should be "Not Discussed". If there is essentially unanimous agreement among the members of the review panel who are not in conflict with the application, the application will not be discussed. The summary statement for applications not discussed will include the criterion scores from assigned reviewers for Projects, along with the essentially unedited critiques from all assigned reviewers for all components of the application.

If there is not essentially unanimous agreement for "Not Discussed", there will be an abbreviated, expedited discussion of the application before scoring.

Critique Preparation and Preliminary Scores

All reviewers must provide full critiques for each of their assignments, with strengths and weaknesses for each listed review criterion.

General Instructions

The following are general instructions for preparing critiques:

- Use Microsoft Word, in Arial (font) 11 point.
- The first time an acronym is used, it should be defined in full and given in parentheses after the term.
- Use complete thoughts, sentences or very short paragraphs when stating strengths and weaknesses.
- All comments should be de-personalized, without reference to either the applicant or the reviewer.

Structured Critique Templates

There are structured critique templates for (1) Projects, (2) Shared Resource Cores, (3) Program as an Integrated Effort, and (4) Program Leadership. (See examples of each of the Templates at the end of this Section.)

The Templates are available as Microsoft Word documents in the "Meeting Materials" folder in IAR. **It is very important for reviewers to use only these templates to ensure that the critiques will upload properly into IAR and later download properly from IAR into the summary statement.**

For Projects, there are four general sections in the Critique Template: (1) Overall Impact paragraph, (2) "Core" Review Criteria, (3) Additional Review Criteria, and (4) Additional Review Considerations. Within the latter three sections, there are separate "boxes" for entering strengths and weaknesses related to each review criterion. In all, the Critique Template for projects contains 20 "boxes," but reviewers will likely need to provide entries for only 8 - 10 "boxes" for a typical Project.

For Overall Impact, write a short paragraph summarizing the various factors that informed your Overall Impact Score. This paragraph should be a thoughtful synthesis of your opinions, not just cutting and pasting the individual bullets from the core review criteria

For each of the core review criteria and additional review criteria, provide bullets with strengths and weaknesses. These should be written in complete thoughts, sentences or very short paragraphs. You should ensure that all of your statements under Strengths and Weaknesses in the template are evaluative and indicate whether the strength or weakness you are citing is major, moderate or minor. Be sure to include bullets under Weaknesses for any core review criterion receiving a score of 3 or worse. This will ensure that the applicants understand the basis for the criterion scores and the impact score for each Project.

You should refer to an aim or set of experiments to put a strength or weakness in context (for example: "The animal model proposed in Aim 2 does (or does not) adequately reflect the human disease because…. "), but your critiques should not describe what the applicants will do in each experiment or aim, and you should not "cut and paste" from the application. However, you should be prepared to give a brief oral overview of the methods and approaches involved in the Project during the discussion during the review meeting if necessary.

The last section of the critique template for Projects and for Shared Resource Cores, labeled "Additional Comments to Applicants," is OPTIONAL. In this section, you may include a few general issues that the applicants should consider or address, but do not give specific advice about how to fix problems in the research plan in this section.

NOTE that the Critique Template for P01 Projects is essentially the same as the template for R01 applications. However, the Critique Templates for Shared Resource Cores, Program as an Integrated Effort, and Program Leadership are very different. **Be sure to use the correct Template for each review assignment!**

Reviewers will edit their critiques as necessary after the discussion of an application to ensure that their final critiques reflect any change of opinion based on panel discussion. Preliminary critiques for Program as an Integrated Effort and Program Leadership will usually need significant editing after the review to reflect the final panel discussion of these elements. Final critiques may be submitted through the IAR system during or after the review meeting.

NOTE*:* Most reviewers find it helpful to bring an electronic copy and/or a double-spaced paper copy of their critiques to the meeting so that they can easily make edits and corrections after the discussion.

Preliminary Scores for Projects

Each assigned reviewer will indicate a preliminary score for each of the five "Core" Review Criteria for Projects and a preliminary Impact score for the Project using the review criteria in **Table 2** and the scoring standards shown in **Figure 1**.

Preliminary scores for Projects will be "selected" in IAR by using "pull down"

menus. Do not include your criterion scores in your critiques.

Preliminary Ratings for Shared Resource Cores and Integration

IAR will not accept NCI's adjectival ratings for Shared Resource Cores or Program as an Integrated Effort, and will require entry of numeric criterion scores for these items. However, these numeric scores will be disregarded during the review and will not be included in the summary statement. Reviewers will just state their preliminary ratings (see **Table 3 and Table 4**) during the discussion at the review meeting.

Overall Critique and Summaries of Discussion of Projects and Shared Resource Cores

After the review is completed, the Discussion Leader generally drafts the Overall Critique, including a summary of the major goals of the proposed program and the major strengths and weaknesses of the program as a whole based on the review criteria in **Table 5**. This section should encapsulate the comments of the panel as a whole. This critique should be submitted post-review using the IAR Web site.

In addition, the primary (first) reviewer of each Project and Shared Resource Core will usually be asked to prepare a brief Summary of Discussion paragraph that captures the main strengths and weaknesses of the component based on the panel discussion. Ultimately, these summary paragraphs are included in the Overall Critique section of the summary statement.

The Summary of Discussion paragraph should begin with the Project/Shared Resource Core title and the investigator's name. Summarize the research goal in one sentence and provide a brief summary of the key strengths and weaknesses that contributed to the final impact score for the Project or the rating for the Shared Resource Core. The five Core Review Criteria listed in **Table 2** should be addressed for each Project. If there were unresolved differences of opinion among the panel members, all views should be presented.

Review Meeting Procedures

Panel Orientation

The NCI SRO will explain confidentiality and conflict-of-interest policies, review policies and procedures, the meeting agenda, and scoring standards and procedures. Members of the review panel and observers will be introduced, and meeting resources identified.

Discussion of Applications

The Chairperson will call on the Discussion Leader to begin the review of an application by presenting a brief factual, non-evaluative summary of the scope and purpose of the research program.

Projects

Each Project will be discussed in turn. Assigned reviewers will be asked to use **Table 2 and Figure 1** to present their preliminary impact score for the Project as a starting point for the discussion. The preliminary score need not be the same as that posted in the IAR system, if reading other reviewers' critiques in the IAR system caused a change of opinion. The first reviewer will then present a full critique, briefly describing the goal of the Project and then stating both strengths and weaknesses of the Project related to each Core Review Criterion. Discussion of technical details of the research plan should be kept to a minimum. Focus should be on the main strengths and weaknesses that affect the impact score for the project. The Additional Review Criteria listed in **Table 2** also should be addressed, since they affect the Project's impact score.

Each additional assigned reviewer will add his/her opinions without repeating previous points. Other panel members may then question the assigned reviewers or add new points. There will be a brief discussion to resolve issues and differing points of view. Full agreement between reviewers is not necessary. In the rare instance that a question remains that is so substantive that, without resolution, the application would need to be deferred, the SRO may contact the applicant by phone or e-mail during the meeting.

At an appropriate point, the Chairperson will call on the assigned reviewers to state their final recommended impact score for the Project **(Table 2 and Figure 1.)** The recommended impact score must be based on the review criteria for the Project and the balance of strengths and weaknesses of the Project. Other reviewers should ask for clarification from the assigned reviewers if the final recommended scores do not seem to be consistent with the stated strengths and weaknesses**.**

Each reviewer scores privately and is not bound by the recommendations from the assigned reviewers. However, reviewers who think the score should differ significantly from the indicated range should state their reasons. Finally, reviewers may make recommendations about the budget and the duration of support for the component.

Shared Resource Cores

Review of a Shared Resource Core proceeds in a manner similar to that for Projects. The first reviewer will present a full critique, stating both strengths and weaknesses related to each of the review criteria for Shared Resource Cores of NCI P01s **(Table 3)**. Additional Review Criteria, as listed in **Table 2,** should be included in the assessment of the Shared Resource Core when appropriate.

Subsequent reviewers may agree, add comments, or disagree with the first reviewer's views. Other members of the review panel should ask for clarification or add comments. Finally, the Chairperson will call for final rating of the Core by the assigned reviewers, and each reviewer rates the Shared Resource Core privately.

Overall Application -- Discussion and Scoring for Scientific Impact

After each Project and Shared Resource Core is discussed and scored/rated, the Chairperson will call on the assigned reviewers to discuss several elements of the application as a whole, including Progress in the Current Funding Period (for renewal applications), Program Leadership, Program as an Integrated Effort, and Overall Program Impact. The review criteria for each of these elements are summarized in **Tables 4 and 5.**

After a roundtable discussion of the overall application, the Chairperson will call on the assigned reviewers to state a scoring range for the Overall Program based on the scoring guide shown in **Table 6**. The overall impact/priority score should be based on the expected impact that the proposed Program will have on one or more broad areas of cancer research. The impact/priority score should not be just an average of the Project scores and Shared Resource Core ratings. Proper protection of human subjects and use of vertebrate animals should be included when assessing Program Impact.

Again, panel members who think the Overall Impact/Priority Score should be significantly different from the range stated by the assigned reviewers should state their reasons based on the Scoring Guide. Each reviewer then scores the application privately.

Recommendation for Period of Support

After scoring the Overall Program, the reviewers recommend a period of support. The Program should have sufficient proposed meritorious research to justify the number of years requested. However, reviewers may recommend a shorter period of support for individual Project and Shared Resource Core periods and/or the Overall Program.

Review of Revision Applications (Request for Supplemental Funds)

Revision applications requesting additional funding may be submitted only for P01 grants with at least 2 years of support remaining in the award period. The request must have a well-founded basis, such as:

- An additional Project or Shared Resource Core;
- Continuation of a funded Project or Shared Resource Core; or
- A request for additional resources to pursue a unique opportunity or to complete the research.

The Program Overview section of the revision application should summarize briefly the theme and research goals of the funded Program. Progress in the current funding period should be summarized for each funded Project and Shared Resource Core, including publications and completed aims. The structure of the revision application will differ depending on the nature of the funding request.

Review Criteria for Revision Applications

Revision applications (competing supplements) should be assessed according to the type of request: A full Project should be assessed using the review criteria in **Table 2** and a full Shared Resource Core should be assessed according to the review criteria in **Table 3**. In addition, reviewers should evaluate (1) integration of the new component into the ongoing Program, (2) the need for the additional funds for current Program aims, and/or (3) the quality of the unique opportunity for which funds are requested:

- Is the rationale for requesting supplemental funds well founded; e.g., are the requested funds critical to completion of the planned research, and/or does the scientific opportunity clearly deserve support? Does the proposed research augment the goal of the entire Program? Is there adequate justification for the requested expansion of the overall P01 or for additional equipment?
- Is the research approach well designed?
- Is adequate progress being made in the currently funded Program Project?
- Is the budget requested for the new research effort appropriate?

Critiques for Addition of a Project or Shared Resource Core

Critiques for each Project or Shared Resource Core in the revision application should be prepared according to the instructions given above for a Project or Shared Resource Core, using the appropriate Structured Critique Template.

Request for Extension of Research Period of a Project/Shared Resource Core

The critique should include strengths and weaknesses of the proposed Project/Shared Resource Core extension and the evidence that satisfactory progress has been made toward accomplishing the proposed aims of the Project or Shared Resource Core to be extended. The additional aims should be assessed according to the Core Review Criteria for Projects or the Review Criteria for Shared Resource Cores. Progress of the Project or Shared Resource Core and of the overall ongoing Program also should be assessed.

Request for Purchase of Equipment or Expansion of Resources

The need for such items should be evaluated relative to Program goals. Progress of the main Program should also be assessed.

TABLE 1 – ROLES AND RESPONSIBILITIES OF REVIEW PANEL MEMBERS	
Chairperson	• Ensures thorough and unbiased review of all applications • Maintains agenda • Maintains review etiquette • Calls on Discussion Leader to introduce each application • Calls on reviewers and moderates all discussions • Moderates differences of opinion among review panel members • Calls for final scoring recommendations at appropriate point in discussions
Discussion Leader	• Provides brief descriptive, non-evaluative introduction for assigned application • Takes notes of strengths and weaknesses for each element reviewed • Summarizes discussion as requested by the Chairperson • Drafts overall program critique to reflect panel discussion and recommended impact score
Reviewers	• Read applications from a general perspective (in particular the Program Overview and Program Integration sections) and study their specific assignments in detail • Prepare written preliminary critiques of applications assigned to them • Post critiques in IAR system prior to the review meeting • Read critiques posted in IAR by other reviewers • Ask for clarifications if scores recommended by assigned reviewer(s) do not seem consistent with project/core/program characteristics as defined in NCI P01 scoring tables • Score each component of the application following group discussion. • Update critiques in IAR after the review is completed
First named reviewer for each component	• Prepares a “summary of discussion” paragraph for a given component of a P01 application to reflect the final discussion and impact score/core rating.
Patient Advocate	• Serves as the NCI’s link to the patient population • Provides input related to the use of human subjects, focusing on the significance and timeliness of the proposed research. • Reports on the use of human subjects in the application(s) assigned to them. • Considers if participation in a given clinical trial is too onerous or problematic, and if it is likely that patient compliance can be secured for the length of the trial. • Asks questions to gain a clearer understanding of the research/trial plan
NCI SRO	• Serves as the Designated Federal Official with legal responsibility for managing the review and ensuring that it is conducted according to relevant laws, regulations, and established NIH and NCI policies and procedures. • Recruits and assigns reviewers • Explains review policies and procedures as necessary during the review • Prepares summary statement for each application after the review is completed

TABLE 2—ENHANCED REVIEW CRITERIA FOR PROJECTS

Overall Impact: Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in considering the following five core review criteria and the additional review criteria listed below (as applicable for the project proposed).

Core Review Criteria: Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s): Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria: As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items**.** (See NCI P01 Review Guide for further information about each.)

Protections for Human Subjects
Inclusion of Women, Minorities, and Children
Vertebrate Animals
Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.
Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.
Revision Applications. When reviewing a Revision application (formerly called a competing supplement), the committee will consider the appropriateness of the proposed expansion of the scope of the project
Biohazards.

Additional Review Considerations: As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score. (See NCI P01 Review Guide for further information about each.)

Budget and Period Support. .
Select Agent Research.
Applications from Foreign Organizations
Resource Sharing Plans

Figure 1 – Scoring for Projects

Reviewers should consider not only the relative number of strengths and weaknesses noted, but also the importance of these strengths and weaknesses to the criteria or to the overall impact when determining a score. For example, a major strength may outweigh many minor and correctable weaknesses. The table below provides additional guidance to assist reviewers in determining their ratings.

STRENGTHS/WEAKNESSES*	IMPACT	DESCRIPTOR	SCORE
Exceptionally strong with essentially no weaknesses	**High**	**Exceptional**	**1**
Extremely strong with negligible weaknesses		**Outstanding**	**2**
Very strong with only some minor weaknesses		**Excellent**	**3**
Strong with numerous minor weaknesses	**Moderate**	**Very Good**	**4**
Strong but with at least one moderate weakness		**Good**	**5**
Some strengths but also some moderate weaknesses		**Satisfactory**	**6**
Some strengths but with at least one major weakness	**Low**	**Fair**	**7**
A few strengths and a few major weaknesses		**Marginal**	**8**
Very few strengths and numerous major weaknesses		**Poor**	**9**

***Minor Weaknesses: An easily addressable weakness that does not substantially lessen impact.**
Moderate Weakness: A weakness that lessens impact
Major Weaknesses: A weakness that severely limits impact

TABLE 3 – SCORING GUIDELINES FOR SHARED RESOURCE CORES

Shared Resource Core Characteristics	Merit Rating
In addition to the qualities of a Satisfactory Shared Resource Core: • Provides exceptional service(s) encompassing truly unique, innovative approaches and cutting-edge technology • Offers exceptional resources and highly experienced leadership	**Superior** This is an "Honors" rating. Only a few Shared Resource Cores are expected to be rated in this range.
• Services required for completion of program goals • Provides services to at least TWO projects in the program project **AND** 1. Provides services to program efficiently 2. Necessary techniques are in place 3. Methods proposed for providing and prioritizing services are appropriate 4. Has adequate leadership and personnel for proposed core activities	**Satisfactory** This is a "Passing" rating. Most Shared Resource Cores are expected to be rated in this range.
Moderate to serious weaknesses in items 1 – 4 above, but overall the Core should probably be able to support the program	**Minimally Satisfactory** This is a "Barely Passing" rating. Shared Resource Cores rated in this range typically weaken the overall program.
• Supports only one project in the program OR services not required for program and/or • Very serious weaknesses in Items 1 – 4 above, suggesting that the Core will not be able to support the program.	**Unsatisfactory** Shared Resource Cores rated in this range weaken the overall program

TABLE 4—ASSESSMENT OF PROGRAM AS AN INTEGRATED EFFORT

Characteristics of Program Integration	Possible Ratings
• Evidence of coordination, interrelationships, and synergy among the meritorious research project and core components as related to the common theme of the P01 • The advantages or value added by conducting the proposed research as a program rather than separate research efforts; • The presence and quality of mechanisms for regular communication and coordination among investigators • The mechanisms for quality control of the research • For competing renewals, evidence of productive collaborations, such as joint publications, resulting from the P01 award	Highly Integrated* Integrated Not Integrated

* **A highly integrated program is one having both integrated and synergistic relationships among the majority of projects and cores.** Program **Synergy** results from structuring the research effort so that the intellectual and technical exchanges that occur because of the P01 research environment significantly expedite and enhance the overall results and progress. Synergy goes beyond a simple commonality of theme and sharing of reagents and technology.

TABLE 5—REVIEW CRITERIA FOR OVERALL PROGRAM

Significance: Does the program as a whole address an important problem or a critical barrier to progress in the field? If the aims of the program are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the program change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigators/Program Leadership: Are the qualifications of the PD(s)/PI(s) and other senior scientists appropriate to lead the P01 and coordinate all P01 activities? Do they provide effective scientific and administrative leadership, as demonstrated by selection of individual projects for scientific excellence and thematic relatedness? Is the commitment (percent effort) of the PD(s)/PI(s) and other senior investigators adequate? For applications designating multiple PDs/PIs, is the leadership approach, including the designated roles and responsibilities, governance, and organizational structure, consistent with and justified by the aims of the program and the expertise of each of the PDs/PIs?

Innovation: To what degree does the overall program challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Is the overall design of the P01, including strategies, methodologies, and analyses, well-reasoned and appropriate to accomplish the specific aims of the program? What is the overall quality of the projects and the adequacy of services provided by the shared resource cores (if proposed)?

For competing renewal applications, has there been adequate progress during the current funding period?

If the program involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the program adequate for the project proposed? Will the program benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Integration: Is there evidence of scientific and administrative integration of the proposed Program? Is there evidence of coordination, interrelationships, and synergy among the individual research projects and shared resource core components? Are there clear advantages or “value added” by conducting the proposed research as a Program Project rather than through separate research efforts?

For competing renewal applications, is there evidence of productive collaborations during the current funding period?

TABLE 6 – NEW SCORING GUIDELINES FOR OVERALL PROGRAM

Overall Program Characteristics	Overall Program Impact	Scoring Range
• Likely to have sustained powerful influence on broad areas of basic, translational, clinical and/or population-based cancer research • Uniformly exemplary projects and shared resource cores – essentially no weaknesses • Exemplary leadership • Highly integrated • Exceptional overall progress in the current funding period (for competing renewals)	High	**1**
• Likely to have strong and lasting influence on one or more broad fields of cancer research or to advance clinical practice • Uniformly strong projects and shared resource cores – only a few minor weaknesses • Strong leadership • Highly integrated • Strong overall progress in the current funding period (for competing renewals)	High	**2 or 3**
• Likely to have a significant influence on a defined field or have some potential to impact clinical practice • Moderate weaknesses in one or more projects and/or shared resource cores • Strong leadership • Integrated to highly integrated • Appropriate overall progress in the current funding period (for competing renewals)	Moderate	**4 or 5**
• Likely to influence a defined or limited field, or confirmatory, derivative or descriptive studies • Moderate to serious weaknesses in several projects and/or shared resource cores • Adequate leadership • Integrated • Adequate to limited overall progress in the current funding period (for competing renewals)	Moderate to Low	**6 or 7** (Programs likely to be rated in this range based on preliminary scores and critiques in IAR should have expedited discussion or be not discussed)
• Unlikely to have much influence on the field or on clinical practice • Serious to critical weaknesses in several projects and shared resource cores outweigh strengths • Adequate to inadequate leadership • Not integrated to integrated • Limited overall progress in the current funding period (for competing renewals)	Low	**8 or 9** (Programs likely to be rated in this range based on preliminary scores and critiques in IAR should be not discussed)

RESEARCH PROJECT CRITIQUE

For detailed information on the criteria and considerations listed below Refer to Guidelines for P01 Grants. See Review Criteria in the NCI P01 Guidelines. *http://deainfo.nci.nih.gov/awards/P01.pdf*

Application #:
Principal Investigator(s):
Project Number/Name:
Project Leader's Name(s):

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Overall Impact Write a paragraph summarizing the factors that informed your Overall Impact Score

Core Review Criteria

1. Significance
Strengths • **Weaknesses** •

2. Investigator(s)
Strengths • **Weaknesses** •

3. Innovation
Strengths • **Weaknesses** •

4. Approach
Strengths • **Weaknesses** •

5. Environment
Strengths • Add bullets as needed **Weaknesses** •

Additional Review Criteria: The following items are not scored individually, but should be considered when determining the impact score.

Protection of Human Subjects
Click here to select Human Subject Code Comments (Required Unless Not Applicable): • Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): o
Inclusion of Women, Minorities, and Children (Applicable Only for Human Subjects Research)
Click here to Select Gender Code Click here to Select Minority Code Click here to Select Children Code Comments (Required Unless Not Applicable): • Add bullets as needed
Vertebrate Animals
Click here to Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): • Add bullets as needed
Biohazards
Click here to Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): • Add bullets as needed

Resubmission (amended)
Comments (if applicable): • Add bullets as needed

Renewal
Comments (if applicable): • Add bullets as needed

Revision (Competitive Supplement)
Comments (if applicable): • Add bullets as needed

Additional Review Considerations: The impact/priority score should not be affected by the following considerations.

Budget and Period of Support

Select Recommend or Recommend with Modifications • Add bullets as needed
Select Agents
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): • Add bullets as needed
Work Performed at a Foreign Organization
Select Justified, Unjustified, or Not Applicable Comments (Required Unless Not Applicable): • Add bullets as needed
Resources Sharing Plan
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): • Add bullets as needed
Sharing Model Organisms
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): • Add bullets as needed
Genome Wide Association Studies (GWAS)
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): • Add bullets as needed
Additional Comments to Applicant (Optional)
• Add bullets as needed

SHARED RESOURCE CORE CRITIQUE

For detailed information on the Review Criteria for Shared Resource Cores listed below, see Section X. C in the NCI P01 Guidelines.

Application #:
Principal Investigator:
Core Number/Name:
Core Director's Name:

Quality of Services and Plans for Supporting the Projects in a Cost-effective Manner
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed
Investigators
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed
Environment
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed

Additional Review Criteria: The following items are not scored individually, but should be considered when determining the impact score.

Protection of Human Subjects against Research Risk
Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): • Add bullets as needed Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): o
Inclusion of Women, Minorities, and Children - Applicable Only for Human Subjects Research
Select Gender Code

Select Minority Code Select Children Code Comments (Required Unless Not Applicable): • Add bullets as needed
Vertebrate Animals
Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): • Add bullets as needed
Biohazards
Select Acceptable, Unacceptable, or Not Applicable Comments (Required Unless Not Applicable): •

Resubmission (Amended application)
Comments (if applicable): • Add bullets as needed
Renewal
Comments (if applicable): • Add bullets as needed
Revision (competitive supplement)
Comments (if applicable): • Add bullets as needed

Additional Review Considerations: The score should not be affected by the following considerations.

Budget and Period of Support
Select Recommend or Recommend with Modifications • Add bullets as needed
Select Agents
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): •
Applications from Foreign Organizations

Select Justified, Unjustified, or Not Applicable Comments (Required Unless Not Applicable): •
Resource Sharing Plans
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): •
Sharing Model Organisms
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): • Add bullets as needed
Genome Wide Association Studies (GWAS)
Select Acceptable, Unacceptable, or Not Applicable Comments (Required if Unacceptable): • Add bullets as needed

ADDITIONAL COMMENTS TO APPLICANT (OPTIONAL)
• Add bullets as needed

PROGRAM AS AN INTEGRATED EFFORT

For detailed information on the Review Criteria for Program as an Integrated Effort, see Section X. A in the NCI P01 Guidelines and **Table 4** in the NCI P01 Review Guide.

Application #:

Principal Investigator:

Program as an Integrated Effort
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed

PROGRAM LEADERSHIP

For detailed information on the review criteria for Program Leadership, refer to **Table 5** in the NCI P01 Review Guide.

Application #:

Principal Investigator:

Program Leadership
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed

PROGRAM AS AN INTEGRATED EFFORT

For detailed information on the Review Criteria for Program as an Integrated Effort, see Section X. A in the NCI P01 Guidelines and **Table 4** in the NCI P01 Review Guide.

Application #:

Principal Investigator:

Program as an Integrated Effort
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed

PROGRAM LEADERSHIP

For detailed information on the review criteria for Program Leadership, refer to **Table 5** in the NCI P01 Review Guide.

Application #:

Principal Investigator:

Program Leadership
Strengths • Add bullets as needed **Weaknesses** • Add bullets as needed

SECTION 2: CONFLICT OF INTEREST, CONFIDENTIALITY, AND MISCONDUCT: GRANTS AND COOPERATIVE AGREEMENTS

Introduction

This section deals with administrative issues critical to proper conduct of peer review:

- Avoiding conflict of interest;
- Protecting confidentiality; and
- Addressing misconduct.

The National Institutes of Health (NIH) updated its rules on confidentiality and conflict of interest in January 2005. Therefore, even experienced reviewers should read this section to ensure their understanding of the rules is up to date.

Conflict of Interest in Peer Review

All reviewers involved in any National Cancer Institute (NCI) peer review process must unequivocally avoid both **real conflict of interest** and/or **the appearance of conflict of interest**. Such conflicts exist when a peer review committee member or close associate can be viewed as being in a position to gain or lose personally, professionally, or financially from an application under consideration.

There are two broad categories of conflict:

- The reviewer holds an appointment at the applicant's own institution.
- The reviewer has a relationship (personal or professional) with the applicant.

Real conflict of interest means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as determined by the SRO managing the review. Interest in an organization includes ownership of stock in or being a consultant to a for-profit organization.

A reviewer has a **real conflict of interest** if he/she or a close relative or professional associate has

- Received or could receive a direct financial benefit of any amount deriving from an application or proposal under review;
- Received or could receive a financial benefit from the applicant institution, offeror, or Principal Investigator (PI) that in the aggregate exceeds $10,000 per year ($15,000 per year for reviewers who are Federal employees). This amount includes honoraria, fees, stock, or other financial benefit and additionally includes the current value of the reviewer's already-existing stock holdings, apart from any direct financial benefit deriving from an application or proposal under review; or
- Any other interest in the application that is likely to bias the reviewer's evaluation of that application or proposal.

Appearance of a conflict of Interest means that a reviewer or close relative or professional associate of the reviewer has a financial or other interest in an application that is known to the reviewer or the SRO managing the review and would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review. The SRO will evaluate the appearance of a conflict of interest and determine whether the interest would likely bias the reviewer's evaluation of the application. Where there is an appearance of conflict of interest but not sufficient grounds for disqualifying the reviewer, the SRO in charge of the review will document that (1) there is no real conflict of interest, and (2) at the time of the review, no practical alternative exists for obtaining the necessary scientific advice from the reviewer with the apparent conflict.

Regardless of the level of financial involvement or other interest, if the reviewer feels unable to provide objective advice, he/she must recuse him/herself from the review of the relevant application.

Categories of Potential Real or Perceived Conflict

Reviewers should evaluate the following categories of potential conflict and determine whether any of these applies to their review of any given application or proposal:

Employment: A reviewer who is a salaried employee, whether full-time or part-time, of the applicant institution, offeror, or PI or is negotiating for employment is in real conflict of interest with an application from that organization or PI. The Director of the NIH or his/her designee may determine there is no real conflict of interest or an appearance of a conflict of interest where the components of a large or multicomponent organization are sufficiently independent to constitute, in effect, separate organizations, provided that the reviewer has no responsibilities at the institution that would significantly affect the other component. Membership in a scientific review group (SRG) does not make an individual an employee or officer of the Federal Government.

Financial Benefit: See definition of **real conflict of interest** on page 1.

Personal Relationships (Relatives): A close relative is a parent, spouse, sibling, son, daughter, or domestic partner. A conflict of interest exists if a close relative of a reviewer submits an application or receives or could receive financial benefits from or provides financial benefits to an applicant or offeror.

Professional Associates: Professional associate means any colleague, scientific mentor, teacher, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities within 3 years of the date of the review.

Standing Review Group Membership: When an SRG meets regularly, a relationship exists among the members. Therefore, the group as a whole may not be objective about evaluating the work of one of its members. In such a case, a group member's application will be reviewed by another qualified review group to ensure that a competent and objective review is obtained.

Longstanding Disagreements: A conflict of interest may exist where a potential reviewer has had longstanding scientific, personal, or professional differences with an applicant.

Multisite or Multicomponent Projects: An individual serving as either the PI or key personnel on one component of a multisite or multicomponent project has a conflict of interest with all of the applications from all investigators or key personnel associated with the project. The individual should be considered a professional associate when evaluating applications submitted by the other participants in the project.

Request for Applications (RFA): Any individual serving as the PI or key personnel on an application submitted in response to an RFA is generally considered to have a conflict of interest with all of the applications submitted in response to the RFA. However, if no other reviewer is available with the expertise necessary to ensure a competent and fair review, a waiver may be granted by the Director of the NIH or his/her designee that will permit an individual to review only those applications with which he/she has no conflict of interest that would be likely to affect the integrity of the reviewer's advice.

Waivers

A blanket waiver of conflict of interest has been obtained for the following collaborations **so long as any real or apparent conflict of interest is resolved:**

- If an individual supplies a resource or service to an applicant and that resource or service is freely available to anyone in the scientific community, neither the institution nor the individual supplying the resource is in conflict.
- For fellowship and K-award applications, peer reviewers who write reference letters for an applicant are in conflict and must leave the room for the review of the application. This does not, however, constitute an **institutional** conflict. If the applicant's sponsor is a member of the review group, this constitutes a **member** conflict for the study section; i.e., the study section may not review the application.
- Reviewers from institutions that are part of a multicenter network (e.g., accrual sites for a multicenter clinical trial) are not in conflict with

other applications/proposals from other institutions in the network; furthermore, reviewers from institutions that provide members of an applicant's advisory board or data and safety monitoring board are not in conflict with other applications from those institutions.

Before the Review Meeting

Prior to the peer review meeting, each reviewer will complete a Certification of Conflict of Interest and Confidentiality after examining a list of investigators and institutions associated with the applications to be reviewed. Reviewers must notify the SRO of any conflict of interest prior to the meeting and certify that the confidentiality of the review proceedings will be maintained.

At the Review Meeting

At the actual review meeting, the reviewer must leave the room when an application with which he/she is in conflict is being discussed.

During the meeting, a log will be kept of which reviewers leave the room because of potential conflict of interest with individual applications.

At the end of the meeting, the SRO will ask all review committee members to certify in writing that they have not, in fact, participated in the review of any applications when their presence would have constituted a real or apparent conflict of interest and that the confidentiality of actions will be maintained.

Confidentiality and Communications With Investigators

The NCI assures applicants that their identity, their applications, and the associated reviews will be held in confidence. To provide for this assurance, all materials pertinent to the review are privileged communications prepared for use only by reviewers and NCI staff and should not be shown to or discussed with other persons. Any breach of confidentiality is considered unethical and has adverse effects on a reviewer's reputation and/or the reputation of his/her institution, in addition to undermining the integrity of the peer review process. Reviewers must not, therefore, independently solicit opinions or reviews on particular applications or parts thereof from experts outside the pertinent review committee. Reviewers may, however, suggest scientists from whom the SRO may subsequently obtain advice. Reviewers are required to leave all review materials with the SRO at the conclusion of the review meeting. Privileged information must not be used to the benefit of the reviewer or shared with anyone.

Reviewers must not—under any circumstances—advise applicants, their organizations, or anyone else of recommendations or discuss the review proceedings. Applicants may be led into unwise actions on the basis of premature or erroneous information. Such advice also represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of others serving on review committees. A breach of confidentiality could deter qualified reviewers from serving on future committees and inhibit those who do serve from engaging in free and full discussion of recommendations.

Except during site visits necessary for review of applications for certain types of awards, there must be no direct communication between reviewers and applicants. Reviewers' requests for additional information and telephone inquiries or correspondence from applicants must be directed to the SRO, who will handle all such communication.

Misconduct

"Misconduct" or "misconduct in science" is defined at 42 CFR 50.102 as fabrication, falsification, plagiarism, or other practices that seriously deviate from those practices commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretation or judgments of data.

During the initial review of applications, the review committee may identify instances of suspected or possible misconduct (e.g., suspicions regarding possible plagiarism or questionable data or accomplishments cited in support of the proposed research). The SRO, in consultation with the Chairperson, must first determine from the discussions of the SRG whether the review may proceed. Generally, what appears to be a relatively "minor" impropriety (such as the unattributed use of small amounts of textbook material in the Background section of an application) would not

prevent the review committee from providing a fair review.

The general principle is that if the SRG is able to provide an unbiased technical/scientific merit review unaffected by the suspicions of misconduct, it should do so. If it is determined that a fair review cannot be carried out because of the existence of reviewers' concerns about possible misconduct, immediate deferral of the application is the correct course of action.

In either case, the concerns of the SRG will be forwarded by the SRO through the Review Group Chief and cognizant agency-level Misconduct Policy Officer to the Office of Scientific Integrity (OSI), Department of Health and Human Services, for resolution.

It is important that reviewers appreciate the seriousness of such allegations and the potential harm that may result if confidentiality is not strictly maintained. The SRO or a reviewer must not communicate—in any instance—the review committee's concerns to the applicant or applicant institution. Any subsequent communication with the applicant and/or applicant institution will occur only through the OSI.

SECTION 3: ADMINISTRATIVE ISSUES AND FEDERAL REQUIREMENTS

Introduction

This section of the review guide covers the Federal requirements reviewers must consider when evaluating grant and cooperative agreement applications and contract proposals:

- Research involving human subjects;
- Research involving vertebrate animals;
- Data and safety monitoring plan;
- Sharing research data;
- Genome Wide Association Studies;
- Sharing of model organisms;
- Research involving human embryonic stem cells (hESC);
- Standards for privacy of individually identifiable health information;
- NIH Public Access Policy; and
- URLs in NIH grant applications or appendixes.

Reviewers have an obligation to examine and note any concerns or comments for all of these items, regardless of whether the issue can have an effect on scientific merit. **For grant review**, research plans for human subjects and vertebrate animals are to be evaluated in assigning merit. **For contract proposal review**, the Technical Proposal Instructions in the Request for Proposal (RFP) will identify the information offerors must provide. The Technical Evaluation Criteria will indicate how the information is to be considered in scoring.

Research Involving Human Subjects

Appropriate use of human subjects in research is a Federal requirement as well as an aspect of research merit.

Federal regulations require that applications and proposals involving human subjects be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

Reviewers should refer to the Human Subjects heading in Section 1 for guidance on evaluating human subjects research as it pertains to this particular grant, cooperative agreement, or contract. Please refer to **Appendix A1,** *Human Subjects Protection and Inclusion of Women, Minorities, and Children: Guidelines for Review of NIH Grant Applications.*

Research Involving Vertebrate Animals

Appropriate use and care of vertebrate animals in research is not only an aspect of research merit, it is also a Federal requirement.

Recipients of Federal support for activities involving live vertebrate animals must comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (*http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf*) as mandated by the Health Research Extension Act of 1985 (*http://grants.nih.gov/grants/olaw/references/hrea1985.htm*) and the U.S. Department of Agriculture (USDA) Animal Welfare Regulations (*http://www.access.gpo.gov/nara/cfr/waisidx_06/9cfrv1_06.html*) as applicable.

Reviewers should refer to the Protection of Vertebrate Animals heading in **Section 1** and **Appendix A2**, *Worksheet for Review of the Vertebrate Animal Section*, for guidance on evaluating applications and proposals for the appropriate care and use of vertebrate animals in research.

Data and Safety Monitoring Plan

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (phase II); and efficacy, effectiveness, and comparative trials (phase III). Monitoring should be commensurate with risk. NIH Policy for Data and

Safety Monitoring requires that all applicants must establish data and safety monitoring boards (DSMBs) for multisite clinical trials involving interventions that entail potential risks to participants.

Sharing Research Data

Applications or contract proposals seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible. Reviewers should consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Genome-Wide Association Studies (GWAS)

All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, *NIH Guide NOT-OD-07-088*. Reviewers should consider the plan for submission of GWAS data but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms

The NIH is committed to supporting efforts that encourage sharing of important research resources, including model organisms for biomedical research. At the same time, consistent with the Bayh-Dole Act of 1980, the NIH recognizes the rights of grantees and contractors to choose to retain title to subject inventions developed with Federal funding.

All investigators submitting an application or contract proposal in which the development of model organisms is anticipated are expected to include a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. Reviewers should consider the plan for sharing model organisms but will not factor the plan into the determination of the scientific merit or the priority score.

Human Embryonic Stem Cells hESCs)

Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at *http://grants.nih.gov/grants/guide/noticefiles/NOT-OD-09-116.html.* Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (*http://escr.nih.gov*). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Issues regarding an investigator's access to a particular stem cell line are not a component of the scientific review and will be handled by NIH grants administrative practices. Under most circumstances, hESC research will not involve human subjects and, therefore, will not require IRB review or approval.

Standards for Privacy of Individually Identifiable Health Information

The U.S. Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html .*

NIH Public Access Policy

In accordance with the NIH Public Access Policy, *investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central* (see *http://www.pubmedcentral.nih.gov/*), *an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.* The NIH Public Access Policy is available at (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html*). For more information, see the Public Access webpage at *http://publicaccess.nih.gov/*.

URLs in NIH Grant Applications or Appendixes

Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used by applicants or offerors to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. In fact, reviewers' anonymity may be compromised if they do so.

SECTION 4: TRAVEL, CONSULTANT FEE, AND REIMBURSEMENT INFORMATION

NEW – CHANGES TO THE REIMBURSEMENT PROCESS EFFECTIVE January 17, 2009

NIH Implements New Registration Process for Reviewer Reimbursement for Participation in NIH Peer Review Meetings

The new reimbursement system called the Secure Payee Registration System (SPRS) replaces the U.S. Treasury Central Contract Registration (CCR) system. SPRS is a secure site used to reimburse reviewers for their review meeting related expenses and pay honorarium through Electronic Funds Transfer (EFT) payments made directly to your bank account. Only the reviewer can access the SPRS page, using their eRA Commons user name and password. Foreign reviewers without a U.S. bank account will also need to register in SPRS, but will receive a paper check via mail. Registration in SPRS is required for all reviewers in order for NIH to process honoraria and reimbursements for expenses related to participation in NIH peer review meetings. If you are not registered, you will not receive reimbursement.

In this package the document, entitled **"Registration Instructions for NIH Reviewers to Receive Reimbursement and Honoraria for Participation in NIH Peer Review"**, provides step-by-step instructions on how to successfully register in SPRS. You may also obtain a copy of the instructions at http://grants.nih.gov/grants/peer/peer.htm.

Important Notes about SPRS:

- Registration in the system is required to receive disbursement.
- Information entered as part of the new registration process will be kept secure and confidential.
- NIH registration does not need to be renewed annually.
- Reviewers will not be spammed by third party solicitations.
- If a reviewer changes to another bank or changes their residential address, the banking and/or residential address information must be updated through eRA Commons.

Reviewers who were registered in CCR in order to receive reimbursement related to NIH peer review meetings, may cancel their CCR registration if they wish. Anyone with an active CCR account will continue receiving automatic reminders from CCR to renew his/her CCR registration. Reviewers **DO NOT** need to renew their CCR registration and should ignore all communications.

To Cancel Your CCR Registration:

- Go to www.ccr.gov
- Click on "Update or Renew Registration"
- Check "I am not a U.S. Government entity"
- Enter your DUNS Number and TPIN and click "Log In"
- On the next screen click "Delete Profile" in the upper left corner to cancel your registration.
- Your CCR profile will be instantly removed from the CCR database.

Or

- Contact the CCR Helpdesk at (888) 227-2423 or (269) 961-5757

Introduction

The NIH Center for Scientific Review (CSR) administers the Scientific Review and Evaluation Activities (SREA) program, which funds the reimbursement of travel, lodging, per diem, and consultant expenses for peer reviewers.

This section contains the following information pertaining to travel in conjunction with peer review meetings:

- An overview of expenses that **are** or **are not** reimbursable;
- Flat-rate reimbursement information;
- Policy on airfare and train rates;
- Guidelines for telephone and mail reviewers; and
- Frequently asked questions about travel reimbursement.

Special Note for Federal Employees

Federal employees traveling in connection with a review meeting **must** have travel orders. Federal employees **must** contact the National Cancer Institute (NCI) Scientific Review Officer (SRO) because regulations that apply to Federal employees differ from those outlined in this section.

Reviewer Reimbursement Fees

The SREA program utilizes a flat rate system to reimburse non-federal reviewers for meals and incidental expenses associated with their service on scientific review groups. The flat rate is calculated based on the number of meeting days and whether the reviewer is local (within 50 miles of the meeting location) or non-local. Additionally, hotel lodging and travel tickets (obtained through the government's travel agency, World Travel Service) are billed directly to the government. Exceptions to this process for covering travel related costs will require prior approval (see details in the section "Request for Travel Exceptions").

Once a review meeting is over and all of the reviewers' assignments are complete, reviewers will be reimbursed for their expenses without the need to submit vouchers or receipts.

CONSULTANT FEES

A consultant fee of **$200** per meeting day will be provided for reviewers' attendance at meetings and teleconferences.

A consultant fee of **$100** will be paid to reviewers' participating by mail review.

FLAT RATE REIMBURSEMENT FEES

Ground Transportation and Incidentals

The **$195 flat-rate** reimbursement per meeting will cover non-local reviewers' ground transportation and incidental expenses related to a single peer review meeting. Local reviewers will receive **$75** each day they make a round trip to the meeting.

The following costs are included in the flat-rate reimbursement for incidental expenses:

- Rental cars and private car/taxi service;
- Telephone calls;
- Postage;
- Internet access charges;
- Baggage and other tips, etc.

Meals

The flat-rate meal reimbursement for peer reviewers is **$80** per meeting day for non-local reviewers and **$45** per meeting day for reviewers within 50 miles of the meeting site.

Expenses That MAY NOT Be Paid to Reviewers

The following expenses may not be charged for reimbursement:

- Consultant fees, per diem, or travel reimbursement to Federal employees—*Federal employees should contact the NCI SRO for further information*;
- Dues (scientific societies and clubs);
- Honoraria or rewards where the primary intent is to confer a distinction on the recipient;
- Equipment purchases, patient care costs, and other expenses not directly related to review activities;

- Social activities, including bar charges, entertainment, gifts for reviewers, and similar activities;
- Personal travel; and
- Dependent care.

Prepaid Expenses

HOTEL

NIH will make and pay for reviewers' hotel accommodations directly. Reviewers will be responsible for ancillary charges to their rooms, such as phone calls, movies, minibar, and/or room service, etc. Please notify the SRO or his/her assistant if you have special lodging needs. The SRO will send reviewers a confirmation number for hotel reservations.

IMPORTANT: Reviewers should notify the NCI SRO and the hotel if their plans change and they will not be attending the meeting or if they do not need lodging for all scheduled nights.

IMPORTANT TRAVEL INFORMATION:

NCI has arranged with World Travel Service (WTS) to provide reviewers' airfare, rail, and rental car ticketing reservation services. Reservations may be made by phone, email, fax, or on-line booking. WTS will respond to reviewers' inquiry within 1 business day.

Airfare

WTS will supply prepaid airline tickets. **Purchase of a non-refundable airline ticket is now mandatory** since NIH can no longer provide Government rate tickets. Nonrefundable tickets will enable reviewers to choose flights from any domestic airport on any domestic airline, to accumulate and use personal frequent flyer miles, and to maintain personal travel preferences. **Reviewers must contact WTS directly to make any changes in nonrefundable tickets**. A request to change a non-refundable ticket will require prior approval by the NCI Committee Management Office for any change that results in a total cost increase **greater than $500.00** (including change fees and fare increases), or if the departing flight is less than two hours from the originally scheduled departing time. (See WTS contact information on the FACT sheet.) WTS will bill the NCI directly for airline tickets.

NOTE: Any reviewer who wishes to make flight arrangements through his/her own travel agent must file an exception through the SRO prior to making the airfare reservation. Reviewers will be reimbursed only up to the cost of a non-refundable WTS ticket when they make their own travel arrangements.

Business- and First-Class Air Travel

Generally, business- and first-class travel is not allowed. However, exceptions can be made in certain instances; e.g., medical reasons. Reviewers should contact the NCI SRO well in advance of the date of the trip because changes to regulations have lengthened the approval process to 45 days.

Foreign Travel

In traveling between the United States and foreign countries, and between foreign countries, U.S. flag air carriers must be used whenever service is available, regardless of cost, convenience, or personal preference. However, a foreign flag carrier can be used if the traveler has to wait more than 4 hours between flights. Reimbursement for transportation on foreign carriers must be disallowed in the absence of prior approval and adequate justification.

Car Rental

Generally, car rentals are not allowable on site visits or for review meetings in the Bethesda/Rockville area.

However, the location of some site visits may make car rental more cost effective than taxi or limousine services. The NCI SRO will indicate when this is the case for specific site visits. If it is necessary to rent a car for any other reason and ground transportation and incidental costs will exceed the flat-rate payment of **$195**, reviewers should provide an estimated cost and a justification to the SRO and request an exception.

Collision damage waiver, collision damage insurance, and personal accident insurance are not reimbursable.

Private Car

Private automobiles may be used for travel only when they represent the most cost-effective mode of travel. When a private car is used, mileage (preferably the odometer readings) must be provided. Reimbursement is provided on a cents-per-mile basis.

The use of your private automobile is a travel exception, you will need to contact the SRO and provide the necessary information.

Additional Information on Travel Reimbursement

Nonattendance of Meetings

If a reviewer finds that he or she is unable to attend an NCI-scheduled meeting, the reviewer **must** contact both the SRO and the hotel. The reviewer is also responsible for canceling travel reservations.

Request for Travel Exceptions

Prior approval from the NCI Committee Management Office is required for all travel exceptions, i.e. a reviewer plans on driving to meeting instead of using WTS; reviewer plans on using a rental car for travel; reviewer plans on purchasing their own airline ticket; etc. and reviewers who expect to exceed the allotted flat rates for ground transportation and incidentals.

No later than 2 weeks before the meeting, reviewers should contact the SRO requesting an exception. The reviewer should provide the SRO with a justification and the estimated costs.

All receipts related to the expense in question **must** be submitted within 2 days of the end of the review to Hing Lee in the SREA office, via e-fax at 301-480-2054.

Exceptions to the flat rate for meals will **not** be considered.

Telephone and Mail Reviewers

Telephone Review

Telephone reviewers may also receive reimbursement for telephone and Internet Assisted Reviews.

Telephone reviewers **do not need** to fill out a reimbursement claims form. After the review call is complete, the NCI SRO will verify the reviewer's attendance and submit information for processing of the reviewer's reimbursement.

Mail Review

Consultant fees **may be paid** to mail reviewers, but mail reviewers **do not need** to fill out a reimbursement form. After the mail reviewer submits any required reports, the NCI SRO will verify the reviewer's participation and submit information for processing of the reviewer's reimbursement.

Frequently Asked Questions

Q: Can a reviewer receive two consultant fees for attending two meetings in the same day?

A: No. The Office of General Counsel has determined that the consultant fee covers all meetings attended within a 24-hour period.

Q: Can a local reviewer be reimbursed for hotel costs?

A: Reviewers fall under the Federal Advisory Committee Act. In accordance with the guidance in NIH Manual Chapter 06-01, persons who reside in the local travel area (defined as a 50-mile radius) are exempt from receiving per diem. However, exceptions may be made. If a reviewer has special requirements, he or she should check with the NCI SRO concerning reimbursement status.

Q: Can reviewers use their own travel agencies, or must they use WTS?

A: Although reviewers are encouraged to use WTS, reviewers may use their own travel agencies. If a reviewer arranges his/her own travel, he/she will be reimbursed only at the cost of a non-refundable WTS ticket and will have to apply for an exception.

Q: Do reviewers really need to provide their Social Security numbers?

A: Yes. The Social Security number is the only identifier used to code reviewers as U.S. citizens or permanent residents in the NIH system. This will ensure that a 1099 is prepared and issued to the reviewer.

Q: How are foreign reviewers paid?

A: Foreign reviewers will be issued a check in U.S. dollars for the consultant fee and travel reimbursement.

OER Communications Office
Division of Communications and Outreach
Office of Extramural Research
National Institutes of Health

Appendix A: Human Subjects and Vertebrate Animals Protection

APPENDIX A1

Human Subjects Protection and Inclusion of Women, Minorities, and Children

Guidelines for Review of NIH Grant Applications

Contents

HUMAN SUBJECTS PROTECTION

Requirements for Review

- Federal regulations for the protection of human research subjects (45 CFR 46), require that the evaluation of research applications that involve human subjects take into consideration the risk to subjects, the adequacy of protections against risk, potential benefits of the research to subjects and others, and the importance of the knowledge to be gained
- The NIH Peer Review regulations (42 C.F.R. 52h) specify that reviewers will take into account, in determining overall impact that the project in the application could have on the research field involved, the adequacy of the proposed protection for humans
- Therefore, reviewers must evaluate the proposed plans to protect human subjects from research risks, as appropriate for the research proposed, as one of the review criteria that factor into the evaluation of scientific and technical merit
- In addition to federal regulations about the protection of human research subjects, NIH policies require that applications involving Clinical Trials include a data and safety monitoring plan and that NIH-defined Phase III clinical trials also describe a data and safety monitoring board
- Data safety and monitoring plans must also be evaluated by peer reviewers.

Reviewer Responsibilities

— For applications involving human subjects:
- Determine if a claim for exemption is adequately justified in applications that indicate the proposed research is exempt **OR**
- Determine whether the involvement of human subjects in the proposed research is justified scientifically; evaluate the proposed plan for the involvement of human subjects in non-exempt human subjects research; and determine if subjects appear to

be adequately protected from research risks.
- For applications that involve a clinical trial, determine if the plans for data and safety monitoring, including the description of a data and safety monitoring board if necessary, are adequate.

— For applications that claim no involvement of human subjects but propose the use of existing human data or biological specimens, evaluate if the justification provided for not involving human subjects is acceptable.
- Rate the application as Acceptable, Unacceptable, or Not Applicable in terms of human subjects involvement and prepare written comments, including specific comments describing concerns for applications rated as Unacceptable.

— For applications that do not involve human subjects or the use of human data or specimens, rate the application as Not Applicable for this criterion. In this case, the Inclusion criterion, as described below, will also be Not Applicable.

Reviewer Comments

Reviewer Comments are required for Protections for Human Subjects (unless Not Applicable). An example follows:
- The applicant states that the proposed research involves minimal physical risk; however, genetics research is considered of moderate risk due to the possibility of breaches in confidentiality. Insufficient detail is provided regarding measures to protect against such risk.

INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

Requirements for Review

- Public Law 103-43 requires that women and minority subjects be included in all clinical research studies, as appropriate for the scientific goals of the work proposed
- Additionally, NIH policy requires that women and members of minority groups and their subpopulations must be included in Phase III clinical trials in numbers adequate to allow for valid analyses of gender and/or racial/ethnic differences in intervention effects
- NIH policy also states that children (defined as persons under the age of 21) be included in human subjects research projects supported by NIH unless an acceptable justification for their exclusion is provided
- The NIH Peer Review regulations (42 C.F.R. 52h) specify that reviewers will take into account, in determining overall impact that the project in the application could have on the research field involved, the adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research
- Therefore, reviewers must evaluate the proposed plans for inclusion of women, minorities and children as one of the review criteria that factor into the evaluation of scientific and technical merit.

Reviewer Responsibilities

— Evaluate whether the gender and minority characteristics of the proposed sample and the plan for the inclusion of children are scientifically acceptable given the aims of the research.

— Rate the application as Acceptable or Unacceptable with respect to the proposed inclusion of Women, Minorities and Children, assign codes, and include specific comments describing concerns for applications rated as Unacceptable.

Reviewer Coding

Three digit alphanumeric codes are used to summarize reviewers' evaluation of inclusion of women, minorities, and children. The three digit code is comprised as follows.

- First digit: G, M, or C to indicate gender, minority or children, respectively
- Second digit: 1-5 to define the inclusion status
- Third digit: A or U to indicate scientific acceptability, given the stated research aims

Each application involving human subjects receives three separate alphanumeric codes, for gender, minorities, and children, respectively. A code should be assigned to each individual project or subproject in an application containing multiple projects or subprojects and involving distinct populations or specimen collections. A single overall code ALSO should be assigned to the entire application. If any project/subproject is found "Unacceptable" (U), the overall code should be U. The overall coding should reflect the representation in all projects/subprojects, even if some are single gender or involve no minorities.

Gender Inclusion Codes

- **G1A** = Both genders, acceptable
- **G1U** = Both genders, unacceptable
- **G2A** = Only women, acceptable
- **G2U** = Only women, unacceptable
- **G3A** = Only men, acceptable
- **G3U** = Only men, unacceptable
- **G4A** = gender composition unknown, acceptable
- **G4U** = gender composition unknown, unacceptable

Minority Inclusion Codes

- **M1A** = Minority and nonminority, acceptable
- **M1U** = Minority and nonminority, unacceptable
- **M2A** = Only minority, acceptable
- **M2U** = Only minority, unacceptable
- **M3A** = Only nonminority, acceptable
- **M3U** = Only nonminority, unacceptable
- **M4A** = minority composition unknown, acceptable
- **M4U** = minority composition unknown, unacceptable
- **M5A** = only foreign subjects, acceptable
- **M5U** = only foreign subjects, unacceptable

Children Inclusion Codes

- **CIA** = Children and adults, acceptable
- **C1U** = Children and adults, unacceptable
- **C2A** = Only children, acceptable
- **C2U** = Only children, unacceptable
- **C3A** = No children included, acceptable
- **C3U** = No children included, unacceptable
- **C4A** = Representation of children unknown, acceptable

- **C4U =** Representation of children unknown, unacceptable

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. Applications should describe and justify fully the samples that will be included in the research.

Reviewer Comments

Reviewer Comments are required for Inclusion of Women/ Minorities/ and Children (unless Not Applicable). Examples of comments follow.

- (G1U) Gender representation is unacceptable. Although both genders are represented/ too few members of one gender are included to answer the questions posed.
- (G2A) Gender composition is scientifically acceptable, although only females are represented/ because the disease under study is not found in male subjects.
- (GIA) Although there are relatively few females in the sample, the representation reflects the gender ratio in the prevalence of the disorder; the plan is scientifically acceptable.
- (C3A) No children included. This is acceptable as knee replacement is rare in children as compared to adults.
- (M4U) Minority representation is unknown. The application does not provide sufficient information about the racial/ethnic composition of the study population. The application does not comply with requirements and is unacceptable.

BACKGROUND AND REFERENCES

Human Subjects Protection

Federal Regulations for Protection of Human Research Subjects (45 CFR 46): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Definition of Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains

1) Data through intervention or interaction with the individual/ or
2) Identifiable private information.

— *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

— *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place/ and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example/ a medical record). Private information must be individually identifiable (i.e./ the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research Involving Coded Private information or Biological Specimens

Research that involves only the use of human specimens or data is not considered human

subjects research if:

- All subjects are deceased **OR**
- The data/specimens were not obtained specifically for the proposed research AND none of the investigators involved in the research can ascertain the identity of the subjects, either directly or indirectly.

  See http://www.hhs.gov/ohrp/policy/cdebiol.html for more detailed information.

***Human Subjects Research Exemptions* (45 *CFR 46.101*)**

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   i. research on regular and special education instructional strategies, or
   ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   i. the human subjects are elected or appointed public officials or candidates for public office; or
   ii. (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4) Research involving the collection or study 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.
5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   i. Public benefit or service programs;
   ii. procedures for obtaining benefits or services under those programs;
   iii. possible changes in or alternatives to those programs or procedures; or
   iv. possible changes in methods or levels of payment for benefits or services under those programs.
6) Taste and food quality evaluation and consumer acceptance studies,
   i. if wholesome foods without additives are consumed or
   ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Data and Safety Monitoring Plan

For information, visit Data and Safety Monitoring Plan.

Inclusion of Women, Minorities, and Children

NIH Policies Regarding Inclusion of Women and Minorities

NIH Policies Regarding Inclusion of Children

Definitions

Clinical research:

1) 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 that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2) Epidemiologic and behavioral studies.
3) Outcomes research and health services research.

Phase III clinical trials research:

Phase III clinical trials research is defined as 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) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

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

Minority group: A readily identifiable subset of the U.S. population distinguished by either 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.

Children: Individuals under the age of 21 years.

More Information:

Peer Review Decision Trees for Human Subjects Protections and Inclusion Issues

Appendix A2
Worksheet for Review of the Vertebrate Animal Section (VAS)

This worksheet is provided to assist applicants in preparing the VAS for submission to the NIH, and as guidance to reviewers in evaluating the VAS of grant applications and cooperative agreements. The responsibilities of extramural scientists and NIH staff are clarified on page 1. A worksheet to assist in preparing or evaluating the VAS is provided on page 2, with more detailed instructions provided on pages 3-4. An example of a complete VAS, coded as ACCEPTABLE, is presented on page 5.

I. Instructions for Applicants, Reviewers and NIH Staff

Overview of requirements

If live vertebrate animals are to be used, federal policy requires that the following five points are addressed in all applications.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex and number of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the *AVMA Guidelines on Euthanasia.* If not, include a scientific justification for not following *the* recommendations.

Applicants should be aware that NIH may release information contained in funded applications pursuant to a Freedom of Information Act request.

Applicant responsibilities

Each of the five points must be addressed in the VAS of NIH grant applications. Failure to address the five points may result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected.

Scientific review group (SRG) responsibilities

The SRGs evaluate the involvement of live vertebrate animals as part of the scientific assessment of the applications submitted to NIH according to *the* five points.

NIH Staff responsibilities

- *Review staff* a) performs an administrative review of each application, checking that it includes a VAS if the use of vertebrate animals is indicated; b) provides reviewers with instructions for reviewing the VAS (VAS Worksheet, PDF) instructing them that the responses to all five points must be appropriate for the VAS to be acceptable; c) codes the application according to the SRG's recommendation and includes reviewers' comments in the Resume of the summary statement.
- *Program staff* a) obtains additional information or clarification to resolve concerns related to any application for which the VAS is found to be unacceptable, if the application is to be recommended for funding; b) works with the applicant to provide revisions to OLAW, facilitating approval of the VAS.
- *Grants Management staff* a) verifies that the organization's Assurance number is provided; b) obtains verification of IACUC approval.

II. Worksheet to Assist in Addressing the Required Five Points of the VAS

Performance site(s): The five points must be addressed for all performance sites.

_ If the applicant's institution is not where animal work will be performed, are all collaborative performance site(s) identified?

_ If more than one performance site is planned, are descriptions of animal care and use addressing the five points provided for each site?

Point 1 Describe the animals and their proposed use; address the following for all species to be used:

_ Species
_Strains
_ Ages
_Sex
_Number of animals to be used
_ A concise, complete description of proposed procedures (i.e., sufficient information for evaluation)

Point 2 Provide justifications for:

_The use of animals
_ Choice of species
_ Number of animals to be used (cite power calculations, if appropriate) with specific justification for large numbers of animals
_ Use of animals that are in short supply or are costly

Point 3 Provide a general description of veterinary care, including veterinary support that is relevant to the proposed procedures. Examples of the kinds of items that may be appropriate to include are:

_ A brief account of veterinary staff and their availability
_ The regular schedule of monitoring of animals by veterinary staff
_ Any additional monitoring and veterinary support that may be required to ensure humane care, if relevant to the procedures proposed (e.g., post-surgical)
_ Indicators for veterinary intervention to alleviate discomfort, distress or pain, if relevant

Point 4 Describe procedures to minimize discomfort, distress, pain and injury to that which is scientifically unavoidable in the conduct of research. Examples of the kinds of items that may be appropriate to include are:

_ Circumstances relevant to the proposed work, when animals may experience discomfort, distress, pain or injury
_ Procedures to alleviate discomfort, distress, pain or injury
_ Identify (by name or class) any tranquilizers, analgesics, anesthetics and other treatments (e.g., antibiotics) and describe their use
_ Provisions for special care or housing that may be necessary after experimental procedures
Plans for post-surgical care, if survival surgeries are proposed
Indicators for humane experimental endpoints, if relevant
Describe the use of restraint devices, if relevant

Point 5 Describe methods of euthanasia:

_ Describe the method(s) of euthanasia and rationale for selection of method(s)
_ Indicate if the method is consistent with *AVMA Guidelines on Euthanasia*
_Provide a scientific justification for the choice of method if not AVMA recommended

III. Detailed Instructions for Preparation, Review and Coding of the VAS

Subsequent to evaluation of the VAS by a SRG, all applications or proposals are coded as NO VERTEBRATE ANIMALS (10), NO CONCERNS/ACCEPTABLE (30) or CONCERNS/UNACCEPTABLE (44).

Coding as NO VERTEBRATE ANIMALS (10)

If animal tissue used in the study is obtained from other sources (e.g., tissue repository, animals euthanized for an unrelated purpose), the application is coded as no vertebrate animals used. The source of the tissue should be described in the application to validate the coding as no vertebrate animals used.

Vertebrate animals: If animals are obtained or euthanized for tissue harvest, the proposed research is coded as use of live vertebrate animals. The generation of custom antibodies must be coded as use of live vertebrate animals.

Coding as NO CONCERNS/ACCEPTABLE (30) or CONCERNS/UNACCEPTABLE (44)

Coding is based on peer review of the five required points for each of the performance sites.

Performance site(s): This is defined as the institutions where procedures with animals will be performed. If the applicant institution is not the site where animal work will be performed, the performance site must be identified. If there is more than one performance site, the description of animal care and use at each site must be included in addressing the five points.

Preparation of the VAS: Typically, all of the required elements for the VAS can be addressed within 1-2 pages. Following the detailed guidelines below, an example of a concise, but complete VAS section is included on the last page of this document.

Point 1 Description of animals and how they will be used

A concise, complete description of the proposed procedures must be included in the VAS. While additional details may be included in the Research Strategy, a coherent, albeit brief, description of the proposed use of the animals must be provided within the VAS. The description must include sufficient detail to allow evaluation of the procedures. Examples of the types of procedures that may be described include blood collection, surgical procedures, administration of substances, tumor induction and post-irradiation procedures. In describing the animals, investigators must provide the following information for each species or strain:

- Species
- Strain
- Ages
- Sex
- Number of animals to be used

Point 2 Justifications for use of animals

Investigators must justify the use of animals in the proposed research. U.S. Government Principles require grantees to consider mathematical models, computer simulation, and in vitro biological systems. The justification should indicate why alternatives to animals (e.g., computer models, cell culture) cannot be used and the potential benefits and knowledge to be gained. In addressing this point, researchers are encouraged to consider means to replace, reduce and refine the use of animals. Rationale for the choice of species must be provided (e.g., advantages of the species chosen and why alternative species are not appropriate). If less highly evolved or simpler animal models are available, justification should be provided for using more advanced species. For example, the use of non-human primates (NHP), dogs or cats should be thoroughly justified. If NHP species are to be used, a comparison to other NHP species may be appropriate. If animals are in short supply, costly, or to be used in large numbers, an additional rationale for their selection and the number of animals to be used is required.

Estimates for the number of animals to be used should be as accurate as possible. Justification for the number of animals to be used may include considerations of animal availability, experimental success rate, inclusion of control groups and requirements for statistical significance; cite power calculations where appropriate.

Point 3 Veterinary care

Descriptions of veterinary care should indicate the availability of veterinarians or veterinary technicians. For example, the VAS might indicate the number of veterinarians and veterinary technicians associated with the applicant institution, and their proximity to the performance site(s). The frequency with which veterinary staff observe or monitor animals may also be stated.

If survival surgeries are proposed, descriptions of veterinary involvement or post-surgical monitoring may be described. For example, if animal use involves invasive approaches that might result in discomfort, distress or pain, the investigator may describe the indicators for veterinary intervention and the ways in which veterinary staff may intervene.

Point 4 Provisions to minimize discomfort, distress, pain and injury

Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury should be identified. Methods to alleviate discomfort, distress or pain should be described. If pharmacological agents are used, the agent(s) may be specified by name or class. Any additional (e.g., non-pharmaceutical) means to avoid discomfort, distress, pain or injury may be briefly described. The manner, circumstances and duration of all post-surgical provisions and care may be described. If special housing is necessary following surgery or manipulations, the VAS may describe these. If procedures (e.g., pharmacological or surgical) might lead to severe discomfort, distress, pain or injury, indicators for humane endpoints and euthanasia (e.g., severe infection, respiratory distress, failure to eat, tumor size) may be described. All of these issues are particularly important for survival surgeries. If multiple surgeries are proposed, these should be well justified and provisions to avoid any potential complications may be described. Describe how restraining devices will be used, if applicable.

Point 5 Euthanasia

The method(s) of euthanasia must be described and must comply with the *AVMA Guidelines on Euthanasia.* If the method(s) do not comply with AVMA recommendations, the rationale and scientific justification for use of the method(s) must be provided. The indicators for euthanasia (i.e., termination of experiment or humane endpoints) may be stated. It is not sufficient to state simply that humane methods will be used, that are consistent with the recommendations of the *AVMA Guidelines on Euthanasia* or the Institutional Animal Care and Use Committee (IACUC).

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 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).

• PHS Policy
http://grants.nih.gov/grants/olaw/references/phspol.htm
• U.S. Government Principles
http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples
• Guide for the Care and Use of Laboratory Animals
http://www.nap.edu/openbook.php?record_id=5140

- *AVMA Guidelines on Euthanasia* - http://www.avma.org/issues/animal_welfare/euthanasia.pdf
- NIH Guide for Grants and Contracts Notice - NOT-OD-1 0-027

IV. Example (This VAS has been modified from the original. It addresses all five points concisely.)

F. Vertebrate Animals
Aims 1-3 will be addressed *in vitro;* Aim 4 will be addressed using a mouse model of ocular infection.

1. Female Balb/c mice will be used to determine if virions treated with enzyme can cause viral keratitis, and to test the *in vivo* efficacy of the test articles. The studies will require 700 mice, 4 to 6 weeks old. Based on prior experience, 70 groups, each including 10 mice will be required over five years to achieve adequate statistical power. Ocular infection is accomplished by scratching the cornea of anesthetized mice with a sterile needle and exposing the scarred portion of the cornea to inoculum. Test articles are applied directly to the scarified cornea as liquid or cream. Following inoculation and recovery, mice are monitored for 30 days. With the mice under anesthesia, the eyes will be examined at intervals, microscopically, and are flushed with medium with 2% serum to determine viral titers. Thirty days post-infection, with the mice under deep anesthesia, the trigeminal ganglia are removed aseptically for viral assay, followed immediately by euthanasia.

2. The proposal is to study mechanisms for the prevention of ocular disease caused by viral infections, a leading cause of blindness in the US. Mice are needed for these experiments because no alternative *in vitro* model incorporates all elements of the mammalian ocular immune system; too little is known about this system for the development of computer simulations. Mice are a well accepted model for studying viral keratitis, assessing the virulence of viral strains and testing the efficacy of antivirals. Mice provide several advantages: a) The murine ocular immune system is similar enough to that of humans to allow extrapolation of the results; b) Their small size allows the use of smaller amounts of drugs for testing; c) The entire mouse genome is known and easily manipulated genetically, allowing extension of the work in future genetic studies. Female mice will be used due to compatibility issues. Balb/c mice will be used because they have intermediate resistance to infection. ABC-4 knockout and ABC-4 test-strains will be used. For the enzyme study, we will use 4 treatment groups: enzyme-1, enzyme-2, enzyme-3, and mock treated virus. We will also use different amounts of inoculum for each condition allowing a more accurate calculation as to the effect of the digestions on infectivity. For the test-article peptide study, we will use two formulations (one aqueous and one hydrophobic), test 4 different concentrations and also vary the treatment protocol. Two groups will receive a single dose of drug in each of the two formulations prior to the addition of virus to assess prophylactic activity. These groups will not receive any additional enzyme treatments. Two groups will be infected with virus and beginning 4 h post-infection, we will treat with each formulation and concentration 4 times daily for 7 days.

3. All mice are housed in the Animal Resources Center of the University. Animal housing rooms are under temperature and humidity control. The mice will not be subjected to water or food restrictions, and bedding material is placed in each cage. The facility is staffed by four full time veterinarians and six veterinary technicians; the veterinary staff is on site and a clinical veterinarian is available at all times. Animal care staff conducts routine husbandry procedures (e.g., cage cleaning, feeding and watering) and checks animals daily to assess their condition. Laboratory staff monitors mice when treatments are given, disease is scored or samples are collected for titering. The veterinary staff monitors mice in their home cages, weekly. If animals exhibit any indication of infection or distress, the veterinary staff confers with laboratory personnel to recommend appropriate antibiotics, analgesics or other pharmaceuticals. The veterinary staff may intervene or recommend euthanasia based on animal welfare concerns.

4. Mice will be anesthetized with isoflurane (3-5%) during the infection process, when treatments are administered and titer samples are collected. This eliminates the need for restraint devices and topical anesthetics that would interfere with the infection and disease process. For post-procedural pain relief, we will administer buprenorphine twice daily for the duration of the experiments (i.e., approximately two weeks post-inoculation). Death is not an endpoint for the studies; the Balb/c strain was chosen because of its resiliency and resistance to this particular virus. Our goal is to avoid severe infections leading to death. Though unlikely, if an animal reacts severely, it will be euthanized, based on humane indicators (e.g., failure to groom or feed). These experiments involve no post-surgical survival animals.

5. All mice will be euthanized by cervical dislocation under isoflurane anesthesia. Isoflurane ensures that the mice are unconscious, while dislocation ensures quick death. This minimizes animal distress, is effective and efficient; it is consistent with the recommendations of the *AVMA Guidelines on Euthanasia.*

APPENDIX B

INTERNET ASSISTED REVIEW REVIEWER USER GUIDE
(1 February 2007)

National Institutes of Health Office of Extramural Research

Internet Assisted Review (IAR) Web Plus Reviewer Users' Guide

Version 2.8.1.1 – February 23, 2007

Electronic Research Administration

Table of Contents

Introduction

Overview

The eRA Internet-Assisted Review (IAR) system is a Web-based system to manage the process of electronic submission of critiques by reviewers. IAR expedites the scientific review of grant applications by standardizing the current process of critique and initial priority score submissions by reviewers via the Internet. IAR enables reviewers to submit critiques and view each other's reviews before the actual meeting. As a result, review meetings can contain more informed discussions because reviewers are able to read the evaluations entered by others prior to the review meeting (except where there is a conflict of interest).

Using the IAR Module

IAR Reviewer capabilities include:

- electronically submit critiques and preliminary scores prior to scheduled meetings
- review the critiques submitted by others online
- modify critiques after the scheduled meeting
- maintain personal information (single point of ownership)
- acceptance of critiques in Microsoft Word (*.doc) or plain text (*.txt) format

IAR Phases

The IAR process included the following phases:

- **Submit**— Reviewers log in and submit critiques and preliminary scores for their applications. During this phase you only see your assigned applications. The phase end date is the Critique due date.
- **Read**—Time period after the Submit phase (the Submit phase end date determines the start of the Read Phase). After submission deadline, Reviewers may read other Reviewer's critiques. If a reviewer has not submitted, the SRA may block the Reviewer from reading until he

submits his own. During the Read phase, except where in conflict or blocked, you can see all applications and may read all critiques. At the end of the Read phase, the actual meeting is usually held.

- **Edit**—Your SRA/GTA determines whether or not to hold the optional Edit Phase which follows the Read phase. In this phase, you can correct/resubmit your critiques based on comments in the meeting or can post critiques for unassigned applications. At the end of the phase, the meeting in IAR goes back to Read Phase until assignments are manually purged or the Assignment Purge date is reached (the purge date is set automatically for 15 days after the meeting release date). After assignments are purged, you will lose access to the meeting.

Creating/Accessing an IAR Account

In order to access IAR Reviewers must:

- have an NIH Commons account in order to access IAR
- be listed on the official Meeting Roster (the reviewer must be a real person with person_id, no placeholders)
- have an email address on their profile MLG

Your SRA/GTA grants you access to utilize IAR to submit and view critiques for applications in meetings. When this occurs, you receive an email informing you of your ability to access IAR. If you do not have an IAR account, the email directs you to create a new IAR account. If you already have an IAR account, you are directed to access the eRA Commons Login page.

To create a new account:

1. Click the hyperlink in the email to open the NIH eRA Commons and the Create New Account page.

2. In the account form, enter the requested information noting the following:

   - If a field name is followed by an asterisk (*), it is a required field.

   - The username has a 6 character minimum and a 20 character maximum.
   - Passwords must contain a minimum of six characters. For additional protection, include a combination of letters and numbers.

3. Click **Submit** to enter the information. After your account information has been reviewed and authorized, you will receive a notification email containing the URL to the NIH eRA Commons Login page.

NOTE: To access IAR if you already have an IAR account or once you receive the notification email, see Introduction: *Logging On To IAR.*

Logging On To IAR

To log on to IAR, access IAR via the NIH eRA Commons. NIH eRA Commons is a web-based system that allows principal investigators (PIs) and central research administration offices to communicate and send information electronically. To access the NIH eRA Commons you must be registered as a user. Contact your Office of Sponsored Programs or Office of Clinical Research representative for information about registering.

Any registered user with a Web browser (Internet Explorer 5.01 or greater or Netscape 4.7 or greater) and Internet access can log on to the application. Other Web browsers are also supported, but some functionality may be lost.

To log on to IAR:

1. Open your web browser.

2. In the Address/Location field of your web browser, type **https://commons.era.nih.gov/commons/** and then press Enter. The eRA Commons Login Page (Figure 1) appears.

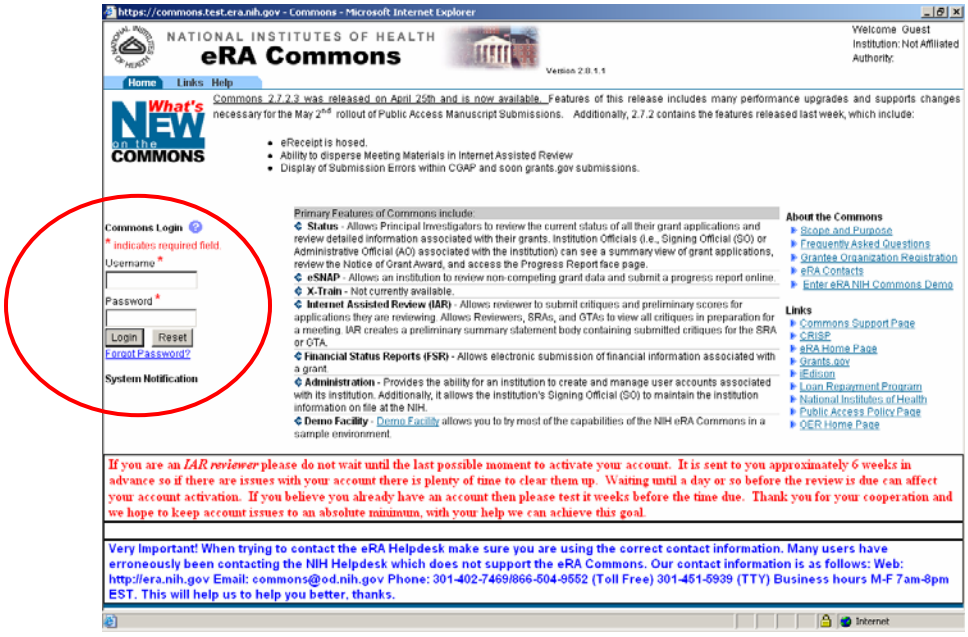

Figure 1: eRA Commons Login Page

3. In the **Username** field, type your eRA Commons username.

4. In the **Password** field, type your eRA Commons password.

NOTE: For security purposes, eRA Commons user passwords expire and must be reset. If your password is soon to expire, a "password close to expiration" message is generated when you log in.

If you get this notification, you will be directed to select a new password. When you change your password, you do not need to notify anyone.

5. Click **Login** (or press **Enter**). The eRA Commons Home page appears.

NOTE: You can only access eRA Commons for one session at a time. If you attempt to log in to another session, using a second browser instance, the system gives you the option of either terminating the first session or canceling the request.

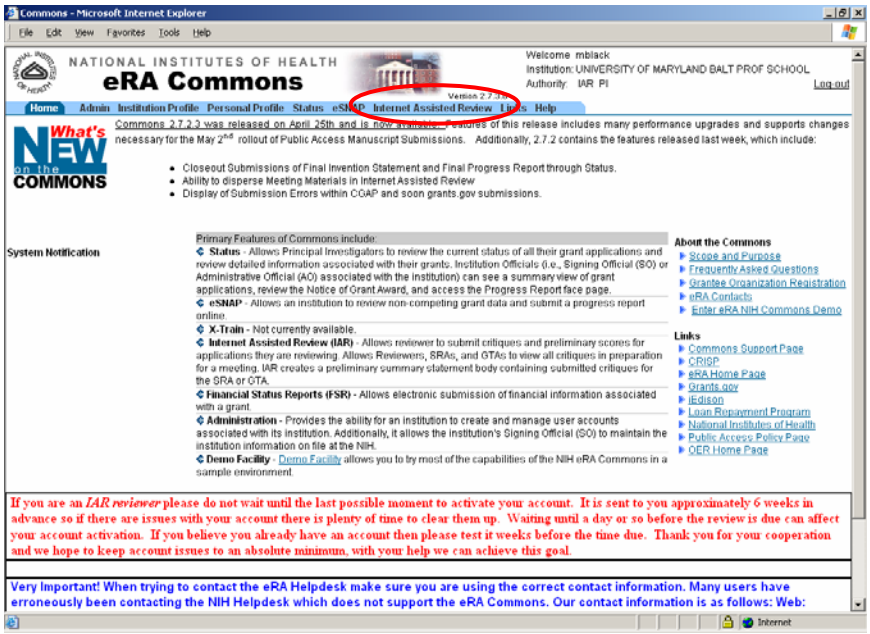

Figure 2: Internet Assisted Review Access Tab

6. Select the **Internet Assisted Review** access tab. The IAR **List of Meetings** page (IAR0001) appears (Figure 3).

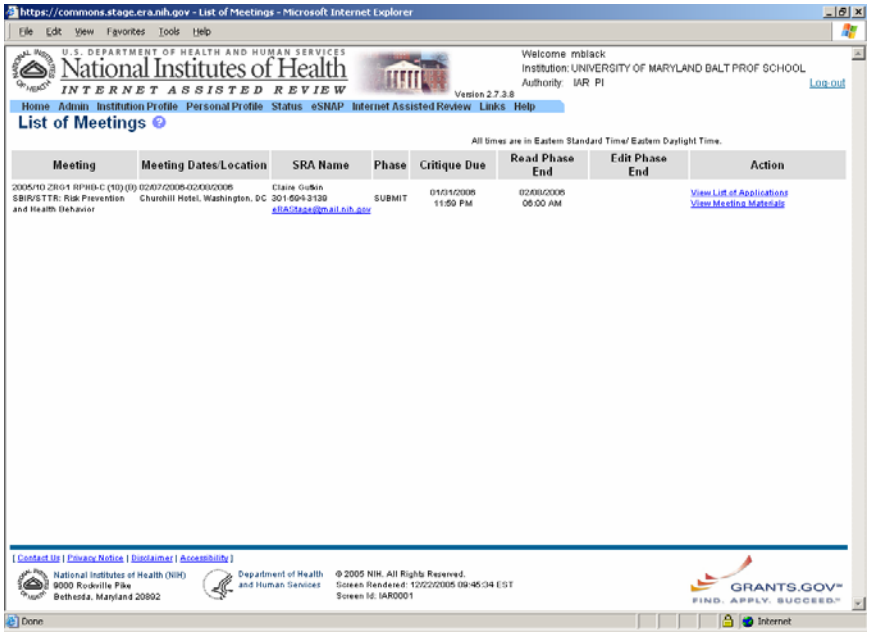

Figure 3: IAR Main Page

Logging Out of IAR

To log out of IAR:

- Select the **Log-out** hypertext link located at the top of each page.

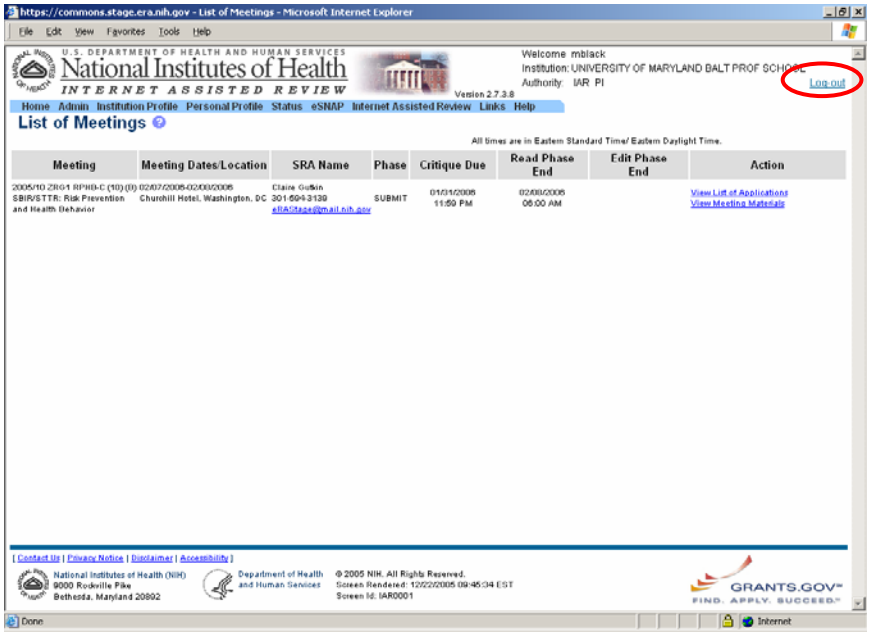

Figure 4: Select the Log-out hypertext link to log out of the IAR System

Expired Session

Your IAR session expires after 45 minutes of inactivity. Five minutes before expiration, an expiration message is displayed. Click **Keep Session** to resume your work or **Abandon Session** to force your account to log out.

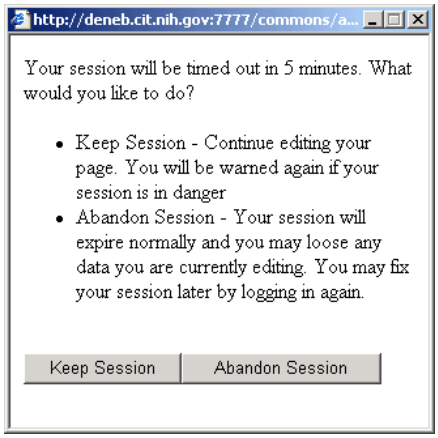

Figure 5: Select Abandon Session to log out of the IAR System

If your session expires while the NIH eRA Commons is open, because you did not respond to the expiration message within the allotted five minutes, you will experience errors or lost functionality in the system (such as disappearing buttons, Internal Server Error 500, pages displaying with no data, or prompts to log in again). If any of these problems occur, close your Web browser window and then reopen it to log in and start a new session.

List of Meetings

The IAR Home Page

When you log on to IAR, the IAR **List of Meetings** Screen (IAR0001, shown in Figure 6) appears with the navigation menu displayed across the top of the screen.

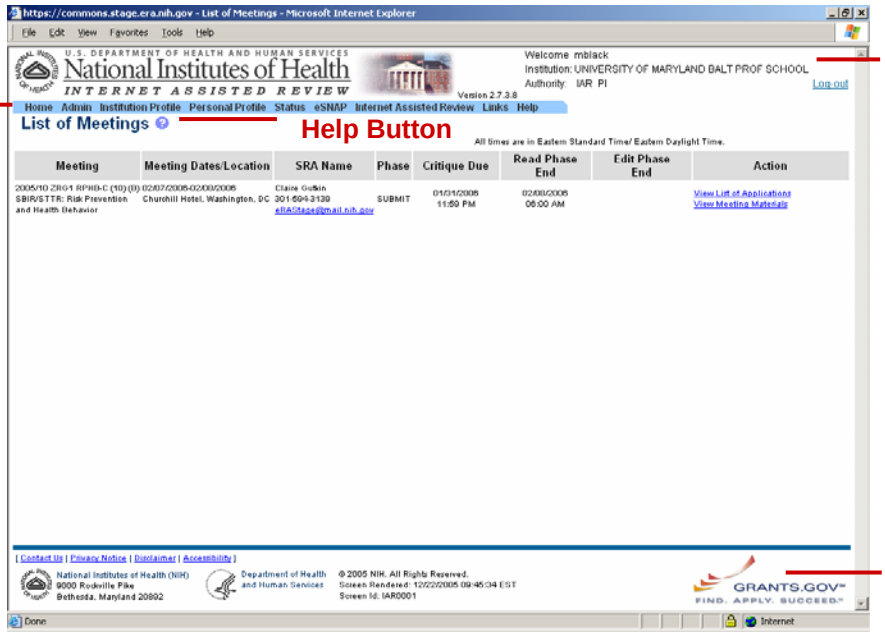

Figure 6: IAR List of Meetings Screen (IAR0001)

Navigation Menu

You use the blue navigation menu that appears at the top of the IAR screens to access the various functions associated with IAR. The navigation menu links are

- Home
- Status

- eSNAP
- FSR
- Internet Assisted Review
- Links
- Help

List of Meetings Block

The following information is included on the **List of Meetings** block:

- **Meeting**- Includes the meeting identifier and title.

  Meeting identifier is made up of seven fields: Council Date, IRG (SRG) Code, IRG (SRG) Flex Code, SRA Designator Code, SRA Flex Code, Group Code, Group Extension Code, and the Workgroup Number.

  Meeting title indicates the title of the meeting or panel name if the meeting is a SEP.

- **Meeting Dates/Location**- Identifies the meeting start and end date, hotel name, city and state of meeting location.

- **SRA Name-** First and last name, work telephone number, and work email address of the SRA. SRA email address is a hypertext link that can be selected in order to send an email directly to the SRA.

- **Phase**- The current IAR Phase for the meeting.

- **Critique Due**- Lists the date and time the application critiques are due. This is considered the phase end date.

- **Read Phase End**- The Read phase end date and time.

- **Edit Phase End**- The Edit phase end date and time.

- **# of Appls**- The number of applications scheduled for review in the listed meeting.

- **Action**- Hypertext link that allows access to the **List of Applications** page.

Meeting Materials

To view meeting materials:

1. Log in to IAR to access the **List of Meetings** screen as described in *Logging On To IAR* on page 3.

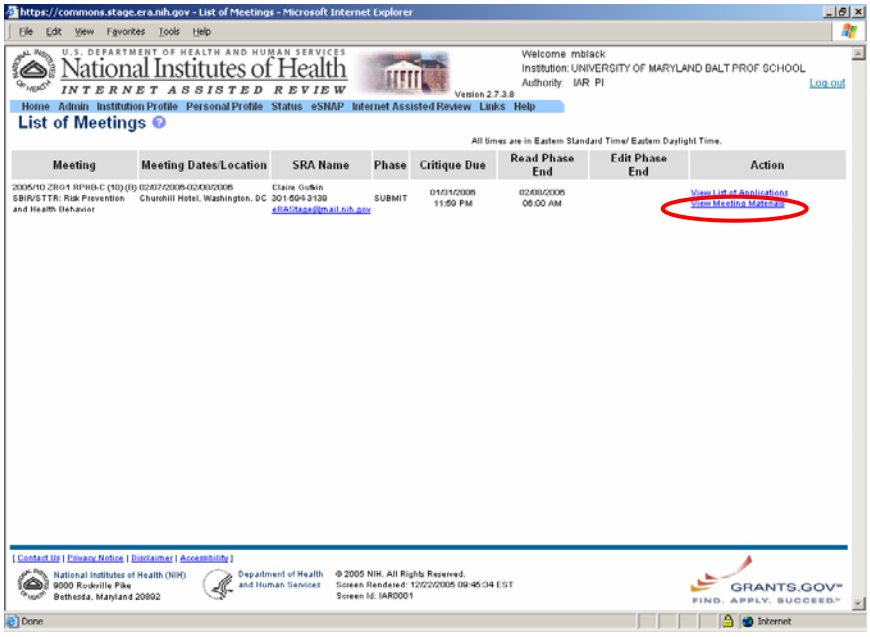

Figure 7: List of Meetings Screen (IAR0001)

2. Select the **View Meeting Materials** hypertext link. To access the **Meeting Materials** screen (Figure 8).

Figure 8: Meeting Materials Screen

3. To view details of any of the meeting materials select the **View** hypertext link in the **Action** column.

A listing of all the meeting materials associated with the selected meeting, appears.

List of Applications

Overview

The List of Applications page lets you view information about the applications in your meeting and provides access to actions such as submitting and viewing critiques. The data viewed on the List of Applications page is customized based on the current IAR phase and the type of reviewer you are. By default, the page initially shows only applications assigned to you but it provides access to show all applications in the meeting if your SRA/GTA has opened the meeting for unassigned critiques or comments to be posted.

Note:
Mail reviewers can only see their own assigned applications.

By default, you are blocked from reading application critiques submitted by other reviewers before you submit your own critique. This default may be changed for selected reviewers by the SRA/GTA.

Applications with conflicts are marked COI and have no links available for submitting, deleting, or viewing a critique.

Accessing the List of Applications Screen

The **List of Applications** screen lists all applications assigned to you. Each application has a link for submitting critique. Details concerning the available information according to the IAR phase include:

Submit Phase:

- If a critique has already been submitted, links are available to delete or to view the critique.

Read Phase:

- If you have been permitted by your SRA/GTA to view the critiques of other reviewers, the list of available applications will list only assigned applications or all reviewed applications.

- If you have not submitted a critique on an application and are blocked from reading the critiques of other reviewers, the only option available for the blocked application is the *Submit* option.
- All other applications will each have a separate link for viewing critiques

Edit Phase:

- Each application has a link for submitting a critique. If you have already submitted a critique, other links allow you to delete and view the critique.
- If you have not submitted a critique on an application and are blocked from reading the critiques of other reviewers, the only option available for blocked applications is the *Submit* option.

To access the **List of Applications** screen:

1. Access the IAR **List of Meetings** screen.

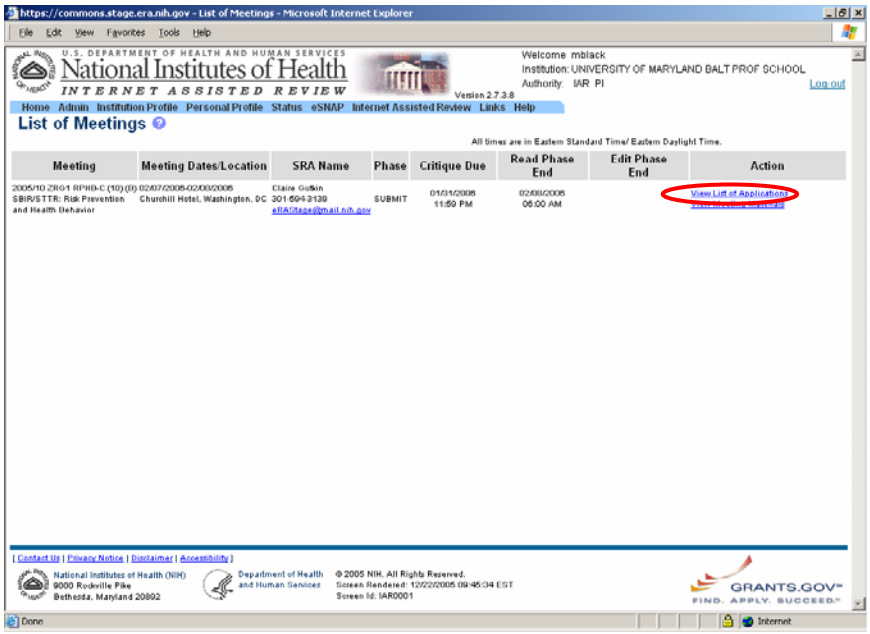

Figure 9: Select the View List of Application hypertext link to access the List of Application screen

2. Select the **View List of Applications** hypertext link displayed in the **Action** column of the application you would like to view. The **List of Applications** screen appears (Figure 10).

Figure 10: List of Applications Screen

List of Applications Screen

At the top of the **List of Applications** screen specific details pertaining to the application you selected appear. The details include:

- **Meeting Title** – Lists the title of the meeting or the pane name if the meeting is a SEP.
- **Meeting Identifier** – The meeting identifier is made up of seven fields: Council Date (in YYYY/MM format), IRG (SRG) Code, IRG (SRG) Flex Code, SRA Designator Code, SRA Flex Code, Group Code, Group Extension Code, and the Workgroup Number.

  Example: SRG Meeting is 2002/10 PC-1 (01)

  Example: SEP Meeting is 2002/10 ZRG1 SRG-F (GC) X 001
- **Meeting Phase** – Displays the current IAR phase for the meeting.
- **Meeting Dates** – The dates that the actual meeting starts and ends
- **Critiques Due** – The date and time critiques are due. This is also known as the Submit phase end date.

List of Applications Available Links

There are several links on the **List of Applications** screen that allow you to navigate the IAR application in several ways.

Back to List of Meetings

Use the **Back to List of Meetings** hypertext link to return to the **List of Meetings** screen (Figure 11). Use this link instead of using the browser's Back button.

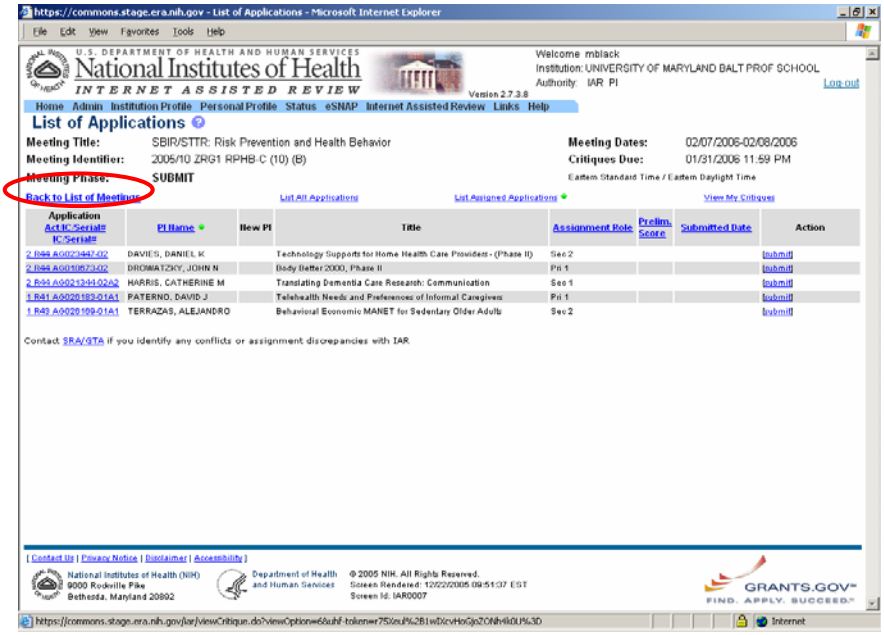

Figure 11: Select the Back to List of Meetings hypertext link to return to the List of Meetings Screen

List of All Applications

Select the **List of All Applications** hypertext link to view a list of all applications for the selected meeting, including those with conflicts in ascending sort order by reviewer name.

List Assigned Applications

Select the **List Assigned Applications** hypertext link to view a list of all applications assigned to the user. This view is only available in the Submit phase. This is the default view when you first access the List of Applications page.

View My Critiques

Select the **View My Critiques** hypertext link to access a Adobe Acrobat PDF file of all critiques that you have submitted thus far.

SRA/GTA

Contact information is provided as a convenient way to contact your SRA/GTA to discuss any issues that may arise. (For example, when there are assignment discrepancies or conflicts of interest with an application viewed in IAR).

1. Select the **SRA/GTA** hypertext link located at the bottom of the **List of Applications** screen to obtain SRA/GTA contact information.

Figure 12: Select the SRA/GTA hypertext link to access contact information for the assigned SRA/GTA

- The **SRA/GTA Name and Contact Information** page (IAR0010) appears. The page displays SRA/GTA name, telephone number and email address.

Figure 13: SRA/GTA Name and Contact Information (IAR0010)

2. The email address is in the form of a hyperlink so that an email can be sent to the SRA/GTA. Select the hyperlink to open your default email program.

Action Column Hypertext Links

A [**submit**] hypertext link appears in the **Action** column, this link allows you to submit application critiques. See *Submitting Critiques/Scores* on page 13.

Submitting Critiques/Scores

Overview

IAR allows you to submit critiques and scores for your assigned applications during the *Submit* and *Edit* phases. During the *Read* phase, only reviewers who have missed the due date may submit late critiques.

NOTE:
Only critiques uploaded in Microsoft Word format (with a *.doc extension) or in plain text format (with a *.txt extension) can be submitted.

Critiques cannot be edited online and must be resubmitted if you want to make changes to a previously submitted critique. Critiques cannot be resubmitted during the Read phase.

The WP Greek font family is not supported during the conversion of uploaded critiques to Adobe PDF. In order to include Greek characters (for example, α orβ) insert them as symbols within the Microsoft Word document.

Unassigned reviewers can not submit scores for any applications.

Review Criteria

The following special considerations are part of the review criteria:

- protection of human subjects from research risks
- data and safety monitoring
- inclusion of women
- inclusion of minorities
- inclusion of children
- animal welfare
- biohazards

This above list is not inclusive; other criteria may apply for a specific review group. Contact your SRA for guidance.

View Grant Application Image, Prior Summary Statements, and Appendices

To vie the PDF image of the Grant Application, prior Summary Statements (if they exist), and Appendices (if they exist), click on the **Grant Number** hypertext link. The **Grant Folder** screen appears:

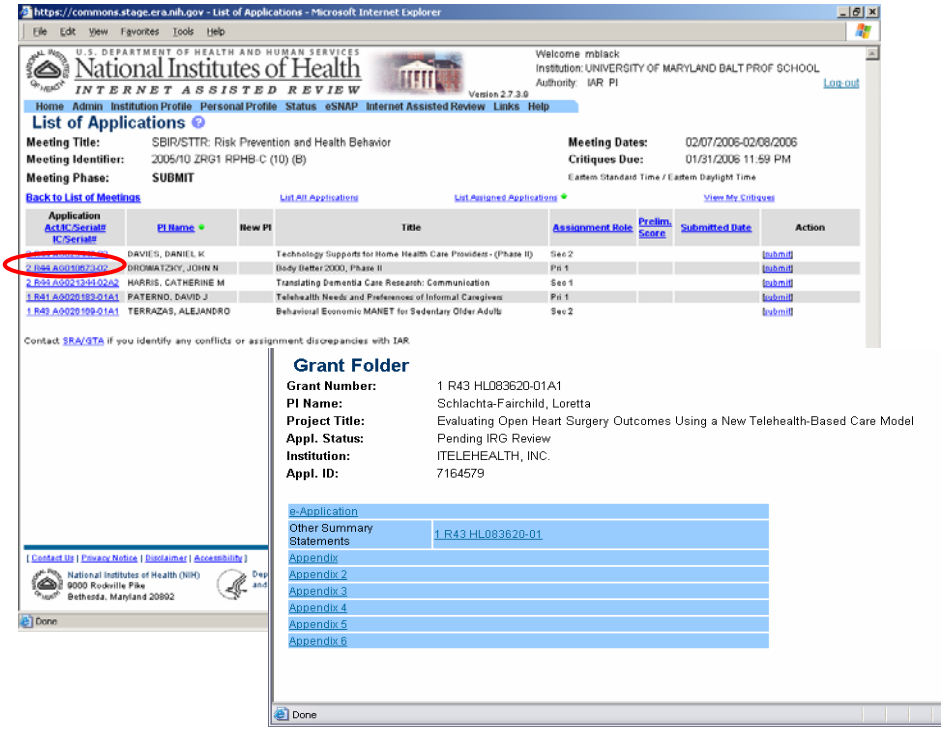

Figure 14: Click on the hypertext link of the grant number to access the Grant Folder Screen

NOTE: To access each individual document, select the Document hypertext link from the **Grant Folder** screen.

Submit Critique and Preliminary Score Screen

Use the **Submit Critique and Preliminary Score** screen to submit application scores and critiques.

To submit critiques/scores:

1. Access the IAR application as described in *Logging On To IAR* on page 3.

2. From the **List of Meetings** screen, select the **View List of Applications** hypertext link (in the **Action** column) to open

the **List of Applications** screen for the application you desire (IAR0007).

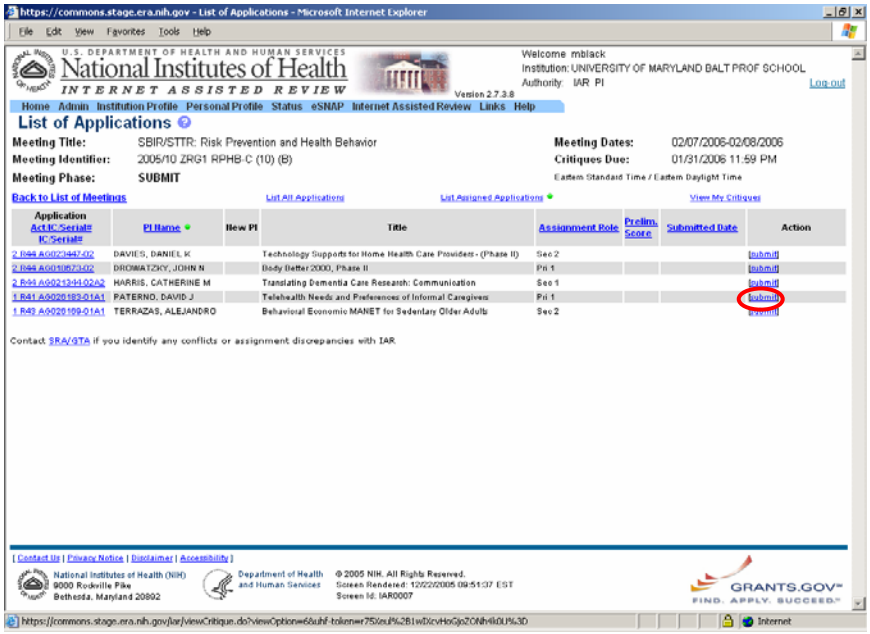

Figure 15: Select the Submit hypertext link to submit critiques and scores

3. Click the **Submit** hypertext link in the **Action** column for the desired application to access the **Submit Critique and Preliminary Score** screen (IAR0011).

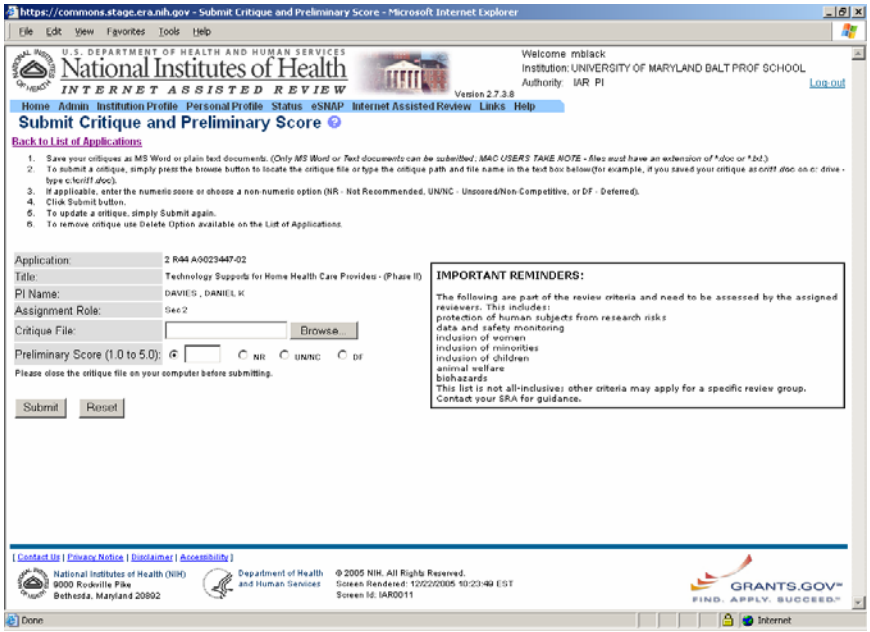

Figure 16: Submit Critique and Preliminary Score Screen (IAR0011)

4. Enter the full path and filename (including extension) of the critique or click **Browse** to locate the file.

5. If applicable, either a numeric score or a score code can be entered.

NOTE: A numeric score must be within a range of 1.0–5.0. If you do not wish to add a numeric score you must use one of the following codes: NR (not recommended), UN/NC (unscored/not competitive), or DF (deferred). Only one option is permitted.

6. Click **Submit** to upload the file. The file is checked for the proper file type and is virus-checked. A message appears to validate the submission, with an option to cancel or submit critique and score.

Viewing Critiques

Your ability to view critiques depends upon the type of reviewer that you are and the current IAR phase of the meeting. Critiques cannot be modified during the *Read* Phase. You are not able to view critiques and scores for applications that cause a conflict of interest for you. When there is more than one critique to display, the critiques are merged into one file with each critique printed on a new page.

- **Regular reviewers**—During the *Read* phase, you can usually view critiques posted by other reviewers to help you prepare for review meeting discussions. However, if you have not submitted your critique during the *Submit* phase, your SRA/GTA can block you from reading other critiques until you have submitted your own. If you are blocked from reading, you must submit your critique before you will be able to read other critiques.
- **Mail reviewers**—You will not be able to view critiques that are submitted by other reviewers. During the *Submit* phase, you can view critiques you have submitted from the List of Applications page, one at a time. During the Read Phase, you can view critiques in several ways:
    - all critiques for all applications in a specific meeting
    - all of your own critiques for a specific meeting
    - all critiques for your assigned applications
    - all critiques for one application merged into one file

NOTE: Subprojects are treated like all other applications. For example, if you are assigned to two subprojects and don't submit a critique on time for one of them, if the SRA/GTA blocks you from viewing other critiques you only will be blocked from viewing critiques for the specific subproject that doesn't yet have a critique submitted.

To view critiques:

1. From the List of Meetings screen, select the **View List of Applications** hypertext link of the desired application to access the **List of Applications** screen (IAR0007).

2. To view an individual critique (during all IAR phases):

   Select the **View My Critiques** hypertext link of the desired application. The critique is usually viewed in Adobe PDF, but may be displayed in the original Word/text format if the conversion has not occurred.

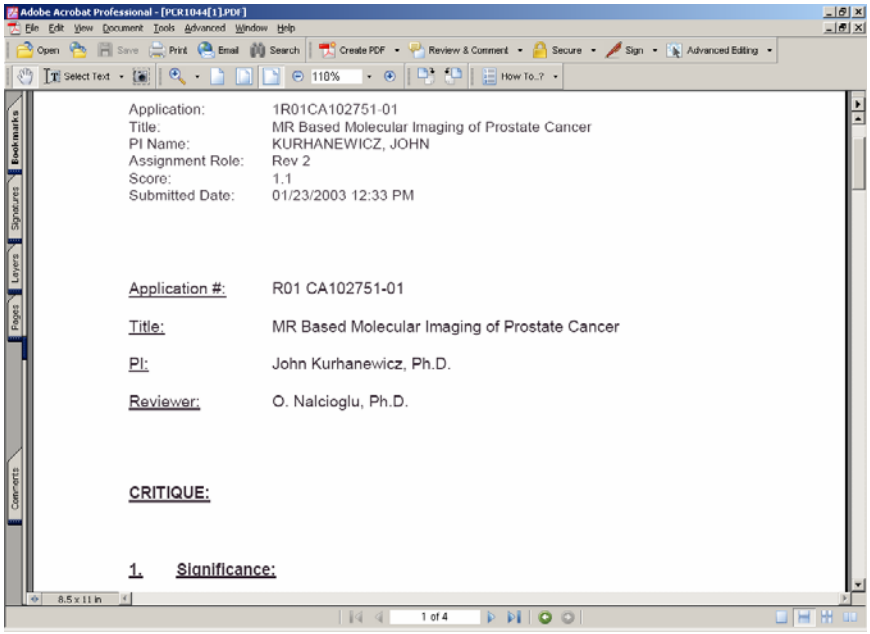

Figure 17: Critique View as it appears in Adobe Acrobat Reader®

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National Institutes of Health Office of Extramural Research

eCOI Users' Guide

(Peer Review/IAR)

Version 2.13.0.0 – December 14, 2007

Table of Contents

Electronic Conflict of Interest (eCOI)

With this IAR release, Reviewers can ***electronically*** sign Conflict of Interest forms. The eCOI forms are accessed from the IAR module. eCOIs will co-exist with the paper forms. The form will be available as long as reviewers have access to the Internet Assisted Review (IAR) module for that particular meeting. There is no change in the conflict of interest policy with the electronic forms' introduction (*see* **Grant Application Reviewers—Confidentiality and Non Disclosure Rules** on page 22, or access the policy at **http://grants.nih.gov/grants/peer/COI_Information.pdf**).

NOTE: The eRA system maintains a meeting's eCOI information for 10 years.

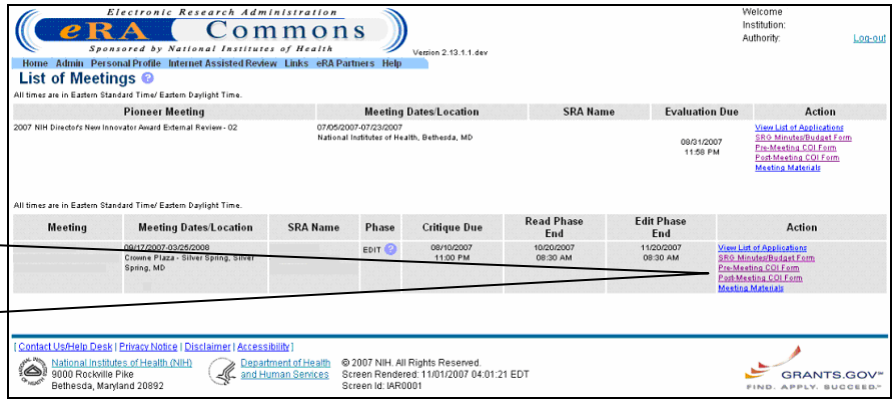
Reviewers—eCOI

Access eCOI Forms

Reviewers access specific eCOI forms from the **List of Meetings** screen when the "Allow eCOI Submission" meeting option is enabled (*see* **Enable/Disable eCOI Meeting-Wide Option** on page 12).

To access an eCOI form:

1. Click the desired form's link on the **List of Meetings** screen (*see* Figure 1).



Form Links:

Action

View List of Applications
SRG Minutes/Budget Form
Pre-Meeting COI Form
Post-Meeting COI Form
Meeting Materials

Figure 1: List of Meetings Screen (IAR0001).

NOTE: The **Post-Meeting COI Form** link is not available for reviewers designated as "Mail/Outside Opinion Reviewers" in the Committee Management system.

Sign the Pre-meeting COI Form

To sign the **Pre-meeting COI Form**:

1. Open the **Pre-meeting COI Form** (*see* **Access eCOI Forms** on page 2).

- The **Pre Meeting Form** screen displays (*see* Figure 2).

Links

The following information was removed from Figure 2 to maintain data privacy:

Reviewer Name
Scientific Review Group
Electronic Signature (Reviewer Name)

Figure 2: Pre Meeting Form Screen.

2. Click the **Pre-meeting COI Form – Page 2-3 (suffix)** link to read COI certification rules and information.

Pre-meeting COI Form – Page 2-3 (Fed / non-Fed)

NOTE: The **Pre-meeting COI Form – Page 2-3 (suffix)** links displays as follows:

The link displays with the "**Fed**" suffix when the user is a federal employee as specified within the Committee Management system.

The link displays with the "**non-Fed**" suffix when the user is **not** a federal employee as specified within the Committee Management system.

3. Click the desired radio button (*see* **Pre-meeting COI Form Fields/Links/Actions** on page 4 for radio button selection descriptions).

NOTE: Only one radio button can be selected and at least one radio button must be selected to certify the form.

4. Click the I Certify button to electronically sign the form.

The system redisplays the **Pre Meeting Form** screen with the electronic signature (*see* Figure 3).

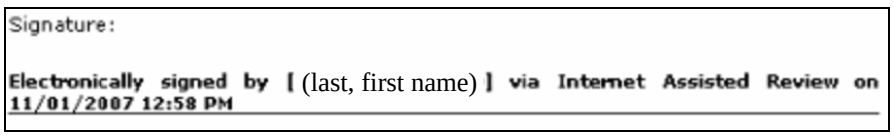


Figure 3: Pre Meeting Form—Electronic Signature.

NOTE: Click the Cancel button to return to the **List of Meetings** screen.

NOTE: The **Pre-meeting COI Form** can be re-signed when necessary. To re-sign the form, follow steps 1 through 4 above.

Pre-meeting COI Form Fields/Links/Actions

The following list describes **Pre Meeting Form** screen fields, links, and actions.

Field/Link/Action	Description
List of Meetings **(Hypertext Link)**	When clicked, displays the **List of Meetings** screen.
Project Personnel Institutions **(Hypertext Link)**	When clicked, displays the "Unique Institutions - Project Personnel Report".
Pre-Meeting COI Form – Page 2-3 (Fed) **(Hypertext Link)**	When clicked, displays rules and information related to COI certification for federal employees. *See* **Pre-meeting COI Form – Page 2-3 (Fed / non-Fed)** on page 3.
Pre-Meeting COI Form – Page 2-3 (non-Fed) **(Hypertext Link)**	When clicked, displays rules and information related to COI certification for non-federal employees. *See* **Pre-meeting COI Form – Page 2-3 (Fed / non-Fed)** on page 3.
Reviewer Name	The last and first name of the individual certifying the form. The system automatically determines the displayed value.
Address	The reviewer's address—the system automatically determines the displayed value.
Scientific Review Group	Identifies the meeting related to the COI certification. The system automatically determines the displayed value.
Date(s) of Review	The meeting's start and end date in Month DD, YYYY – Month DD, YYYY format. The system automatically determines the displayed value.
Radio Button 1	"I have read the attached "DHHS Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and have examined the list of applications/proposals to be reviewed, and hereby certify that, based on the information provided to me, **I do not have a conflict of interest in any of them."**

Field/Link/Action	Description
Radio Button 2	**"For grant application reviews only:** I have read the attached "DHHS Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and examined the list of applications to be reviewed and hereby certify that, based on the information provided, **I have a conflict of interest in the specific applications listed below** and hereby recuse myself from their review."
Radio Button 3	**"For contract proposal reviews only:** I have read the attached "DHHS Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and examined the list of proposals to be reviewed and hereby certify that based on the information provided, **I have a conflict of interest in the specific proposals listed below** and hereby recuse myself from their reviews (requires a waiver to participate in review meeting)."
Applications in Conflict	A list of applications that the SRA has designated as in conflict. Displays the following: PI Name – last, First name of the PI Grant # - The grant Number of the proposal The system automatically determines the displayed value.
Certification	"I certify that I have read the attached "DHHS Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers." Under penalty of perjury (US Code Title 18 chapter 47 section 1001), I certify that to the best of my knowledge I have disclosed all conflicts of interest that I may have with the applications or R&D contract proposals and I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the review, my evaluation, or the review meeting with any other individual except as authorized by the Scientific Review Administrator (SRA) or other designated DHHS official; (3) not to disclose procurement information prior to the award of a contract; and (4) to refer all inquiries concerning the review to the SRA or other designated DHHS official."
I Certify **(Action Button)**	*See* **Click the**  **button to electronically sign the form** on page 3
Cancel **(Action Button)**	When clicked before signing, returns the user to the **List of Meetings** screen leaving the form unsigned.

Field/Link/Action	Description
Signature	Displays the following when the form is signed: "Electronically signed by [Reviewer Last Name, Reviewer First Name] via Internet Assisted Review on MM/DD/YYYY HH:MI AM/PM. The system automatically determines the displayed name value.

Sign the Post-meeting COI Form

A system generated email (*see* **Email Reminder Text** on page 8) is forwarded to reviewers as a reminder to sign the Post-meeting COI Form when the following conditions exist:

- The "Allow eCOI Submission" option is enabled.
- The reviewer is not designated as "Mail/Outside Opinion Reviewers" in the Committee Management system.
- The reviewer did not sign the form.
- The meeting end date has past.
- The meeting "Edit" phase (if exists) has not yet past.
- The meeting "Read" phase (if "Edit" phase does not exist) has not yet past.

To sign the **Post-meeting COI Form**:

1. Open the **Post-meeting COI Form** (*see* **Access eCOI Forms** on page 2).

NOTE: The Post-meeting COI Form is **not** available to reviewers designated as "Mail/Outside Opinion Reviewers" in the Committee Management system.

- The **Post Meeting Form** screen displays (*see* Figure 4).

Link

The following information was removed from Figure 4 to maintain data privacy:

Scientific Review Group
Printed Name (Reviewer Name)
Electronic Signature (Reviewer Name)

Figure 4: Post Meeting Form Screen.

2. Click the I Certify button to electronically sign the form.

- The system redisplays the **Post Meeting Form** screen with the reviewer's printed name and electronic signature (*see* Figure 5).

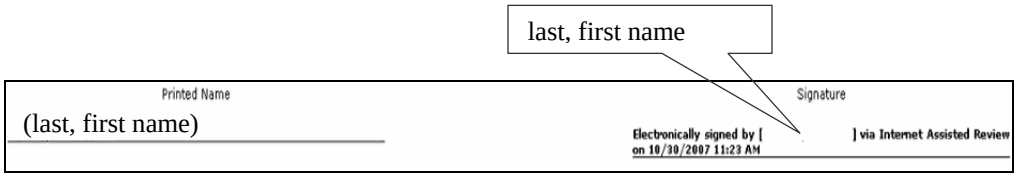


Figure 5: Post Meeting Form—Electronic Signature.

NOTE: Click the Cancel button to return to the **List of Meetings** screen.

NOTE: The **Post-meeting COI Form** can be re-signed when necessary. To re-sign the form, follow steps 1 and 2 above.

Post-meeting COI Form Fields, Links, Actions

The following list describes **Post Meeting Form** screen fields, links, and actions.

Field/Link/Action	Description
List of Meetings (Hypertext Link)	When clicked, displays the **List of Meetings** screen.
Scientific Review Group	Identifies the meeting related to the COI certification. The system automatically determines the displayed value.

Field/Link/Action	Description
Date(s) of Review	The meeting's start and end date in Month DD, YYYY – Month DD, YYYY format. The system automatically determines the displayed value.
I Certify **(Action Button)**	*See* **Click the**  **button to electronically sign the form** on page 7.
Cancel **(Action Button)**	When clicked before signing, returns the user to the **List of Meetings** screen leaving the form unsigned.
Signature	Displays the following when the form is signed: "Electronically signed by [Reviewer Last Name, Reviewer First Name] via Internet Assisted Review on MM/DD/YYYY HH:MI AM/PM" The system automatically determines the displayed name value.

Email Reminder Text

"Our records indicate that you still need to certify the Post-Meeting Conflict of Interest form for the [Meeting Identifier] meeting that took place on [Meeting Start Date]. The Federal Advisory Committee Act (FACA) requires us to file these documents in order to close out the meeting, and timely completion of this task is an essential part of my duties as the Designated Federal Official who was appointed to this meeting. Please log into your Commons account at http://commons.era.nih.gov, navigate to Internet Assisted Review, and click the Post-Meeting COI Form link next to the meeting. Click [I Certify] button on the bottom of the page after you read the form.

Thank you for your cooperation with this request. As always, we are grateful for your participation in the peer review process."

Sign the SRG Minutes/Budget Form

The SRG Minutes/Budget Form is accessed from the **List of Meetings** screen. SRAs sign the form; reviewers sign the form only when the "Allow eCOI Submission" option is enabled (*see* **Enable/Disable eCOI Meeting-Wide Option** on page 12), and the reviewer is designated as a signee by the SRA (*see* **Designate SRG Minutes/Budget Signee** on page 17).

To sign the **SRG Minutes/Budget Form**:

1. Open the **SRG Minutes/Budget Form** (*see* **Access eCOI Forms** on page 2).

- The **SRG Minutes/Budget Form** screen displays (*see* Figure 6).

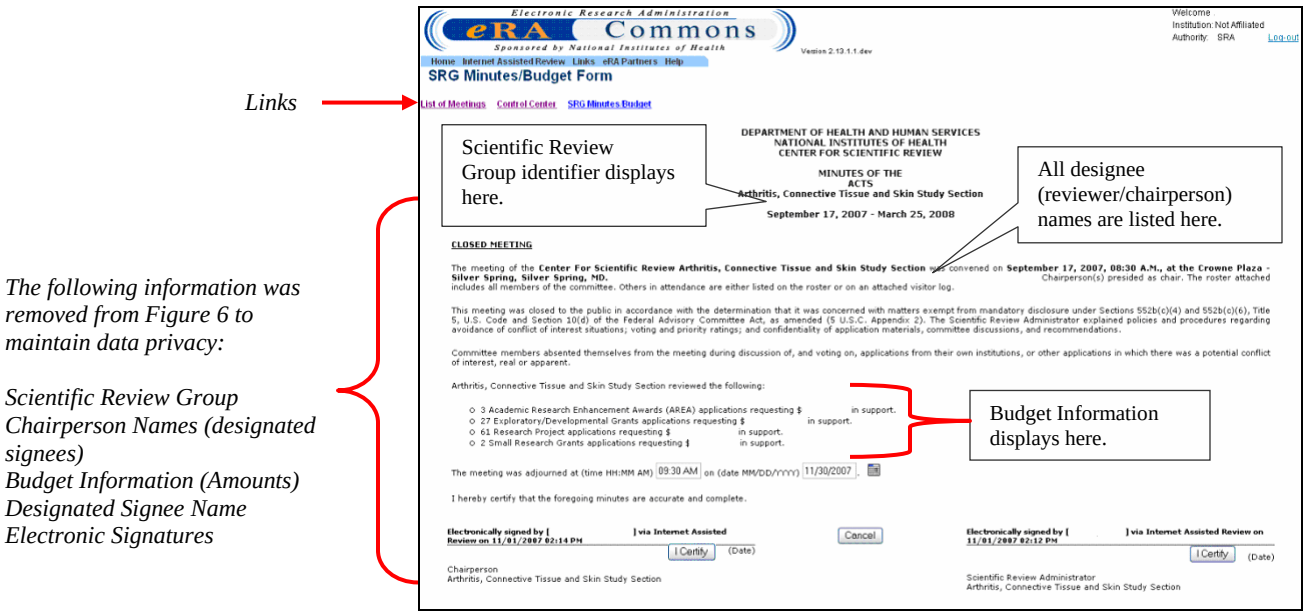


Figure 6: SRG Minutes/Budget Form (IAR0904).

2. Enter the **Meeting Adjourned Time** and **Meeting Adjourned Date** (*see* Figure 7).

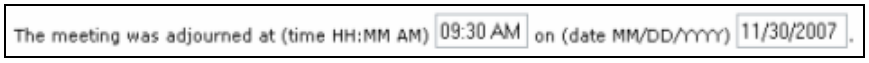


Figure 7: View of Meeting Adjourned Time and Date.

NOTE: The time and date fields must be entered before signing the form.

3. Click the I Certify button to electronically sign the form:

   a. Designees (reviewers/chairpersons)—click the I Certify button adjacent to their name on the lower **left** of the screen.

   b. SRAs—click the I Certify button adjacent to their name on the lower **right** of the screen.

- The system redisplays the **SRG Minutes/Budget Form** screen with the electronic signature (*see* Figure 8).

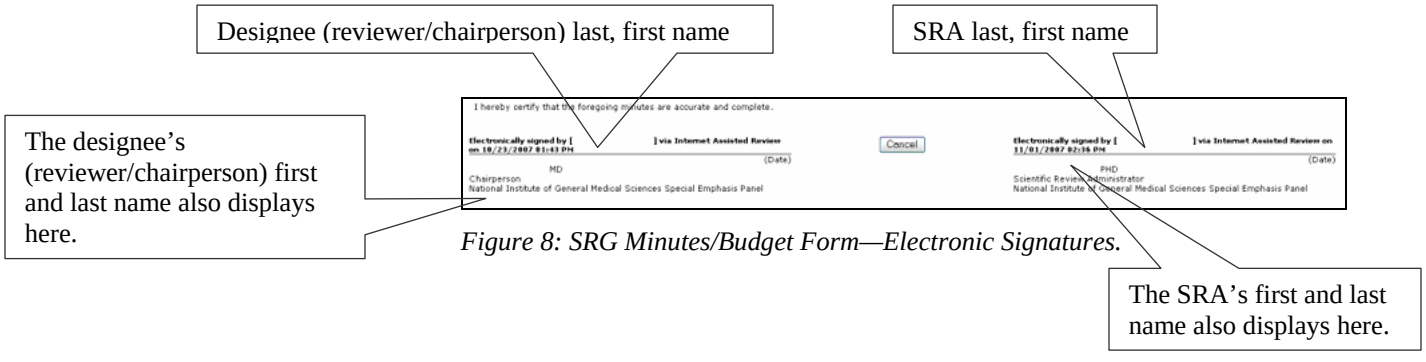


Figure 8: SRG Minutes/Budget Form—Electronic Signatures.

NOTE: Click the Cancel button to return to the **List of Meetings** screen.

NOTE: The **SRG Minutes/Budget Form** can be re-signed and the **Meeting Adjourned Time** and **Meeting Adjourned Date** can be re-entered. To re-sign the form, follow steps 1 through 3 above.

Multiple Reviewers (designees)

The **SRG Minutes/Budget Form** screen displays all reviewers with signee designation and displays the I Certify button only for the specific designee accessing the form (*see* Figure 9). SRAs and reviewers cannot sign the form for other designees.

Multiple designees (reviewers/chairpersons)

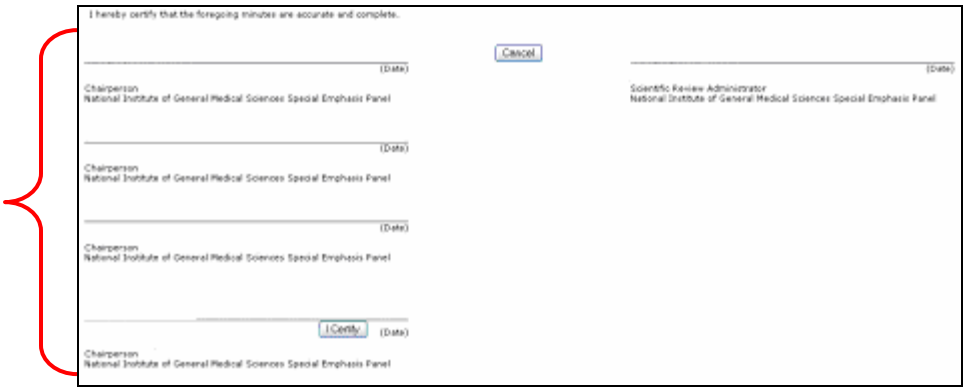


Figure 9: Partial View SRG Minutes/Budget Form Screen (IAR0904).

SRG Minutes/Budget Form Fields, Links, Actions

The following list describes **SRG Minutes/Budget Form** screen fields, links, and actions.

Field/Link/Action	Description
Adjourned Meeting Date	The date the meeting was adjourned. The **Adjourned Meeting Date** must be entered before singing the form. The valid format is mm/dd/yyyy.
Adjourned Meeting Time	The time the meeting was adjourned. The **Adjourned Meeting Time** must be entered before singing the form. The valid format is HH:MI AM/PM, for example—1:15 PM
SRA	The meeting's SRA first and last name. The **SRA** field displays on the screen's lower right. The system automatically determines the displayed value.

Field/Link/Action	Description
Chairperson	The reviewer's (designated as signee) first and last name. The **Chairperson** field displays on the screen's lower left. More than one can display. The system automatically determines the displayed value.
I Certify **(Action Button)**	*See* **Click the**  **button to electronically sign the form** on page 9. This button displays for reviewers designated as signees and SRAs.
Signature	Displays the following when the form is signed: "Electronically signed by [last, first name] via Internet Assisted Review on MM/DD/YYYY HH:MI AM/PM. The system automatically determines the displayed name value. The SRA's electronic signature displays on the **SRG Minutes/Budget Form** screen's lower right. The reviewer's (with signee designation) electronic signature displays on the **SRG Minutes/Budget Form** screen's lower left for each designee.
Cancel **(Action Button)**	When clicked before signing, returns the user to the **List of Meetings** screen leaving the form unsigned.

APPENDIX C: USEFUL WEB SITES

General Information

- NCI DEA Web Site
  http://deainfo.nci.nih.gov
- NCI Web Site
  http://www.nci.nih.gov/
  http://cancer.gov/
- NCI Extramural Funding Opportunities
  http://deainfo.nci.nih.gov/funding.htm
- NCI Notices Related to Initiatives
  http://deainfo.nci.nih.gov/extra/notices/index.htm
- NIH Office of Extramural Research (OER) Peer Review Policy and Issues
  http://grants.nih.gov/grants/peer/peer.htm
- NCI Research Funding—General Information
  http://www.nci.nih.gov/researchfunding/
- PHS 398 Form and Instructions
  http://grants.nih.gov/grants/funding/phs398/phs398.html
- NIH Guide for Grants and Contracts
  http://grants1.nih.gov/grants/guide/index.html
- Modular Budget Information
  http://grants.nih.gov/grants/funding/modular/modular.htm
- NIH Data Sharing Policy and Implementation Guidance
  http://grants1.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
- Center for Scientific Review
  Policy, Procedure, and Review Guidelines
  http://www.csr.nih.gov/review/policy.asp
- NIH Announces Updated Criteria for Evaluating Research Grant Applications
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html

Human Subjects

- NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects
  http://grants.nih.gov/grants/peer/hs_review_inst.pdf
- Protection of Human Subjects From Research Risk
  http://grants.nih.gov/grants/peer/tree_protection_hs.pdf
- Monitoring Plan and Data Safety and Monitoring Board Information
  http://grants.nih.gov/grants/guide/notice-files/not98-084.html
- Inclusion of Women and Minorities Policy Implementation
  http://grants.nih.gov/grants/funding/women_min/women_min.htm
- NIH Policy on Inclusion of Children as Participants in Research Involving Human Subjects
  http://grants.nih.gov/grants/funding/children/children.htm
- Research on Human Specimens
  http://www-cdp.ims.nci.nih.gov/policy.html
- Required Education in the Protection of Human Research Participants
  http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Internet Assisted Review

- NIH Commons Home Page
  http://commons.era.nih.gov
- ERA Home Page
  http://era.nih.gov
- NIH Commons Support Page
  http://era.nih.gov/commons/

Vertebrate Animals

- U.S. Government Principals for the Use/Care of Vertebrate Animals in Testing, Research, and Training
  http://oacu.od.nih.gov/NIHpolicy/3040-2app3.htm

APPENDIX D: GLOSSARY OF TERMS

Academic Research Enhancement Award (AREA - R15): Grant award stimulating research at health professional academic institutions with less than $3 million of NIH support in total costs in four or more of the last seven years. Go to *AREA*: *http://grants.nih.gov/grants/funding/area.htm*.

Account: As used by the *NIH eRA Commons* (*https://commons.era.nih.gov/*), a personal account an individual uses to log into the NIH eRA Commons which is identified by a unique combination of username and password.

Activity Codes: A 3-character code (e.g., R01, R43) used to identify areas of extramural research activity applied to various funding mechanisms. Go to: *http://grants.nih.gov/grants/funding/ac.pdf*.

Administrative Supplement: Funds added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Advisory Council: Chartered Institute advisory committee that performs the second level of peer review, makes funding and policy recommendations, and helps develop research initiatives. In the NCI, this council is called the National Cancer Advisory Board.

Alien Registration Receipt Card: Commonly known as "Green Card," shows a person's status as a permanent resident with a right to live and work permanently in the U.S. Also called Form I-551.

Amendment (Amended or Resubmitted Application): Resubmission of an unfunded application that has been revised in response to a prior review.

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America and maintaining tribal affiliation or community.

American Recovery and Reinvestment Act (ARRA): The *American Recovery and Reinvestment Act of 2009* was signed into law by President Obama on February 17th, 2009. The Act includes measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

Animal Welfare Assurance: Document an institution and all performance sites involving animals in research must have on file with the *Office of Laboratory Animal Welfare* (*http://grants.nih.gov/grants/olaw/olaw.htm*) before a *PHS* Agency may award a grant or contract.

Appeal: A procedure for contesting the peer review of a grant application (synonymous with rebuttal).

Application: A request for financial support of a project/activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Types:

Type I	New
Type 2	Competing continuation (a.k.a. renewal, re-competing)
Type 3	Application for additional (supplemental) support
Type 4	Competing extension for an R37 award or first non competing year of a Fast Track SBIR/STTR award
Type 5	Non-competing continuation
Type 7	Change of grantee institution
Type 9	Change of NIH awarding Institute or Division (competing continuation)

Approved Budget: The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee.

AREA: See *Academic Research Enhancement Award*.

ARRA: See *American Recovery and Reinvestment Act*.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia,

Pakistan, the Philippine Islands, Thailand, and Vietnam.

Assistance: The award of money, property, or services to a recipient to accomplish a public purpose as authorized by Federal statute. Assistance relationships (e.g., grants) are expressed in less detail than are acquisition relationships (contracts), and responsibilities for ensuring performance rest largely with the recipient or are shared with the Government.

Authorized Organizational Representative: The individual authorized by the applicant organization to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is equivalent to the "signing official" or SO in NIH's eRA Commons.

Awaiting Receipt of Application: An internal NIH document submitted to CSR by NCI staff to indicate willingness to accept an application (a) requesting $500,000 or more in direct costs in any year, or (b) for programmatic relevance.

Award: The provision of funds by NIH, based on an approved application and budget, to an organizational entity or a person to carry out an activity or project. This includes both direct and indirect costs (F & A) unless otherwise indicated.

Bayh-Dole Act: A law encouraging universities and researchers to develop their inventions into marketable products.

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" also can be used.

Blinded Study: A clinical trial in which participants are unaware if they are in the experimental or control arm of the study.

Bridge Awards (R56): Provides one year of funding so investigators can continue research while reapplying for an R01 grant or enables new investigators to gather preliminary data to improve their applications. Investigators do not apply for Bridge Awards but are selected from R01 grants near payline.

Budget Period: The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

Cancer Center Support Grants (P30): Center grant to support shared resources, clinical translational research infrastructure and administrative needs for a group of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort. The NCI Cancer Center Support Grants support research programs in more than 60 institutions across the United States.

Career Development Awards: Award that supports Ph.D.s and clinicians who wish to develop or enhance a career in biomedical research; *activity codes* are in the K series.

Carryover: As indicated by the Notice of Award (NoA), carryover authority provides grantees permission to carry over funds unobligated at the end of a budget period to the next budget period.

Catchment Area: The geographical area served by a medical facility and from which the majority of its patients are drawn.

CCR: See *Central Contractor Registration Database*.

CCSG – see *Cancer Center Support Grants*.

Center Grants: Financial assistance awards to institutions on behalf of research leaders and groups of collaborating investigators. Center grants provide support for long-term, multidisciplinary programs of research and development.

Center for Scientific Review (CSR): The NIH component responsible for the receipt and referral of applications to the PHS, as well as the initial review for scientific merit of most applications submitted to the NIH.

Central Contractor Registration database: Primary database for organizations and persons who do business with the federal government. Grant-applicant institutions need to register with the *CCR* (*http://www.ccr.gov/)* to apply for a grant through *www.Grants.gov*.

Chartered Advisory Committee: Any committee formed for advisory purposes composed not wholly

of Federal officials. Under the Federal Advisory Committee Act, standing committees must be chartered (i.e., approved by their parent agency in collaboration with the Government Services Agency) to ensure a properly balanced representation (in terms of geography, gender, and minority) and that other legal requirements are met.

Child: For NIH purposes, a child is a person under 21 years of age. This policy and definition do not affect the human subject protection regulations for research on children (45 CFR 46), and their provisions for assent. This definition pertains notwithstanding the FDA definition of a child as a person from infancy to 16 years of age, or varying definitions employed by some States. Children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and is sufficient to participate in research under State law.

Clinical Research: The NIH definition is based on the 1997 Report of the NIH Directors Panel on Clinical Research that defines clinical research in three parts: (1) Patient-oriented 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 that use human tissues that cannot be linked to a living person. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes and health services research. Autopsy material is not covered by the policy.

Clinical Trial: For review of applications submitted to the NIH, a clinical trial is defined as a prospective biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of experimental drug, treatment, device, or behavioral intervention may proceed through four phases: Phase I, Phase II, Phase III, and Phase IV. [See separate definitions below.]

Close Out: A procedure to officially conclude a grant.

CO – see *Contracting Officer/Contract Specialist*.

Co-funding: Funding arrangement through which two or more Institutes or Centers pay for a grant.

Commercialization: The third phase of the NCI's Small Business Innovation Research contracting process is commercialization. In this phase, small businesses aim to advance the results of research and development performed in Phase I and II contracts into commercially viable products or services for Government use.

Commons: NIH eRA commons - See *Electronic Research Administration*.

Competing Applications: Applications that are either new or renewals. They must undergo initial peer review.

Competing Continuation (Application): An application that requires competitive peer review and Institute/Center action to continue beyond the current competitive segment. Also known as a renewal or type 2 application.

Competitive Range: A contracting term denoting a group of proposals considered acceptable by the initial peer review group and to be potential candidates for an award.

Competitive Revision: Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review.

Computer Retrieval of Information on Scientific Projects (CRISP): A searchable biomedical database of federally-supported proposed research conducted at universities, hospitals, and other research institutions. Go to: http://crisp.cit.nih.gov/.

Concept: The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts for RFAs and RFPs are brought before the Advisory Council for concept clearance.

Concern: In the context of research involving human subjects and/or vertebrate animals, a

concern is an issue so critical that it must be resolved before funds can be awarded.

Conflict of Interest: Regulations exist to ensure that Government employees, Scientific Review Group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement: A collaborative arrangement in support of a research project in which some portion of the programmatic activity is carried out through a formalized agreement between the grantee and one or more other organizations that are separate legal entities administratively independent of the grantee.

Consultant: A Federal or non-Federal employee who is retained, designated, or appointed to an individual review group or serves as an ad hoc reviewer.

Consumer Advocate: A person chosen to serve on a Scientific Review Group (SRG) or Special Emphasis Panel (SEP) as a public member. This person is allowed to serve based on his/her experience and knowledge of a disease, health status, or public health problem.

Contract (R&D): An award instrument establishing a binding legal procurement relationship between NIH and a recipient, obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute(s) involved to pay for it.

Contracting Officer (CO)/Contract Specialist (CS): The CO and/or CS serve as resources on contract regulations, policies, and procedures during the Technical Evaluation Panel (TEP) meetings in which contract proposals undergo peer review.

Cooperative Agreement: A financial assistance mechanism (U series) used when substantial Federal programmatic involvement with the recipient during performance is anticipated by the NIH Institute or Center.

Core: A separately budgeted component of a multi-component application that provides essential facilities or services to two or more of the proposed research projects.

Core Director: The investigator responsible for the scientific direction and conduct of a core component of a multi-component application.

Council/Board, Advisory: National Advisory Council or Board, mandated by statute, that provides the second level of review for grant applications for each Institute/Center that awards grants. The Councils/Boards are composed of scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the Initial Review Groups) and the relevance of the proposed study to an Institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round: At the NCI, there are three NCAB rounds each February, June, and September for second level review of grant applications. In addition, there is an NCAB meeting in December for intramural reviews.

Cover Letter: Letter attached to a grant application that may request a scientific review group or institute or provide other information (e.g., list of individuals in conflict, disciplines involved). For late applications, include an explanation of the delay as part of the cover letter attachment. A cover letter is required for late applications. Use the *PHS 398 Cover Letter File* for SF424 applications. The cover letter is for internal use only and will not be shared with peer reviewers.

Critique: A written evaluation prepared by a reviewer before an initial peer review meeting and presented to a *Scientific Review Group* at the meeting.

CS – see Contracting Officer/Contract Specialist.

CSR – see Center for Scientific Review.

Data and Safety Monitoring Board (DSMB): An independent committee composed of community representatives and clinical research experts that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

Data and Safety Monitoring Plan: A Data and Safety Monitoring Plan (DSMP) for a clinical study

is an outline set out in advance for the routine review and evaluation of enrollment, data, outcomes, and adverse events.

Data Sharing: Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible *(http://grants.nih.gov/grants/policy/data_sharing/)*. Investigators should seek guidance from their institutions on issues related to institutional policies, local IRB rules, as well as local, State, and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data-sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Deferral: Refers to the delay in the review of an application by a Scientific Review Group, usually to the next review cycle, due to insufficient information in the application.

DHHS: U.S. Department of Health and Human Services. Federal executive department of which the U.S. Public Health Service (PHS) is a component. The NIH is an agency of the PHS.

Direct Costs: Costs that can be specifically identified with a particular project(s) or activity. Examples of research project-specific expenses include expenses for equipment, personnel, travel, and others necessary to carry out a research project.

Double-Blind Study: A clinical trial design in which neither the subject participants nor the study staff know which patients are receiving the experimental drug and which are receiving a placebo or another therapy.

Draft Review Report: A preliminary compilation of reviewer critiques used by Scientific Review Groups to guide final discussion and assignment of overall priority scores to applications.

DSMB – see Data and Safety Monitoring Board.

Dual Assignments: Applications that are simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review Process: The peer review approach used by NIH. The first level of review provides a judgment of scientific merit. The second level of review, usually conducted by an Institute/Center/ Division's Advisory Council, assesses the quality of the first review, sets program priorities, and makes funding recommendations.

Data Universal Numbering System (DUNS) number: Identifier government vendors need to register in the *Central Contractor Registration* database so they can apply for a federal grant. Go to *CCR*: *http://www.ccr.gov*.

Early Stage Investigator (ESI): A subset of *New Investigator*s who are within 10 years of completing his/her terminal research degree or medical residency. A traditional NIH research grant (R01) application from an *ESI* will be identified and the career stage of the applicant will be considered at the time of review and award. See *New Investigator*.

Edison: NIH's electronic invention reporting system (*https://s-edison.info.nih.gov/iEdison/*).

EIN: See *Employee Identification Number*.

Electronic Research Administration (eRA): The NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required. Go to: *http://era.nih.gov/*.

Electronic Review (ER): Internet-assisted method by which reviewers of contract proposals submit their critiques.

Electronic Streamlined Non-competing Award Process (eSNAP): Process allowing an institution to review non-competing grant data and submit a progress report online.

Employee Identification Number (EIN): Identification of a business to the U.S. Internal Revenue Service; also known as a Federal tax identification number. Entered on the SF 424 form of a grant application.

ER – see Electronic Review.

ERA – see Electronic Research Administration.

eRA Commons: A Web interface hosted by NIH where agencies using the eRA System and the grantee community are able conduct their extramural research administration business electronically. Go to: *https://commons.era.nih.gov*.

Expanded Authorities (EA): Operating authorities provided to grantees that waive the requirement for NIH prior approval for specified actions. Go to: *http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Expanded_Authorities*).

Expiration Date: The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Awards: Funds provided by NIH to researchers and organizations outside NIH.

Extramural Research: Research supported by NIH to researchers and organizations outside NIH through a grant, contract, or cooperative agreement.

Facilities and Administrative Costs (F&A): Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

FAR – see Federal Acquisition Regulations.

Fast-Track Initiative: The Fast-Track Initiative is an opportunity for small businesses to submit both Phase I and II contract proposals for concurrent peer review. It can be used by small businesses whose proposals are likely to enhance the probability of the project's commercial success. This initiative also helps minimize any funding gaps between Phases I and II.

Federal Acquisition Regulations (FAR): Laws regulating Government contracting.

Federal Register: An official, daily publication of the Federal government communicating proposed and final regulations and legal notices issued by federal agencies, including announcements of the availability of funds for financial assistance. Go to *Federal Register* (*http://www.gpoaccess.gov/fr/*).

Federal Wide Assurance (FWA): Online form every institution and collaborating institution conducting human subjects research must file with the *Office for Human Research Protections--HHS* (http://www.hhs.gov/ohrp) to establish policies and procedures to protect human subjects as required by *45 CFR 46*.

Fee: An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as "profit."

Fellowship: An NIH training program award where NIH specifies who receives the award. Fellowships comprise the F activity codes.

Final Proposal Revision: After completing negotiations, offerors are asked to submit a final proposal revision that documents all cost and technical agreements reached during negotiations.

Financial Status Report (FSR): A financial report due 90 days after the end of each budget period for those awards not under SNAP, and at the end of the competitive segment for those awards under SNAP, showing the status of awarded funds for that period.

Fiscal year: Federal budget year from October 1 to September 30.

FOA – see Funding Opportunity Announcement.

Foreign Component: The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended.

Funding Opportunity Announcement: A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements (FOAs) may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the

Agency and type of program.

Gender: Refers to the classification of research subjects into two categories: women and men. In some cases, representation is unknown, because gender composition cannot be accurately determined (e.g., pooled blood samples or stored specimens without gender designation).

Grant: A financial-assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever an NIH Institute or Center anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals: A DHHS policy that provides for an appeal by the grantee institution of postaward administrative decisions made by awarding offices. There are two levels of appeal available: (1) An informal NIH procedure, and (2) a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Application Guide: Instructions for completing an electronic Grant Application Package. Each Funding Opportunity Announcement has its own package and guide. Go to NIH Application Guides: http://grants.nih.gov/grants/forms.htm.

Grantee: The organization or person awarded a grant or cooperative agreement by NIH responsible and accountable for the use of the funds provided and the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Specialist: The NCI official who serves as the focal point for all business-related activities associated with the negotiation, award, and administration of grants.

Grants.gov: An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for competitive grant opportunities from the 26 Federal grant-making Agencies. Registration is required to apply. Go to *www.grants.gov*.

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” can be used in addition to “Hispanic” or “Latino.”

Human Subjects: The Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46) defines a human subject as a living person about whom an investigator (professional or student) conducting research obtains (1) data through intervention or interaction with the person, or (2) identifiable private information.

Human Subjects Assurance: A document filed by an institution conducting research on human subjects with the *Office for Human Research Protections--HHS* (http://www.hhs.gov/ohrp) which formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

Human Subjects Concern: Any actual or potential unacceptable risk, or inadequate protection against risk, to human subjects as described in any portion of an application.

Human Subjects Exemption: Research that qualifies for exemption from coverage by the human subjects regulations includes activities in which the only involvement of those subjects will be in one or more of the following six categories: (1) Instructional strategies in established educational settings; (2) educational tests unlinkable to individual persons and with no risks from disclosure; (3) educational tests on public officials, or absolute federally mandated confidentiality; (4) existing data/specimens, publicly available, unlinkable to persons; (5) demonstration projects concerning public benefit or service programs; and/or (6) taste and quality evaluation of foods without additives exceeding regulated levels.

Human Subjects Risk and Protection Issues: Applicants are required to address the following items in their research plan: Subjects’ involvement and characteristics, sources of materials, recruitment and informed consent, potential risks, protection against risk, and benefits.

IACUC – see Institutional Animal Care and Use Committee.

IC: Institute/Center. The NIH organizational component responsible for a particular grant program or set of activities.

Indirect Costs - See *Facilities and Administrative Costs (F&A)*.

Informed Consent: Permission given by a person before surgery or other medical procedure(s). The patient, or a parent or guardian, must understand the potential risks and benefits of the procedure and legally agree to accept those risks.

Initial Peer Review: First level of peer review by non-*NIH* scientific experts, called peer reviewers, who assess the scientific and technical merit of grant applications and contract proposals.

Initial Review Group (IRG): A group primarily composed of non-Federal scientific experts that conducts the initial scientific and technical merit review of grant and cooperative agreement applications, contract proposals, and/or applications for the Loan Repayment Program. [See also Scientific Review Group.]

Initiative: A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating an Institute's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not.

Institute/Center (IC): Institutes and Centers are components of NIH. (This includes the National Library of Medicine.) ICs can make extramural awards.

Institutional Animal Care and Use Committee (IACUC): Established at institutions in accordance with PHS Policy on Humane Care and Use of Laboratory Animals, IACUCs have broad responsibilities to oversee and evaluate an institution's animal programs, procedures, and facilities. IACUC review and approval is required for all PHS-supported activities involving live vertebrate animals prior to funding.

Institutional Business Officer: Person working in a research organization's business office who has signature or other authority. That person is the same as Grants.gov's Authorized Organizational Representative (AOR) and the Commons' Signing Official (SO).

Institutional Review Board (IRB): A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the United States must be approved by an IRB before they begin. Every institution that conducts or supports biomedical or behavioral research involving human subjects must, by Federal regulation, have an IRB that initially approves and periodically reviews the research so as to protect the rights of human subjects.

Integrated Review Group: Group of study sections organized around an area of science that perform initial peer review in the *NIH Center for Scientific Review* (CSR).

Intramural Research: Research conducted by, or in support of, NIH employees.

Investigational New Drug (IND): Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research: Research funded as a result of an investigator, on his or her own, submitting an application (also known as unsolicited research). Unsolicited applications are reviewed by chartered CSR review committees.

IRB – see Institutional Review Board.

IRG – see Initial/Integrated Review Group.

Just in Time: A reinvention innovation in which applicants send some information to NIH only if an award is likely, streamlining the application process.

Key Personnel: Persons who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the funds supporting that project. The Principal Investigator and collaborators are included in this category.

Letter of Intent: A nonbinding notification

submitted to NCI staff by a Principal Investigator indicating intent to submit an application.

Majority Group: White, not of Hispanic origin. A person having origins in any of the original peoples of Europe, North Africa, or the Middle East. NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms “minority groups” and “minority subpopulations” are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

Mandatory Criteria: In some RFPs, the Project Officer (PO) identifies the basic requirements that proposals must meet to execute the contract properly. These criteria are usually specific to a particular RFP and are generally outside the scope of the Technical Evaluation Criteria in each RFP.

Material Transfer Agreement: A legal document defining the conditions under which research or other materials can be transferred and used among research laboratories.

Mechanism - See *Activity Code*.

MEDLINE: National Library of Medicine's database for scientific publications. Go to: *http://medlineplus.gov*.

Minority Group: A readily identifiable subset of the U.S. population distinguished by racial, ethnic, and/or cultural heritage. It is not anticipated that every study will include all minority groups and subgroups. The inclusion of minority groups should be determined by the scientific questions under examination and their relevance to racial or ethnic groups. Applicants should describe the subgroups to be included in the research. In foreign research projects involving human subjects, the definition of minority groups may be different from the United States.

Minority Report: In cases when two or more member(s) of a review committee hold(s) a strong opinion dissenting from that of the majority (e.g., when the majority recommends that an application be not recommended for further consideration), a minority report should be prepared by the dissenting member(s).

Model Organism: Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms. Go to NIH's *Model Organism for Biomedical Research* (*http://www.nih.gov/science/models/*)

Modular Application: A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award. Go to: *http://grants.nih.gov/grants/funding/modular/modular.htm*

Multiple Principal Investigator: Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution. Go to: *http://grants.nih.gov/grants/multi_pi/overview.htm*.

National Cancer Advisory Board (NCAB): A Presidentially appointed, chartered advisory committee to the Secretary, DHHS, and the Director, NCI, composed of scientists and lay members. The NCAB performs final review of grant applications and advises on matters of significance to the policies, missions, and goals of the NCI. Members include outstanding authorities knowledgeable in relevant programmatic areas who are especially concerned with the health needs of the American people.

National Institutes of Health (NIH): A Federal agency whose mission is to improve the health of the people of the United States. NIH is part of the PHS, which is part of the U.S. DHHS.

National Research Service Award (NRSA): An award made to a person and/or institution to provide research training in specified health-related areas.

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

NCAB – see National Cancer Advisory Board.

ND – see *Not Discussed*.

Negotiation -This term refers to contracts for supplies or services without the use of formal

advertising. Under negotiated contracts, the lowest price offeror may not necessarily receive the award. Award is made on the basis of the proposal that offers the greatest advantage to the government, price and other factors considered. Typically, when contracting for Research and Development, technical competence is primary.

New Application (Award, Grant): An application not previously proposed, or one that has not received prior funding (also known as a type 1 application).

New Investigator- For the purpose of review and funding, a PD/PI is identified as a New Investigator if he/she has **not** previously competed successfully for an NIH-supported research project **other than** the following small or early stage research awards:

- Pathway to Independence Award-Research Phase (R00)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Clinical Trial Planning Grant (R34)
- Dissertation Award (R36)
- SBIR Grant - Phase I (R43)
- STTR Grant - Phase I (R41)
- Shannon Award (R55)
- NIH High Priority, Short-Term Project Award (R56)
- Competitive Research Pilot Projects (SC2, SC3)

Additionally, the PD/PI is not excluded from consideration as a "New Investigator" if he/she has received an award from any of the following classes of awards:

Training-Related and Mentored Career Awards

- All Fellowships (F awards)
- All career awards (K awards)
- Loan repayment contracts (L30, L32, L40, L50, L60)

Instrumentation, Construction, Education, Health Disparity Endowment Grants, or Meeting Awards

- G07, G08, G11, G13, G20
- S10, S15, S21, S22

NIH – see National Institutes of Health.

NIH Guide for Grants and Contracts: The official publication for NIH's medical and behavioral research grants policies, guidelines and funding opportunities. Go to *Funding Opportunities and Notices* (http://grants.nih.gov/grants/guide/index.html).

NIH-Defined Phase III Clinical Trial: For the purpose of the Guidelines on the Inclusion of Women and Minorities, an NIH-defined Phase III clinical trial is a broadly based, prospective clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention, or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, nonpharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

NIH Manuscript Submission System (NIHMS): NIHMS is a system developed by NIH, and allows users to deposit and manage manuscripts. Go to: *http://www.nihms.nih.gov/*.

Non-competing Continuation: A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review, but are administratively reviewed by the funding Institute/Center and receive an award based on prior award commitments (also known as type 5).

Non-competing Grant: An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Not Recommended for Further Consideration (NRFC): An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

Notice of Grant Award: A legally binding document that notifies the grantee and others that an award has been made. It contains or references all terms and conditions of the award and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.

Not Discussed: Lower 50 percent of applications in the study section--criterion and impact scores provided by assigned reviewers but no discussion at meeting.

NRFC – see Not Recommended for Further Consideration.

NRSA – see National Research Service Award.\

Offeror: A contracting term denoting an applicant responding to an RFP.

Office of Extramural Research (OER): NIH office overseeing policies and guidelines for extramural research grants. Go to: *http://grants.nih.gov/grants/oer.htm*.

Office of Human Research Protections (OHRP): HHS office overseeing human subject protection for HHS-supported research. Go to: http://www.hhs.gov/ohrp/.

Office of Laboratory Animal Welfare (OLAW): NIH office overseeing compliance with the *PHS Policy on Humane Care and Use of Laboratory Animals*. Go to: *http://grants.nih.gov/grants/olaw/olaw.htm*.

Office of Research Integrity (ORI): HHS office promoting integrity in biomedical and behavioral research supported by the Public Health Service by monitoring institutional investigations of scientific misconduct and facilitating the responsible conduct of research. Go to *ORI* (*http://ori.dhhs.gov/*).

Other Support: Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

P01 – see Program Project Grant.

P30 – see Cancer Center Support Grant.

P50 – see Specialized Center.

PA – see Program Announcement.

PAR – see Program Announcement Reviewed in an Institute.

Parent Announcement: NIH-wide *funding opportunity announcement* enabling applicants to submit an electronic *investigator-initiated* grant *application* for a single grant mechanism, e.g., *Research Project Grant (Parent R01)*.

Parent Committee: The review committee responsible for scientific peer review and final merit scoring of multi-component (e.g., Centers, Cooperative Groups) applications. To make its assessment, the parent committee draws on written reports from work groups, the response of the applicant to the draft review report, and deliberations of panel members.

PAS – See *Program Announcement with Set-Aside Funds*.

Patient Advocate – See *Consumer Advocate*.

Patient Oriented Research: Research into disease mechanisms, therapeutic interventions, clinical trials, or the development of new technologies. Also see *clinical research*.

Payline: A percentile-based and numerical funding cutoff point determined at the beginning of the fiscal year. Institutes determine paylines by balancing projected grant numbers, grant budgets, and monies in the budget.

Peer Review: The process by which applications for NIH support are evaluated by groups of scientists from the extramural research community. The objective of peer review is to evaluate and rate the scientific and technical merit of the proposed research or research training. [See also *Dual Review Process*.]

Peer Reviewer: Scientist and expert in their field who reviews grant applications or contract proposals for NIH. This includes the scientific

review group chair, who leads the discussions.

Percentile Rank: In the context of scoring applications for funding, the relative position of each priority score among the scores assigned by a scientific review group at its last three meetings. The lower the numeric value of the percentile score the better. The range is from 1 to 99.

Person Months: Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Phase 0 Clinical Trial: A Phase 0 (zero) clinical trial is designed to study the pharmacodynamic and pharmacokinetic properties of a drug. In a Phase 0 trial, a limited number of doses, and much lower doses of the drug are administered, therefore there is less risk to the participant.

Phase I Clinical Trial: Phase I clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (20 to 80) for the first time to determine the metabolism and pharmacologic actions of the drug in humans, safety, side effects associated with increasing doses, and if possible, early evidence of effectiveness. Phase I trials are closely monitored and may be conducted in patients or healthy volunteers.

Phase II Clinical Trial: Phase II clinical trials are done to study the biomedical or behavioral intervention in a large group of people (several hundred) to determine efficacy and to further evaluate safety. They include controlled clinical studies of effectiveness of a drug for a particular indication or indications in patients with the disease or condition under study and determination of common, short-term side effects and risks associated with the drug. Phase II studies are typically well controlled and closely monitored.

Phase III Clinical Trial: Phase III studies are expanded controlled and uncontrolled studies performed after preliminary evidence of drug effectiveness has been obtained. They are intended to gather additional information about effectiveness and safety needed to evaluate the overall benefit-risk relationship of the drug and to provide adequate basis for physician labeling. These studies usually include anywhere from several hundred to several thousand subjects.

Phase IV Clinical Trial: Phase IV studies are postmarketing studies (genera*l*ly randomized and controlled) carried out after licensure of a drug. These studies are designed to monitor effectiveness of an approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

PHS – see *Public Health Service*.

PHS Policy on Humane Care and Use of Laboratory Animals: Compliance with PHS policy is a term and condition of all PHS awards involving live vertebrate animals.

Placebo-Controlled Study: A method of investigation of drugs in which an inactive substance (placebo) is given to one group of patients, while the drug being tested is given to another group.

PO – see *Project Officer*.

Pre-application: A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

Principal Investigator (PI): The individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The applicant organization may designate multiple individuals as PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PI is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program including the submission of all required reports.

Priority Score: A numeric rating that reflects the scientific and technical merit of proposed research relative to the “state of the science.” The score is a quantitative indicator that ranges from 100 to 500. Individual IRG members assign scores from 1.0 (highest merit) to 5.0 (lowest merit). Votes are cast in 0.1 increments. The priority scores are the

average of member votes multiplied by 100.

Privacy Act: A law that protects against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Procurement: The acquisition of property or services for the direct benefit or use of the Government, generally via a contract.

Program Announcement (PA): An announcement by an NIH Institute or Center requesting applications in stated scientific areas. Generally, money is not set aside to pay for them. [See *Program Announcement with Set-Aside Funds*, below.]

Program Announcement Reviewed in an Institute (PAR): Program Announcement with special receipt, referral and/or review considerations.

Program Announcement with Set-Aside Funds (PAS): A PAS is a PA that includes specific set-aside funds, as described in the announcement.

Program Director/Officer: The NCI scientist administrator responsible for development of initiatives and scientific management of NCI-sponsored research programs. He/she is the focal point for all science-related activities associated with the negotiation, award, and administration of grants.

Program Income: Gross income earned by a grantee directly generated by the grant-supported project or activity or earned as a result of the award.

Program Project Grant (P01): An assistance award for the support of a broadly based multidisciplinary research program that has a well-defined central research focus or objective. It may also include support for common resources (cores) required for conduct of the P01 research projects. Interrelationships between projects are expected to result in a greater contribution to program goals than if each project were pursued separately.

Programmatic Reduction: The dollar amount a grant award is reduced from the amount recommended by the Scientific Review Group. This is done so that Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Project: A research component of a larger multicomponent application (e.g., P01), with a separate detailed budget.

Project Leader: The person responsible for the scientific direction and conduct of an individual research project within a multi-component application.

Project Officer (PO): The PO serves in an administrative and advisory capacity throughout the contracting process. The PO recommends potential Technical Evaluation Panel members to the SRA. Although serving in an advisory capacity with no voting rights, the PO may fully participate in the oral discussion of proposals, providing supportable comments that voting panel members may consider in their evaluations.

Project Period: The total time for which support of a project has been recommended (usually no more than 5 years), consisting of one or more budget periods. Competing extensions of a project period are subject to peer review, reevaluation of the activity, and recompetition for available funds.

Proposal: A document submitted by an offeror in response to an RFP.

Protocol: The detailed plan for conducting a clinical trial. It states the trial's rationale, purpose, drug or vaccine dosages, length of study, routes of administration, who may participate, and other aspects of trial design.

Public Access Policy: The NIH policy designed to ensure that the public has access to the published results of NIH-funded research. Go to: *http://publicaccess.nih.gov/*

Public Health Service (PHS): A component of the U.S. DHHS. NIH is the largest agency within the PHS.

PubMed: PubMed provides access to citations from biomedical literature. These citations are indexed with a PMID, a series of numbers.

PubMed Central: PubMed Central (PMC) is the

NIH digital archive of full-text, peer-reviewed journal papers. These papers are indexed with a PMCID, a series of numbers preceded by 'PMC'. PMC content is publicly accessible and integrated with other databases. Go to: *http://www.pubmedcentral.nih.gov/*.

PubMed Central Reference Number (PMCID): The reference number assigned to an article or manuscript archived in *PubMed Central*. The PMCID is the number that must be cited on applications, proposals or reports as part of compliance with the *Public Access Policy* (*http://publicaccess.nih.gov/*).

R01 – see Traditional Research Project Award.

R03 – see Small Research Grant.

Racial and Ethnic Categories: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories used by NIH. These definitions are used because they allow comparisons to many national databases, especially national health databases. Therefore, the racial and ethnic categories described in this document should be used as basic guidance, cognizant of the distinction based on cultural heritage.

Randomized Trial: A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms or regimens of a clinical trial. Occasionally, placebos are utilized. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms.

Rebuttal: Procedure for contesting the peer review of a grant application. Synonymous with *appeal*.

Receipt, Referral, and Assignment of Applications: The routing of applications that arrive at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a Scientific Review Group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self-assign.

Recommended: A designation given by a study section advising that an application be funded. The application receives a priority score. Roughly the top half of applications reviewed are recommended for funding.

Recommended Levels of Future Support: Funding level recommended for each future year approved by the Scientific Review Group, subject to availability of funds and scientific progress.

Recompeting (a.k.a. Type 2, Competing Continuation Application, Renewal): A grant whose term is over and for which the applicant is again seeking NIH support.

Renewal – see Competing Continuation (Application).

Request For Applications (RFA): The official statement that invites grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request For Proposals (RFP): An RFP announces that NIH would like to award a contract to meet a specific need, such as development of an animal model. RFPs have a single receipt date and are published in the *NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide/).*

Research and Development (R&D) Contract: A funding mechanism by which the NIH procures specific services. These are negotiated contracts which may be funded from intramural or extramural accounts.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, results, processes, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Projects: Projects that are primarily investigator initiated and involve basic scientific research. Includes the following selected Research Grant and Cooperative Agreement activities: R01,

R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Supplement: Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Resubmission: Sending NIH an application for initial peer review after it has been reviewed by a study section and revised by the applicant. Each resubmission is given a code (e.g., A1). NIH limits applicants to one resubmission.

Review Cycle: The CSR's thrice-yearly initial peer review cycle, from the receipt of applications to the date of the review.

Review Panel: An advisory group of scientific experts, typically including representatives of a Scientific Review Group (SRG) subcommittee plus ad hoc members.

Revision: Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review.

The NIH term has been "competing supplement".

RFA – see Request For Applications.

RFP – see Request For Proposals.

RPG (Research Project Grant) – see Research Projects.

RPRB – see Research Programs Review Branch.

Ruth L. Kirschstein National Research Service Awards (NRSA): Awards to both individuals and institutions to provide research training in specified health-related areas.

Salary Cap/Limitation: A legislatively-mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts. Go to Salary Cap Summary: *http://grants.nih.gov/grants/policy/salcap_summary.htm*

SBIR – see Small Business Innovation Research.

Scientific Review Group (SRG): The generic functional name for any group engaged in scientific and technical peer review. SRGs are analogous to study sections used throughout the NIH peer review process. SRGs may be individually chartered. Special Emphasis Panels (SEPs) are also considered SRGs.. [Go to: *http://deainfo.nci.nih.gov/Advisory/irg/sub-cmte/index.htm*.]

Scientific Review Officer (SRO): An NIH health scientist administrator responsible for arranging, conducting, managing, and documenting the initial review process for applications and proposals. The SRA serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed. Formerly Scientific Review Administrator.

Scientifically Acceptable or Unacceptable: A determination based on whether or not the gender or minority representation proposed in a research protocol conforms with NIH policy guidelines pertinent to the scientific purpose and type of study. A determination of unacceptable is reflected in the priority score assigned to the application. In addition, the definition of what constitutes scientifically acceptable or unacceptable changes if the research being conducted is a clinical trial, as opposed to clinical research.

Scored: In the peer review process, applications that are judged by a Scientific Review Group to be competitive (i.e., generally in the upper half of the applications reviewed) are scored. These applications are assigned a priority score and forwarded to the appropriate Institute/Center Advisory Board for the second level of review.

Second Level Review: Review generally conducted by institute's Advisory Council or the National Cancer Advisory Board that results in funding recommendations to the NCI Director.

Second-level review looks at program priorities and balance and a lack of barriers to funding such as unresolved human subjects issues. It does not reassess the science.

SEP – see *Special Emphasis Panel*.

Select Agent: Biological agent or toxin listed in *42*

CFR Part 73, *7 CFR Part 331* and *9 CFR Part 121*, or the *HHS and USDA Select Agents and Toxins List* (*http://www.selectagents.gov/*).

Set Aside: Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Significant Rebudgeting: A threshold reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant re-budgeting is one indicator of change in scope.

Signing Official: A Signing Official (SO) has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The label, "Signing Official," is used in conjunction with the *NIH eRA Commons*.

Small Business: A business independently owned and operated; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees.

Small Business Innovation Research (SBIR): An award designed to support projects from small businesses that ultimately may have commercial viability. For the computation of success rates, SBIR awards are not included in the count of RPGs. Web address: *http://grants.nih.gov/grants/funding/sbir.htm*

Small Business Technology Transfer (STTR): A 3-year pilot program, begun in FY 1994 under the Small Business Innovation Research Program, designed to foster technological innovations through cooperative efforts between small business and research institutions. STTR grants are awarded for projects that have potential for commercial use. For the computation of success rates, STTR awards are not included in the count of RPGs. Web address: *http://grants.nih.gov/grants/funding/sbir.htm*

Streamlined Non-Competing Award Process (SNAP): Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period.

Source Selection: A contracting term denoting the review process by which a contractor is selected.

SOW – see *Statement of Work*.

Special Emphasis Panel (SEP): An advisory group of scientific experts chartered for the specific review or collection of reviews by a blanket chartering mechanism. SEP membership is fluid, with individuals designated to serve for individual meetings rather than for fixed terms of service. SEPs are a type of IRG/SRG.

Special Government Employee: An individual on a Federal personnel appointment employed for a period not to exceed 130 days during any period of 365 days (e.g., members of the National Advisory Councils; Boards, Program Advisory Committees; and Boards of Scientific Counselors). Members of SRGs are not special Government employees.

Specialized Center: Center grant (P50) to support any part of the full range of research and development from very basic to clinical for a multidisciplinary research group of investigators focused on a common research topic. Applications may include individual projects, shared resources, training components, and developmental funds.

Specialized Center of Research Excellence (SPORE): Specialized center grant to support interdisciplinary teams of investigators who conduct translational research focused on an organ-specific human cancer (e.g., breast cancer) or a highly related group of human cancer types (e.g., gastrointestinal cancers).

Specific Aims: A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant.

SPORE – see *Specialized Center of Research Excellence.*

SRA – see *Scientific Review Officer*.

SRO – see *Scientific Review Officer*.

Statement of Work (SOW): In a contract proposal, the document which states the technical objectives, level of effort, and requirements of the contracts.

Stimulus Plan: See *American Recovery and Reinvestment Act*.

Stipend: A payment made to an individual under a fellowship or training grant in accordance with preestablished levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

Streamlining (formerly Triage): A review committee process whereby discussions are limited to applications reviewers agree are likely to be competitive for funding (i.e., scored in the upper half of applications reviewed). Applications judged to be non-competitive (scored in the lower half) do not necessarily lack scientific merit, but, given the number of applications received and awards to be made, have no likelihood of being funded. These applications are returned to the applicant with the assigned reviewers' written comments.

STTR – see *Small Business Technology Transfer*.

Study Section: A panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called Scientific Review Groups (SRGs).

Subcontract Under a Grant: A written agreement between a grantee and a third party to acquire routine goods and services.

Subpopulations: Each minority group contains subpopulations delimited by geographic origins, national origins, and/or cultural differences. There are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

Success Rate: Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis.

Summary Statement: Composed of the reviewers' written comments and the SRA's summary of the review panel's discussion, a summary statement is the official record of the evaluation and recommendations of the IRG concerning a particular application or proposal. It includes overall panel recommendations, a recommended budget, and any administrative notes.

Supplement: A request for additional funds for the current operating year or any future year recommended previously. A supplement is now referred to as a "revision" and can be either a non-competing (administrative) or competing (subject to peer review) revision.

Targeted Planned/Enrollment Data: Provides race and ethnicity data for projected number of human subject participants to be enrolled in an NIH-funded clinical research study. The data is provided in competing applications and annual progress reports.

TEC – see *Technical Evaluation Criteria*.

Technical Evaluation Criteria (TEC): The Technical Evaluation Criteria published in every RFP are the only criteria reviewers can use in evaluating a contract proposal's technical merits. TEC direct the reviewers' attention toward factors critical to completing the project successfully. They are listed in order of their importance and are weighted to convey the relative importance of each factor and provide a numerical score framework.

Technical Evaluation Panel (TEP): The NCI convenes a Special Emphasis Panel (SEP) to review proposals that respond to a specific RFP. When an SEP convenes to review contract proposals, it is referred to as a Technical Evaluation Panel. TEPs evaluate proposals according to the Technical Evaluation Criteria stated in the RFP. Based on the TEC, reviewers determine each proposal's strengths and weaknesses, providing written documentation of the reasons for the evaluation, scoring the proposals, and recommending them to be deemed

either technically acceptable or technically unacceptable.

Temporary Member: A special reviewer invited to serve on a study section/SRG when NIH staff determine there is a need for additional expertise.

TEP – see *Technical Evaluation Panel*.

Terms and Conditions of Award: All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award or specified by the grant award document itself. The Notice of Grant Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate postaward administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Total Project Costs: The total allowable costs (direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Traditional Research Project Award (R01): An award that supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies.

Training Awards: Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, and to help professional schools establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Triage – see *Streamlining*.

Underrepresented Group: Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders.

Unsolicited Research – see *Investigator-Initiated Research*.

Valid Analysis: An unbiased assessment that will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for small and large studies. A valid analysis need not have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are: Allocation of study participants of both sexes/genders and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization; unbiased evaluation of the outcome(s) of study participants; and use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the gender and racial/ethnic groups.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Withholding of Support: A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Work Group: A review panel that reports to a parent committee. Work groups commonly review multicomponent applications such as P30s. The group's draft review report is provided to the SRG, where final merit scoring is made.

APPENDIX E: ACRONYMS

A

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
AACR	American Association of Cancer Research
AALAS	American Association for Laboratory Animal Science
ACCC	Association of Community Cancer Centers
ACLAM	American College of Laboratory Animal Medicine
ACS	American Cancer Society
ADA	Americans with Disabilities Act
AHRQ	Agency for Healthcare Research and Quality
AJCC	American Joint Committee on Cancer
ALARA	As Low As Reasonably Achievable
AMA	American Medical Association
ANSI	American National Standards Institute
AoA	Administration on Aging
APR	Accelerated Peer Review
ASCO	American Society of Clinical Oncology
ATSDR	Agency for Toxic Substances and Disease Registry
AVMA	American Veterinary Medical Association
AWA	Animal Welfare Act

B

BDP	Biopharmaceutical Development Program
BECON	Bioengineering Consortium
BL	Biosafety Level (Interchangeable with BSL)
BLA	Biologics License Application
BRDPI	Biomedical Research and Development Price Index
BSC	Biological Safety Cabinet
BSL	Biological Safety Level (Interchangeable with BL)
BSO	Biological Safety Officer

C

CAA	Clean Air Act
CAS	Chemical Abstracts Service
CBER	Center for Biologics Evaluation and Research (NCI)
CCOP	Community Clinical Oncology Program
CCSG	Cancer Center Support Grant
CCR	Center for Cancer Research (NCI)
CDA	Confidential Disclosure Agreement
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CFR	Code of Federal Regulations
CHID	Combined Health Information Database
CIS	Cancer Information Service
CIT	Center for Information Technology
CMHS	Center for Mental Health Services
CO	Contracting Officer
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRISP	Computer Retrieval of Information on Scientific Projects
CS	Contract Specialist
CSAP	Center for Substance Abuse Prevention

CSAT	Center for Substance Abuse Treatment
CSR	Center for Scientific Review
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTEP	Cancer Therapeutics Evaluation Program

D

DDG	Drug Development Group
DHHS	U.S. Department of Health and Human Services (also HHS)
DOELAP	Department of Energy–Laboratory Accreditation Program
DOT	Department of Transportation
DSMB	Data and Safety Monitoring Board
DTP	Developmental Therapeutics Program

E

EC&HS	Environmental Compliance and Health and Safety, SAIC Corporate
EIS	Epidemic Intelligence Service
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ER	Electronic Review
ERA	Electronic Research Administration
ES	Embryonic Stem

F

F&A	Facilities and Administrative (Costs)
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FIC	John E. Fogarty International Center
FME	Facilities Maintenance and Engineering, SAIC Frederick
FOIA	Freedom of Information Act
FPDC	Federal Procurement Data Center
FPF	Fermentation Production Facility, SAIC Frederick
FR	Federal Register
FTE	Full-time Equivalent
FTTA	Federal Technology Transfer Act
FY	Fiscal Year

G

GAO	General Accounting Office
GMO	Grants Management Officer

H

HAZMAT	Hazardous Material
hESC	Human Embryonic Stem Cell
HHS	U.S. Department of Health and Human Services (also DHHS)
HRSA	Health Resources and Services Administration
HSECP	Health, Safety, and Environmental Compliance Program
HVAC	Heating, Ventilation, and Air Conditioning

I

IACR	International Association of Cancer Registries
IACUC	Institutional Animal Care and Use Committee
IAQ	Indoor Air Quality
IARC	International Agency for Research on Cancer
IBC	Institutional Biosafety Committee
IC	NIH Institute or Center

IDLH	Immediately Dangerous to Life or Health
IHS	Indian Health Service
ILAR	Institute for Laboratory Animal Research
IMPAC	Information for Management, Planning, Analysis, and Coordination
IND	Investigational New Drug (Application)
IRB	Institutional Review Board
IRG	Initial Review Group

J

JCAHCO	Joint Commission on Accreditation of Health Care Organizations (formerly Joint Commission on Accreditation of Hospitals)

L

LASP	Laboratory of Animal Sciences Program, SAIC Frederick
LC50	Lethal Concentration Fifty
LD50	Lethal Dose Fifty
LDR	Land Disposal Restrictions
LOI	Letter of Intent

M

MDE	Maryland Department of the Environment
MERIT	Method to Extend Research in Time Award
MOSH	Maryland Occupational Safety and Health
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
MTA	Materials Transfer Agreement

N

NAACCR	North American Association of Central Cancer Registries
NARM	Naturally Occurring or Accelerator-Produced Radioactive Material
NCAB	National Cancer Advisory Board
NCBI	National Center for Biotechnology Information
NCCAM	National Center for Complementary and Alternative Medicine
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCEH	National Center for Environmental Health
NCHS	National Center for Health Statistics
NCHSTP	National Center for HIV, STD, and TB Prevention
NCI	National Cancer Institute
NCID	National Center for Infectious Diseases
NCI-DEA	National Cancer Institute-Division of Extramural Activities
NCI-FCRDC	National Cancer Institute–Frederick Cancer Research and Development Center
NCIPC	National Center for Injury Prevention and Control
NCMHD	National Center on Minority Health and Health Disparities
NCRA	National Cancer Registrars Association
NCRR	National Center for Research Resources
NCTR	National Center for Toxicological Research
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDIC	National Drug Intelligence Center
NEI	National Eye Institute
NHGRI	National Human Genome Research Institute
NHIC	National Health Information Center
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases

NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Disease
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
NORM	Naturally Occurring Radioactive Material
NPCR	National Program of Cancer Registries
NRC	Nuclear Regulatory Agency
NRFC	Not Recommended for Further Consideration
NRRPT	National Registry of Radiation Protection Technologists
NRSA	National Research Service Award
NSF	National Science Foundation
NTP	National Toxicology Program
NVLAP	National Voluntary Laboratory Accreditation Program

O

OACU	Office of Animal Care and Use
OD	Office of the Director
ODP	Office of Disease Prevention
OER	Office of Extramural Research (NIH)
OHRP	Office for Human Research Protections
OHS	Occupational Health Services, SAIC Frederick
OLAW	Office of Laboratory Animal Welfare
OMAR	Office of Medical Applications of Research
OMB	Office of Management and Budget
OMH	Office of Minority Health
OPRR	Office for Protection from Research Risks
ORDA	Office of Recombinant DNA Activities
ORHP	Office of Rural Health Policy
ORI	Office of Research Integrity
ORMH	Office of Research on Minority Health
ORWH	Office of Research on Women's Health
OSHA	Occupational Safety and Health Administration
OSTI	Office of Scientific and Technical Information
OWH	Office on Women's Health

P

PA	Program Announcement
PAHO	Pan American Health Organization
PAR	Program Announcement Reviewed in an Institute
PAS	Program Announcement with Set-Aside Funds
PCBE	President's Council on Bioethics
PEL	Permissible Exposure Limit

PHS	Public Health Service
PI	Principal Investigator
PO	Project Officer
PPE	Personal Protective Equipment
PR	Purchase Request
PRMC	Protocol Review and Monitoring Committee

R

RAID	Rapid Access to Intervention Development
RCRA	Resource Conservation and Recovery Act
RDL	Recombinant DNA Laboratory
rDNA	Recombinant DNA
REL	Recommended Exposure Level (NIOSH)
RFA	Request For Applications (Grants)
RFP	Request For Proposals (Contracts)
RPG	Research Project Grant
RQ	Reportable Quantity
RTRB	Resources and Training Review Branch (NCI DEA)

S

SAMHSA	Substance Abuse and Mental Health Services Administration
SAR	Specially Authorized Representative
SBIR	Small Business Innovation Research
SEER	Surveillance, Epidemiology, and End Results
SEP	Special Emphasis Panel
SEPP	Safety and Environmental Protection Program, SAIC Frederick
SI	International System of Units
SLA	Simple Letter of Agreement
SNAP	Streamlined Noncompeting Award Process
SOPs	Standard Operating Procedures
SOW	Statement of Work
SQG	Small Quantity Generator
SPORE	Specialized Programs of Research Excellence
SRA	Scientific Review Administrator
SRG	Scientific Review Group
SRLB	Special Review and Logistics Branch
SSO	Society of Surgical Oncology
STEL	Short Term Exposure Limit
STI	Scientific and Technical Information
STTR	Small Business Technology Transfer

T

TEC	Technical Evaluation Criteria
TEDE	Total Effective Dose Equivalent
TEP	Technical Evaluation Panel
TLC	Thin Layer Chromatography
TLV	Threshold Limit Value
TSDF	Treatment, Storage, and Disposal Facility
TRI	Toxics Release Inventory Translational Research Initiative
TTB	Technology Transfer Branch (NCI CCR)

U

UICC	International Union Against Cancer (Union Internationale Centre le Cancer)
USAG	United States Army Garrison

V

VA	Department of Veterans Affairs
VHA	Veterans Health Administration

W

WHO	World Health Organization