PROGRAM PROJECT (P01)
REVIEW GUIDE

DEA, NCI, NIH, DHHS

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PROGRAM PROJECT (P01) REVIEW GUIDE

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PREFACE

Action Pack: For Immediate Attention

Along with this guide, reviewers receive an **Action Pack** that includes several items that require immediate attention. Reviewers should address these items before reading through this guide or evaluating the documents 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 review process for NCI program project (P01) applications changed, beginning with the February 1, 2004, application receipt date. The new review format is described in detail in the first section of this guide.

The NCI 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 P01 application review process.

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; sharing research data; standards for privacy of individually identifiable health information; and URLs in NIH grant applications or appendixes.

Section 4 – Travel, Consultant Fee, and Reimbursement Information

This section provides an overview of reviewer expenses (including travel) that are reimbursable. The guidelines for reimbursement of travel costs, per diem, and consultant fees are included.

IMPORTANT: New information has been added about allowable costs for travel, meals, and other expenses and about a new **required** registration process that enables electronic transfer of travel expense reimbursements 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 and inclusion of women, minorities, and children is an important part of reviewing an application for a research grant. For an explanation of these considerations, the *NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications (5 April 2002)* is provided in Appendix A;
- Appendix B provides detailed instructions for using the NIH Internet Assisted Review (IAR) system to post application critiques.
- A list of useful Web sites appears in Appendix C;
- Appendix D is a glossary of peer review terms; and
- Appendix E contains a list of acronyms.

The Next Steps

The purpose of the upcoming review meeting is to evaluate the technical and scientific merit of submitted applications. Review panel recommendations and reviewer critiques will be used in preparing summary statements that will be presented to the National Cancer Advisory Board (NCAB) at the second level in the peer review process. The dual review process helps ensure that the NCI uses its resources wisely and funds research that has potential to make a significant contribution to science and medicine.

In Fiscal Year (FY) 2005, NCI's Division of Extramural Activities (DEA) managed, organized, and reported on the review of 2,401 grant and cooperative agreement applications and 471 contract proposals.

NCI's success in discovery concerning the causes, treatment, and prevention of cancer is dependent upon the selection of outstanding scientists at research and academic institutions for support. Identification of the best research projects and programs is guided by the advice of the peer review system. Therefore, the importance of reviewer participation in peer review panels cannot be overstated. The NCI understands the commitment that is involved and is very appreciative of all reviewers' time, effort, and expert input in the evaluation process.

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 P01 applications. The purpose of this section is to inform reviewers of their part in that important process.

Distinguishing Features of a Program Project (P01) Grant

Reviewers should 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 in the review package and are also at *http://deainfo.nci.nih.gov/awards/P01.htm.*

Briefly, the purpose of the P01 award mechanism is to support 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. The individual projects should be related to the central theme of the overall program. P01 applications may include one or more core component(s), each with its own budget, for administrative or research support services required for—and shared solely within—that P01. Cores should be important to the overall success of the program, and each core must serve at least two projects.

Central to the quality of a P01 is the leadership of the Principal Investigator (PI) and the other senior participating investigators. The 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.

Interaction 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. Individual investigators apply their specialized research capabilities in such a way as to achieve research synergy through the sharing of personnel, facilities, equipment, data, ideas, and concepts.

For Immediate Attention Upon Receipt of Review Materials

The **Action Pack** provided with the review materials includes several items that require immediate attention. These are the Memo to the Reviewers, the NIH Pre-Review Conflict of Interest/Confidentiality Certification Form, the Fact Sheet, Reviewer Assignment Sheets for each application, Consultant Information Form, and CDs with electronic files of the applications and of appendix material.

Conflict of Interest/Confidentiality Form

It is critical that members of the review panel are free of conflicts of interest and that there is a clear understanding of 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 are also at: *http://grants.nih.gov/grants/peer/COI_Information.pdf.*

Reviewers should carefully read the NIH Pre-Review Certification Form (pink) in the **Action Pack**, note conflicts of interest (or the appearance thereof) for any applications, sign the form, and return all immediately in the envelope provided. Reviewers will be excused from the review of specific applications based on information provided on the form. At the end of the review meeting, reviewers will also sign the NIH Post-Review Certification Form. In addition, NCI review staff will keep a log during the review meeting, noting who left the room because of potential conflict of interest and for which applications.

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 the completion of the review, all contacts should be made through the NCI Scientific Review Administrator (SRA).

SRA's Memo to the Reviewers

Read the memo from the SRA carefully. It includes information about the date, time, and place of the review; instructions for making travel arrangements; and contact information for the NCI SRA and support staff involved in the review meeting. The memo 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 memo will also contain a list of the items that should be in the review package. Contact the SRA if any materials are missing.

Fact Sheet

The **Fact Sheet** shows the meeting schedule, critique submission window, and hotel and travel information specific to the review meeting.

Consultant Information Form

Each reviewer should check the NCI Consultant Verification Information sheet for completeness and accuracy (especially the Social Security number) and home address. Return the signed form immediately to the NCI SRA. This will ensure that the NCI has the most current information in its database and that reviewers receive their consultant fees and flat-rate reimbursements in a timely way following the review meeting.

Arrangements for Hotel, Travel, and Reimbursement

Reviewers must read **Section 4** of this review guide for full instructions regarding travel arrangements before making travel arrangements. The NIH will make lodging reservations for reviewers who must travel to the review meeting and will pay the hotel directly for reviewers' rooms.

If unable to attend the meeting, reviewers must notify the NCI SRA and World Travel Service, the NIH travel contractor, immediately so that all flight and hotel reservations can be canceled.

IMPORTANT: The NIH recently instituted a direct deposit payment system for reviewers' consultant fee and a "flat rate" reimbursement for reviewers' meals, ground transportation, and incidentals. To receive these direct deposit payments, all reviewers must (1) register to obtain a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number and (2) register in the Central Contractor Registry (CCR) system. A DUNS number is required to register with the CCR. The CCR is a secure, Federal database of all non-Federal persons, companies, or other entities that do business with the Federal Government. See the complete instructions for registering in DUNS and CCR in the Action Pack.

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

Reviewers must submit/post their application critiques using the NIH Internet Assisted Review (IAR) system. **Appendix B** of this review guide contains detailed instructions for obtaining access to the IAR Web site. Reviewers should refer to these instructions well in advance of trying to submit critiques. Due dates for submission of critiques are indicated on the "Fact Sheet."

Advance Preparation for the Review Meeting—Overview of Activities

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

Reviewers should read the NCI P01 Guidelines, which include information about the purpose of the P01 mechanism and program requirements as well as instructions for application preparation.

2. Study the NCI P01 Procedures and Review Criteria

The new review procedures for the NCI P01s are outlined below. Tables 2 through 7 present the review criteria and scoring guidelines for projects, cores, Program as an Integrated Effort, program leadership, and Overall Program.

3. Read Applications and Prepare Critiques

There will be a separate assignment sheet (yellow) for each application. Check each assignment sheet to identify individual reviewer assignments. While an individual reviewer may not have the expertise to evaluate all aspects of every application, the combined efforts of all assigned reviewers should address them.

Reviewers will receive paper copies of only their assigned applications. Paper copies of nonassigned applications will be sent on request.

Reviewers will also receive a CD produced by the NCI staff that contains electronic copies of all of the applications in the meeting, previous summary statements, this "NCI P01 Review Guide," and the NCI "Guidelines for the Program Project Grant."

There also may be CDs provided by the applicants that include digital images of color illustrations and/or appendix materials. If there is difficulty in accessing the files, notify the SRA immediately so that the problem can be resolved prior to the review meeting.

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 SRA. The SRA will contact the applicants and attempt to obtain the necessary information prior to the review.*

4. Submit Critiques Using the IAR system

Reviewers should refer to the detailed instructions for accessing and using the IAR system in **Appendix B**. Briefly, each reviewer will

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

Reviewers should post their critiques by the deadline provided in the memo from the SRA and the Fact Sheet. After posting their own critiques, reviewers should read the other reviewers' critiques. This will facilitate discussion of the applications during the meeting.

P01 Review by Special Emphasis Panels (SEPs)

Beginning with applications received on February 1, 2006, the NCI is implementing a pilot of a single-tier review process for P01 applications. Groups of up to 10 applications will be reviewed by SEPs in the following five broad topic areas:

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

See **Appendix D** in the **NCI P01 Guidelines** for a summary of the areas of science that these SEPs will address. The number of SEPS and/or their topic areas may be modified based on P01 review workload or other factors.

SEP Membership

During the pilot, the NCI P01 Chartered Review Committees will not meet, but the Chartered Committee members will be distributed among the five SEPs to provide a core of reviewers experienced in P01 review.

The SEP membership will be based on the research scope of the applications to be reviewed as determined by the NCI SRA. Applicants may not suggest names of prospective reviewers but may suggest expertise areas needed for review.

The panel will include senior investigators who can view the proposed science in a global perspective, specialists needed to assess specific scientific areas, members of one or more of the three NCI P01 Chartered committees, and one or more patient advocates (for projects that include studies with human subjects). Amended applications will have some reviewers from the previous review, for continuity, as well as reviewers newly assigned to the application.

Each SEP Panel will have a Chairperson who will oversee the meeting; the Chairperson may also have specific review assignments. A Discussion Leader will be designated for each application from among reviewers assigned to the application. The Discussion Leader will assist the Chairman in coordinating the review of the application. Reviewers will generally have assignments in several applications and are responsible for preparing a critique for each assignment. The NCI SRA is the designated Federal official responsible for coordination of the review process. Observers can include the NCI program staff, review staff, and/or other Government staff having an interest in the review meeting. Table 1 summarizes each role.

Overview of SEP Review Process

The review of each application will be based on the submitted application, appendix materials, and any supplemental materials submitted before the review. Teleconferences with applicants will NOT be conducted. Review panel members will evaluate each component (projects and cores) of the application, the program as an integrated effort, the leadership of the program, and progress in the current funding period (for competing renewal applications) and then assign the overall score for the application. The review criteria and the NCI scoring standards for each element of a P01 and the overall program are shown in tables 2 through 6.

The SRA will prepare a summary statement for each application, which will be forwarded to the NCAB as documentation of the review.

Review Meeting Procedures

Panel Orientation

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

Discussion of Applications

The application Discussion Leader will begin the review of an application by presenting a brief summary of the scope and purpose of the research program.

Discussion and Scoring of Projects and Cores

Each project and core will be discussed in turn. Although reviewers may post preliminary scores in the IAR system before the review meeting, these are tentative scores and should **not** be used as a starting point for panel discussion. Instead, the first reviewer will present full commentary stating both strengths and weaknesses of the component based on the review criteria.

Each additional assigned reviewer will add his/her opinions without repeating previous reviewers' 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.

In the rare instance that a question remains after the discussion that is so substantive that the application would need to be deferred, the SRA will attempt to contact the applicant by phone or e-mail during the meeting.

Each assigned reviewer will then use the appropriate NCI P01 Scoring Guide to recommend a scoring range for the component. The recommended scores must be based on the review criteria (described below) for the component and the balance of strengths and weaknesses of the component. Panel members may score as they feel is appropriate, but members who think the merit rating should be significantly different from the range stated by the assigned reviewers should state their reasons based on the Scoring Guide. Each review panel member privately then rates the component.

Finally, reviewers may make recommendations about the budget and the duration of support for the component.

Discussion and Scoring of Overall Application

After each project and core is discussed and 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 competing renewal applications), Program as an Integrated Effort, and Overall Program Merit. The review criteria for each of these elements are described below and summarized in tables 4 through 6.

After a roundtable discussion of the application as a whole, the Chairperson will call on the assigned reviewers to state a scoring range for the program as a whole based on the NCI Scoring Guide for the Overall Program shown in table 6. The overall score should not just be a numeric average of the project and score ratings. Again, panel members who think the overall merit rating should be significantly different from the range stated by the assigned reviewers should state their reasons based on the Scoring Guide. Each review panel member privately then rates the application.

Recommendation for Funding Period

After scoring the overall program, the reviewers will recommend a duration of support. The program should have sufficient proposed meritorious research to justify the number of years requested. Project and core periods can be adjusted individually based on review panel opinion.

Scoring Standards

The integrity of the peer review system is highly dependent on reviewers' fair and unbiased viewpoints. Each reviewer must evaluate the application based on the review criteria and the NCI P01 Scoring Guidelines and not allow disciplinary 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 merit between applications.

Tables 2, 3, 5, and 6 provide the NCI scoring guidelines for projects, cores, Program as an Integrated Effort, and Overall Program. These paradigms should be followed closely because all NCI program projects are awarded from a single pool of funds set aside specifically for P01 applications. Thus, use of the same metric for all applications is essential for a fair and equitable review.

Components Not Recommended for Further Consideration

If reviewers determine that a project lacks merit or a core is unlikely to be able to provide the proposed services, that extremely hazardous procedures are proposed, or that there are extremely serious deficiencies in protection of human subjects or animals, the component 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/core/application further." The recommendation requires concurrence of a majority of the review panel members. A brief minority report is recorded in the summary statement if there are two or more panel members in opposition to the majority. Components or applications that are NRFC are ineligible to receive funding. If one or more projects of a P01 application are not recommended for further consideration and less than three scored projects remain, the entire application will also be not recommended for further consideration.

NOTE: Although the scientific merit of the P01 is based on the overall quality of scored and rated projects and cores, any components not recommended for further consideration should be considered in the peer review evaluation of the PI's leadership and program administration skills.

Triaging/Unscoring of Applications

The NCI has adopted a streamlined review process for P01 applications. The Discussion Leader and/or assigned reviewers of an application may recommend that it be triaged/ unscored with essentially no discussion if it falls in the bottom tier of all P01 applications normally seen by the NCI. The assigned reviewers will very briefly summarize the main reasons why the application should be unscored. If there is essentially unanimous agreement among the members of the review panel who are not in conflict with the application, the application will be unscored. If there is not essentially unanimous agreement for unscoring, there may be an abbreviated discussion of the application before scoring.

Review Criteria

Reviewers must rate the application using the specific review criteria for projects, cores, Program as an Integrated Effort, and Overall Program described below. In addition, reviewers must consider protection of human subjects and animals and inclusion of women, minorities, and children as applicable.

Projects

The goals of NIH-supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Reviewers address and consider each of these criteria in assigning the overall score, weighting them as appropriate for each application. An application does not need to be strong in all categories to be likely to have major scientific impact and thus deserve a meritorious priority score. For example, an investigator may propose

to carry out important work that, by its nature, is not innovative but is essential to move a field forward.

Significance—Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach—Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation—Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice? Does it address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators—Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment —Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment or subject populations, or do they employ useful collaborative arrangements? Is there evidence of institutional support?

Summary Evaluation—The Summary Evaluation should include focused, evaluative statements that encompass the five review criteria above. Each critique should include a Summary Evaluation.

NOTE: Integration and thematic relatedness between projects is rated under Program as an Integrated Effort, not in the individual projects.

Amended/Revised Project (if Applicable) – An amended project should be assessed primarily on the scientific quality as now presented. Previous strengths (and new strengths resulting from the amendments) should be considered. Previous weaknesses and the degree to which they were resolved by proposed amendments to the research plan should be assessed, and any remaining weaknesses identified. It is important to note that an amended application may be improved, the same as, or worse than the previous application.

Cores

Reviewers should use the following criteria when reviewing cores:

- Utility of the core to the program: Each core must provide essential facilities or services for two or more projects judged to have substantial merit;
- Quality of the facilities or services provided by the core (including procedures, techniques, and criteria for prioritization);
- Qualifications, experience, and commitment of the personnel involved in the core;
- Cost-effectiveness of the core;
- Adequacy of the proposed plan to augment and/or complement an existing shared resource supported by an NCI Cancer Center Support Grant (P30) (if applicable);
- ***For an Administrative Core (if included in the P01)***—Quality of administrative resources, decisionmaking process for the allocation of resources and funds, and plans for the evaluation of progress. Although Internal and/or External Advisory Boards are not required, if they are proposed, there should be plans for meeting with them and using recommendations resulting from the meeting. Information relating to program management, decisionmaking, and coordination may also be provided in the “Program Narrative” section of the application; and
- ***For an Amended Core***—The 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 amendments, and any remaining weaknesses (either old or new).

Cores are rated Superior, Satisfactory, or Not Recommended for Further Consideration

(unsatisfactory). Table 3 shows the Scoring Guidelines for Cores.

Progress in the Current Funding Period

For competing renewal applications, reviewers should assess the following:

- The progress and achievements of the project or core 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;
- Publications and accepted manuscripts that resulted from the P01 grant; and
- Cost-effectiveness (for cores).

Overall Program Merit

Table 4 shows the review criteria for the **Overall Program.** Reviewers should evaluate the overall program in more global terms, including the following:

Significance: The potential of the overall program to advance knowledge in one or more broad scientific areas or fields

Approach: The overall adequacy and quality of the approaches in the projects, the services provided by the cores, and the overall design of the P01

Innovation: The degree to which the overall P01 applies novel concepts and innovative approaches

Investigators, Including Program Leadership:

- The qualifications of the PI and other senior scientists to lead the P01 scientifically, promote effective interactions and collaborations, and coordinate all activities;
- The adequacy of the commitment (level of effort) of the PI to scientific and administrative activities. NOTE: Though it is a common practice, it is not required that the PI be a project leader; and
- The selection of individual projects for scientific excellence and thematic relatedness and of individual cores for necessary support of projects.

Environment: Scientific, organizational, and administrative environment of the overall program

Program as an Integrated Effort: Scientific and administrative integration of the overall program, , including the following, as shown in table 5:

- Evidence of coordination, interrelationships, and synergy among the projects and cores as related to the common theme of the P01;
- The advantages of or value added by conducting the proposed research as a program rather than separate research efforts;
- The mechanisms for internal quality control and communication; and
- For competing renewal applications, evidence of productive collaborations, such as joint publications, resulting from the P01 award.

Programs may be rated as Highly Integrated, Integrated, or Not Integrated.

Overall Progress: For competing renewal applications, progress of the overall program in the current funding period should also be evaluated, in addition to evaluating progress of the individual research projects and cores. This should include the following:

- Accomplishments that can be attributed to the P01 grant, particularly those involving more than one project leader; and
- The rationale for discontinuing or substantially modifying previous projects or starting new projects.

Human Subjects Considerations

All NIH-supported research involving human subjects must comply with specific policies for the following considerations:

- 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.

Reviewers are expected to evaluate these issues for any project or core that involves human subjects. Deficiencies in any of these elements should be addressed under the Approach review criterion and factored into the overall merit rating of the project, core, and application as a whole. Unacceptability in any of these issues constitutes a bar to funding.

For your convenience, the *NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications (5 April 2002)* are reprinted in **Appendix A** and on the NIH CD; they are also available online at: *http://grants.nih.gov/grants/peer/hs_review_inst.pdf.*

Protection of Human Subjects From Research Risks

If human subjects are to be included in research, reviewers should indicate which of the following applies:

- No concern—The risks are acceptable, and/or there are adequate protections.
- Concerns—The risks are unacceptable, and/or there are inadequate protections.
- Exempt—See NIH instructions in Appendix A for exemption categories.
- Absent—No information is provided in the application.

Research Involving Coded Specimens and Data

The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) *Guidance on Research Involving Coded Private Information or Biological Specimens* (*http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf*) states that research that uses coded private information/data or coded human biological specimens may be considered **not** human subjects research **if**

- The specimens/data were not collected specifically for this currently proposed research through an interaction/intervention with living individuals; and
- The investigators (including collaborators) cannot readily determine the identity of the individual(s) to whom the coded private information/data or specimens pertain.

PHS 398, "Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan" (*http://grants2.nih.gov/grants/funding/phs398/instructions/phs398instructions.htm#part_ii_titlepage.htm)* provides more detailed guidance about this policy.

Some applications that use coded human tissues or data may indicate "No Human Subjects" on the PHS 398 face page. These applications generally are those for which Exemption 4 would have applied in the past. In these cases, the applicant should have provided justification in the application under Section E, Human Subjects Research for coding the research as "No Human Subjects." Reviewers should evaluate whether the justification provided by the applicants is acceptable or not.

Data and Safety Monitoring Plan

A Data and Safety Monitoring Plan is required for all clinical trials (phase I, II, and/or III). For phase III or multi-institutional trials, a Data and Safety Monitoring Board is necessary.

Plans for the Inclusion of Women, Minorities, and Children

Reviewers are to provide codes for the plans to include women, minorities, and children (each under its own heading) along with a brief statement of appropriateness or concern.

Gender, minority, and children characteristics of the population are rated scientifically acceptable (A) or unacceptable (U). An unacceptable population should be considered a weakness or deficiency in the design of the project or core under the Approach review criterion.

Vertebrate Animals

Appropriate use and care of vertebrate animals also is an aspect of research merit. Reviewers should note any concerns or make comments about the appropriateness of the five required points related to the care and use of vertebrate animals, especially whether the procedures will be limited to those that are unavoidable in the conduct

of scientifically sound research. See **Section 3** of this review guide for additional information on vertebrate animal welfare.

Committee Budget Recommendations

Review of the requested budgets is not part of the assessment of merit unless the requested amounts are extremely out of the norm for a particular technical approach. This is why budgets are reviewed **after** merit scoring.

Note that reviewers cannot reduce budgets to improve the merit ratings of projects, 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 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?

Administrative Considerations

Reviewers should also consider a variety of administrative issues when evaluating P01 grant applications. These issues are addressed in detail in **Section 3** of this review guide:

- Scientific, Budgetary, or Personnel Overlap
- Hazardous Materials and/or Procedures
- Data Sharing
- Model Organism Sharing
- Health Insurance Portability and Accountability Act (HIPAA)

NOTE: Administrative considerations should not determine scientific merit or influence scoring.

Critique Preparation

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

The summary statement that is prepared for each application after the review meeting will include the applicant's Description (inserted verbatim by the NCI staff), the essentially unedited critiques from individual reviewers (with all identifiers removed), the merit rating for each project and core, and the committee budget recommendations.

When preparing a critique, reviewers should keep in mind that the summary statement is read and used by members of the NCAB, NCI program and grants management staff, future reviewers, and applicant investigators.

Critiques for projects should be concise, factual, impersonal, and focused, with minimal descriptive information. Critiques should address all of the stated review criteria. **Key strengths and weaknesses under each review criterion should be stated simply and directly.** Inclusion of advisory statements (i.e., how to fix problems) is not appropriate. For amended applications, critiques should indicate whether the amended application is better, the same, or worse than the previous application and why.

Templates for reviewer critiques of projects and cores are provided at the end of this section.

Reviewers will edit their critiques as necessary at the close of the discussion of an application to ensure their final critiques reflect any change of opinion based on panel discussion. Final critiques may be submitted through the IAR system during or after the review meeting.

NOTE: Some 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 additions to the critiques in real time.

General Instructions for Critique Format

The following are general instructions for preparing critiques:

- Critiques should be prepared using Microsoft Word, in Arial (font) 11 point.
- The first time an acronym is used, it should be defined in full and the acronym given in parentheses after the term.
- Critiques should be written at the level of an article in *Scientific American* or other general scientific publication, keeping in mind the diverse backgrounds of potential readers.
- When submitting critiques In the NIH IAR system, reviewers may use file names convenient to them. However, a format of PI Name—Project Number or Core Letter—is recommended.
- Each critique must be entered into the IAR system separately.

Preliminary Merit Ratings for Projects

A **preliminary** score should be assigned based on the review criteria and the NCI Scoring Guidelines for Projects in table 2. The **final score** may vary considerably from this preliminary rating based on discussion during the review meeting.

Preparing Core Critiques

The text of a core critique (typically 1 to 2 pages) need **not** be subdivided by review criteria. However, all the points listed in Table 3, “Scoring Guidelines for Cores,” should be addressed.

Preliminary Merit Rating for Cores

Reviewers should insert a preliminary merit rating in their critiques based on the criteria in table 3. Cores are rated “Superior,” “Satisfactory,” or “Not Recommended for Further Consideration” (unsatisfactory). Because most cores will be rated “Satisfactory,” the text and tone of the critique should clearly indicate whether the core is very well managed or barely meets requirements.

Final Report Writing

Several parts of the review report are prepared after the review panel discussion: Overall Critique, Program as an Integrated Effort, Program Leadership, and Project and Core Summaries.

The Discussion Leader generally drafts the Overall Critique, including Program as an Integrated Effort and Program Leadership, based on the panel discussion. These sections should encapsulate the comments based on the review criteria listed in Tables 4 and 5. These reports are submitted post-review using the IAR Web site.

In addition, the primary (first) reviewer of each project and core will generally be asked to prepare a brief Summary of Discussion paragraph that captures the main strengths and weaknesses of the components 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/core title and the investigator’s name. The research goal should be summarized in one sentence followed by a brief summary of the key strengths and weaknesses that contributed to the final merit rating. The five NIH review criteria should be addressed. If there were unresolved differences of opinion among the panel members, all views should be presented.

Finally, reviewers should update their critiques in the IAR system to incorporate changes in opinion after the panel discussion. These updates should have “Final Report” added to the text.

The Summary of Discussion paragraph should be added to the reviewer’s personal IAR critique as an additional section: Summary of Meeting

Discussion. It does not replace the reviewer's own Summary Evaluation.

Review of Requests for Supplemental Funding

Requests for supplemental funds may be submitted only for P01 grants with at least 2 years of support remaining in the current award. The request must have a well-founded basis, such as

- An additional project or core;
- Continuation of a funded project or core; or
- A special request for a unique opportunity or additional resources needed to complete the research.

The Program Narrative section of the application should summarize briefly the theme and research goals of the funded program. Progress in the current funding period should be summarized for each project and core, including publications and completed aims.

Review Criteria

Review criteria for requests for supplemental funding are similar to those for competing renewal applications:

- 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?
- 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?

Other review criteria and administrative issues as described for project and cores also apply.

Critique for Addition of a Project or Core

Critiques for each project or core should be prepared in detail according to the instructions for projects/cores within a P01. Particular emphasis should be placed on the relationship of each new project to the goals of the ongoing program project. The newly proposed work should be evaluated for significance, approach, innovation, investigator(s), and environment.

Critique for Extension of Research Period of a Project/Core

The critique should address the rationale for the proposed extension and the evidence that satisfactory progress has been made toward accomplishing the proposed aims of the project or core.

Critique for Purchase of Equipment or Expansion of Resources

The need for such items should be evaluated relative to program goals.

BLANK TEMPLATE FOR PROJECT CRITIQUE

Application Number/Principal Investigator's and Project Leader's Names:
Project Title:
Reviewer's Name:

CRITIQUE

Significance: *[Insert comments here.]*
Approach: *[Insert comments here.]*
Innovation: *[Insert comments here.]*
Investigator(s): *[Insert comments here.]*
Environment: *[Insert comments here.]*
Summary Evaluation: *[Insert comments here.]*
Progress in the Current Funding Period (if applicable): *[Insert comments here.]*

HUMAN SUBJECTS

- **Protection of Human Subjects From Research Risks:** *[Indicate one of the following **AND** provide relevant comments.]*

  No Concerns (acceptable risks and/or adequate protections)
  Concerns (unacceptable risks and/or inadequate protections)
  Exempt (See Appendix A for exemption categories.)
  Absent

- **Data and Safety Monitoring Plan *(required for all clinical trials):*** *[Indicate one of the following **AND** provide relevant comments.]*

  Acceptable
  Unacceptable
  Absent

- **Inclusion of Women Plan:** *[Insert relevant comments. State whether the plan is acceptable or unacceptable.]*
- **Inclusion of Minorities Plan:** *[Insert relevant comments. State whether the plan is acceptable or unacceptable.]*
- **Inclusion of Children Plan:** *[Insert relevant comments. State whether the plan is acceptable or unacceptable.]*

ANIMAL WELFARE: *[Indicate one of the following **AND** provide relevant comments.]*

None
No comments or concerns
Comments/Concerns

BUDGET RECOMMENDATIONS: *[Insert comments here.]*

ADMINISTRATIVE CONSIDERATIONS

- **Hazardous Materials and/or Procedures:** *[Insert relevant comments.]*
- **Overlap of Scientific, Budgetary, or Personnel Effort:** *[Insert relevant comments.]*

MERIT RATING: *[Insert a tentative merit rating in the preliminary report based on the NCI Scoring Guidelines for Projects in table 2. Final scoring will be done after discussion by the review panel.]*

BLANK TEMPLATE FOR CORE CRITIQUE

Application Number/Principal Investigator's and Core Director's Names:
Core Title:
Reviewer's Name:

CRITIQUE: *[Insert comments here. Be sure to address all review criteria.]*

Progress in the Current Funding Period (if applicable): *[Insert comments here.]*

HUMAN SUBJECTS

- **Protection of Human Subjects From Research Risks:** *[Indicate one of the following **AND** provide relevant comments]*

  Absent
  No Concerns (acceptable risks and/or adequate protections)
  Concerns (unacceptable risks and/or inadequate protections)
  Exempt (See Appendix A for exemption categories.)

- **Data and Safety Monitoring Plan *(required only for clinical trials):*** *[Indicate one of the following **AND** provide relevant comments]*

  Acceptable
  Unacceptable
  Absent

- **Inclusion of Women Plan:** *[Insert relevant comments. State whether the plan is acceptable or unacceptable.]*
- **Inclusion of Minorities Plan:** *[Insert relevant comments. State whether the plan is acceptable or unacceptable.]*
- **Inclusion of Children Plan:** *[Insert relevant comments. State whether the plan is acceptable or unacceptable.]*

ANIMAL WELFARE: *[Indicate one of the following **AND** provide relevant comments.]*

None
No comments or concerns
Comments/Concerns

BUDGET RECOMMENDATIONS: *[Insert comments here.]*

ADMINISTRATIVE CONSIDERATIONS

- **Hazardous Materials and/or Procedures:** *[Insert relevant comments.]*
- **Overlap of Scientific, Budgetary, or Personnel Effort:** *[Insert relevant comments.]*

MERIT RATING: *[Insert a tentative merit rating based on the NCI Scoring Guidelines for Cores in table 3. The final merit rating will be based on discussion by the review panel.]*

TABLE 1—ROLES AND RESPONSIBILITIES OF REVIEW PANEL MEMBERS

Chairperson	• Ensures thorough and unbiased review of all applications • Maintains agenda • Maintains review etiquette. • Moderates differences of opinion • Coordinates scoring of projects and cores and discussion of integration, program leadership, and overall program merit
Discussion Leader	• Coordinates project and core discussion • Takes notes of strengths and weaknesses for each element reviewed • Summarizes discussion • Synthesizes Overall Critique to reflect panel discussion and recommended merit.rating
Reviewers	• Read applications from a general perspective (in particular, the Program Narrative) and study their specific assignments in detail • Prepare written preliminary critiques of applications assigned to them • Post critiques in IAR system • Read critiques posted by other reviewers • Assess final merit of project/core following group discussion • Update their critiques after the review is completed
First-named reviewer for each component	• Prepares Summary of Discussion paragraph for a given component of a P01 application to reflect the final discussion and merit 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 SRA	• 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

TABLE 2—SCORING GUIDELINES FOR PROJECTS

Project Characteristics	Scoring Range
Flawless in all respects	**1.0–1.3**
• Paradigm shifting for several broad fields or new translational insights or will change the standard of clinical practice, AND • Exceptional research design and approaches—No weaknesses, AND • Highly innovative (new approaches and/or technologies), AND • Superb leadership and environment • For competing renewals: Exemplary progress in funding period, publications in high-impact journals	**1.3–1.5**
• Strong potential to advance one or more broad fields or to advance clinical practice • Very strong research design and approaches—only a few minor deficiencies • Innovative approaches and/or use of state-of-the-art technology • Strong leadership and environment • For competing renewals: Excellent progress in funding period	**1.5–1.8**
• Significance for clearly defined field or some potential to impact clinical practice • Generally strong research design and approaches, with some deficiencies and/or concerns—*Strengths prevail* • Moderate innovation and/or technology appropriate for study • Effective leadership and appropriate environment • For competing renewals: Good progress in funding period	**1.8–2.2**
• Significance for limited field; possibly confirmatory/derivative studies • Uneven quality of research design and approaches, with some substantial concerns—S*trengths balance weaknesses* • Level of innovation may vary • Quality of leadership and environment may vary • For competing renewals: Fair progress in funding period	**2.2–3.0**
• Realizable significance limited by flaws in research plan • Critical to serious weaknesses in research design and/or approaches, and/or suspect scientific hypotheses — W*eaknesses prevail* • Level of innovation may vary • Quality of leadership and/or environment may vary • For competing renewals: Minimal progress in funding period	**3.0–5.0**

TABLE 3—SCORING GUIDELINES FOR CORES

Core Characteristics	Merit Rating
In addition to the qualities of a Satisfactory 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 cores are expected to score in this range.
• Is critical for completion of program goals • Provides service(s) to at least TWO projects in the program project • Offers cost-effective services and resources • Provides evidence that necessary techniques are in place • Can adequately provide services proposed • Presents a service prioritization plan • Has adequate leadership and personnel for proposed core activities	**Satisfactory** This is a "Passing" rating. Most cores are expected to score in this range.
• Supports only one project in the program • Is unlikely that proposed services can be provided with methods/personnel proposed • Has serious ethical problems with human subjects or animal welfare	**Not Recommended for Further Consideration** (Unsatisfactory)

TABLE 4—REVIEW CRITERIA FOR OVERALL PROGRAM

- **Significance**—The overall potential to advance knowledge in one or more broad scientific areas or fields
- **Approach**—The overall adequacy and quality of the experimental approaches proposed in the projects, the services provided by the cores, and the overall design of the P01
- **Innovation**—The degree to which the overall P01 applies novel concepts and innovative approaches
- **Investigators, including Program Leadership**
    - The qualifications of the Principal Investigator and other senior scientists
    - The demonstrated ability of the Principal Investigator and the other senior participating investigators to provide effective scientific and administrative leadership and to promote effective interactions and collaborations
    - The adequacy of the commitment (percent effort) of the Principal Investigator and the other senior participating investigators.to the P01. There should be a specific commitment to both the scientific and administrative aspects of the P01. NOTE: Though a common practice, it is not mandatory that the Principal Investigator be a project leader of an individual research project.
    - Effective selection of individual projects for scientific excellence and thematic relatedness and cores for necessary support of projects
- **Environment**—Overall scientific, organizational, and administrative environment
- **Program as an Integrated Effort—See table 5**
- **Progress in the Current Funding Period** (for competing renewal applications)

TABLE 5—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 that could be realized by conducting the proposed research as a P01 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 • For competing renewals, evidence of productive collaborations, such as joint publications, resulting from the P01 award	Highly Integrated* Integrated Not Integrated

Program **Synergy** is the structuring of the research effort so that progress is expedited and enhanced significantly by the intellectual and technical exchanges that occur because of the P01 research environment. Synergy goes beyond a simple commonality of theme and sharing of reagents and technology.

***A highly integrated program is one having both integrated and synergistic relationships among the majority of projects and cores.**

TABLE 6—SCORING GUIDELINES FOR OVERALL PROGRAM

Program Characteristics	Scoring Range
Flawless in all respects	**1.0–1.3**
• Paradigm shifting for several broad fields or new translational insights or will change the standard of clinical practice, AND • Exceptional research design and approaches—No weaknesses, AND • Highly innovative (new approaches and/or technologies), AND • Superb leadership and environment • For competing renewals: Exemplary progress in funding period, publications in high-impact journals • Highly integrated	**1.3–1.5**
• Strong potential to advance one or more broad fields or to advance clinical practice • Very strong research design and approaches—only a few minor deficiencies • Innovative approaches and/or use of state-of-the-art technology • Strong leadership and environment • For competing renewals: Excellent progress in funding period • Highly integrated	**1.5–1.8**
• Significance for clearly defined field or some potential to impact clinical practice • Generally strong research design and approaches, with some deficiencies and/or concerns—*Strengths prevail* • Moderate innovation and/or technology appropriate for study • Effective leadership and appropriate environment • For competing renewals: Good progress in funding period • Integrated	**1.8–2.2**
• Significance for limited field; possibly confirmatory/derivative studies • Uneven quality of research design and approaches, with some substantial concerns—S*trengths balance weaknesses* • Level of innovation may vary • Quality of leadership and environment may vary • For competing renewals: Fair progress in funding period • Level of Integration may vary	**2.2–3.0**
• Realizable significance limited by flaws in research plan • Critical to serious weaknesses in research design and/or approaches and/or suspect scientific hypotheses—W*eaknesses prevail* • Level of innovation may vary • Quality of leadership and/or environment may vary • For competing renewals: Minimal progress in funding period • Level of Integration may vary	**3.0–5.0**

SECTION 2: CONFLICT OF INTEREST, CONFIDENTIALITY, AND MISCONDUCT

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 **actual 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 or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as determined by the SRA 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 or proposal 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 or proposal that is known to the reviewer or the SRA 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 SRA will evaluate the appearance of a conflict of interest and determine whether the interest would likely bias the reviewer's evaluation of the application or proposal. Where there is an appearance of conflict of interest but not sufficient grounds for disqualifying the reviewer, the SRA 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 or proposal.

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/proposal from that organization or PI. The Director of 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 proposal 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 or proposal 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 or proposals from all investigators or key personnel associated with the project. The individual should be considered a professional associate when evaluating applications or proposals submitted by the other participants in the project.

Request for Applications (RFA) or Request for Proposals (RFP): Any individual serving as the PI or key personnel on an application submitted in response to an RFA or on a proposal in response to an RFP is generally considered to have a conflict of interest with all of the applications or proposals submitted in response to the RFA or RFP. 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 NIH or his/her designee that will permit an individual to review only those applications or proposals 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/proposals 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 or proposals to be reviewed. Reviewers must notify the SRA of any conflict of interest prior to the meeting and certify that the confidentiality of the review proceedings will be maintained.

In the review of contract proposals, approval must be obtained in advance to permit a reviewer to serve as a member of a committee when he/she is in conflict with any one of the proposals received in response to an RFA.

At the Review Meeting

At the actual review meeting, the reviewer must leave the room when an application or proposal 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 for individual applications.

At the end of the meeting, the SRA 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 and offerors that their identity, their applications or proposals, 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 SRA may subsequently obtain advice. Reviewers are required to leave all review materials with the SRA at the conclusion of the review meeting. Privileged information shall not be used to the benefit of the reviewer or shared with anyone.

Under no circumstances shall reviewers 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 SRA, 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 SRA, 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 SRA 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. In no instance shall the SRA or a reviewer communicate 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: 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;
- Sharing of model organisms;
- Research involving human embryonic stem cells (hESC);
- Standards for privacy of individually identifiable health information; 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 A for *NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications (5 April 2002)*.

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.nal.usda.gov/awic/legislat/usdaleg1.htm*) as applicable.

Reviewers should refer to the Protection of Vertebrate Animals heading in Section 1 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. Please refer to Appendix A for *NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications (5 April 2002)* for reviewer instructions on the evaluation of data and safety monitoring.

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.

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

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/notice-files/NOT-OD-02-005.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*). Applicants are responsible for providing the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned to the applicant by NCI staff without review.

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*

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 directly access an Internet site.

SECTION 4: TRAVEL, CONSULTANT FEE, AND REIMBURSEMENT INFORMATION

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;
- New flat-rate reimbursement information;
- New policy on airfare and train rates;
- Instructions on how to register for electronic funds transfer (EFT) through the U.S. Treasury Department Central Contractor Registration (CCR) system;
- 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 Administrator (SRA) because regulations that apply to Federal employees differ from those outlined in this section.

Travel Reimbursement Policy Changes

Effective October 1, 2005, the SREA has implemented a new policy for managing hotel and travel reimbursements for peer reviewers. These changes are designed to improve overall accountability of the NIH in its peer review expenses, improve service to reviewers, and reduce the costs of running the SREA program.

This new system will ensure that reviewers' expenses are reimbursed at the same level they have been, but the process for reimbursement has changed.

These changes will be described in detail later in this section, but generally the following changes are planned for implementation:

- **Hotels paid by NIH:** NIH will pay directly for lodging, eliminating the out-of-pocket expense to reviewers.
- **Flat-rate reimbursement for ground transportation and incidental expenses:** Nonlocal reviewers will receive a **$185** flat-rate reimbursement per meeting for incidental expenses, including ground transportation, parking, and phone and Internet service. Local reviewers will receive **$70** each day they make a round trip to the meeting.
- **Flat rate for meals:** Nonlocal reviewers will receive a standard rate of **$75** per meeting day for meals. Local reviewers will receive **$40** per meeting day.
- **Travel rates:** Due to rising fuel costs, NIH can no longer provide reviewers Government-rate airline and train tickets. Reviewers who are fairly certain about their travel plans should consider lower cost **nonrefundable tickets**.
- **Request for exceptions:** Reviewers who expect to exceed the allotted flat rates for ground transportation and incidentals should contact the SRA and provide justification and estimated costs for an exception. Exceptions to the flat rate for meals will **not** be considered. Any requests for exceptions must be submitted to the SRA at least 2 weeks before the meeting.
- **Meeting Logistics Coordination:** The SRA responsible for this review meeting will coordinate hotel and meeting logistics. Communications about those logistics will be sent directly to reviewers via e-mail or U.S. Mail. Reviewers should notify the SRA if they have special lodging needs or will not need a hotel room.

After a meeting is finished and all reviewer assignments have been completed, reviewers who do not request an exception will receive a direct electronic transfer of consultant fees and reimbursements without having to submit a voucher.

IMPORTANT: Reviewers must register through the CCR system to enable the electronic transfer of reimbursements to their bank accounts. Detailed information on registering for electronic funds transfer is provided on page 4 in this section.

Expenses That MAY Be Paid to Reviewers

The following expenses related to review committee business may be paid or reimbursed to reviewers:

- Consultant fee—earned by reviewers and payable for each day on which services were rendered at a meeting or project site visit, or when reviewers were otherwise engaged in approved review committee business (including teleconferences);
- Meals; and
- Ground transportation, and incidentals including telephone, facsimile (fax), online computer charges, etc., that are directly related to regular or Internet Assisted Review business, project site visits, or other nonmeeting review committee activities.

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 SRA 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.

Consultant Fees

The consultant fee is **$200** per day for reviewers' attendance at meetings, teleconferences, and mail reviews.

A consultant fee of **$100** will be paid to reviewers who are not members of a chartered committee for mail review.

Hotel

The 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 SRA or his/her assistant if you have special lodging needs. The SRA will send reviewers a confirmation number for hotel reservations.

IMPORTANT: Reviewers should notify the NCI SRA 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.

NOTE: As the NCI transitions to its new travel policies, SRAs may send reviewers periodic e-mail updates on hotel and other travel procedures when changes are implemented.

Ground Transportation and Incidental Expenses

The new **$185 flat-rate** reimbursement per meeting will cover nonlocal reviewers' ground transportation and incidental expenses related to a single peer review meeting. Local reviewers will receive **$70** 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.

Once a review meeting is over and all of the reviewers' assignments are complete, reviewers will be reimbursed for these expenses without the need to submit vouchers or receipts. The reimbursement will be electronically transferred to the reviewer's bank account.

Request for Exception

In the rare cases when reviewers anticipate exceeding the flat rate reimbursement, they should contact the SRA at least two weeks before the meeting and provide an estimated cost and a justification for an exception. All receipts related to the expense in question **must** be submitted within 2 business days after the meeting to Hing Lee in the SREA office, via e-fax at 301-480-2054.

Use of the following modes of ground transportation will usually cause reviewers to exceed the daily flat rate reimbursement, leading to a Request for Exception. Therefore, these services should be used only when they are the least expensive option or when no other mode is available:

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.

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 SRA 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 **$185**, reviewers should provide an estimated cost and a justification to the SRA and request an exception.

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

Meals

The flat rate meal reimbursement for peer reviewers is **$75** per meeting day for nonlocal reviewers and **$40** per meeting day for reviewers within 50 miles of the meeting site.

Once a review meeting is over and all of the reviewers' assignments are complete, reviewers will be reimbursed the daily flat rate for meals without the need to submit vouchers or receipts. The reimbursement will be electronically transferred to the reviewer's bank account.

Airline and Train Fare Reimbursements

Airfare

The NCI's has arranged with World Travel Services (WTS) to supply full-fare refundable tickets since Government-fare tickets can no longer be offered. Since full-fare tickets will substantially increase review costs, reviewers should consider requesting lower cost nonrefundable tickets if they are fairly confident their travel plans will not change. Nonrefundable tickets will enable reviewers to choose flights from any domestic airport, 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. (See WTS contact information on the FACT sheet. Costs incurred include $149 change fees plus difference in new airline ticket price.) WTS will bill the NCI directly for airline tickets.

NOTE: Any reviewer who makes flight arrangements through his/her own travel agent must file an exception through the SRA prior to making the airfare reservation. Reviewers will be reimbursed only at the Government rate 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 SRA 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.

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 SRA will verify the reviewer's attendance and submit information for processing of direct electronic payment to the reviewer's account.

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 SRA will verify the reviewer's participation and submit information for processing of direct electronic payment to the reviewer's account.

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 SRA and the hotel. The reviewer is also responsible for canceling travel reservations.

Frequently Asked Questions

Q: Can a reviewer get paid 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 SRA 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 only be reimbursed only at the Government rate 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. The Social Security number is also required for registry in the CCR system.

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. They must register with the CCR system, described on the next page, to receive a check.

Registration for Electronic Fund Transfer

Reviewers must complete a two-step process to enable the electronic transfer of funds into their bank accounts. They must: (1) Obtain a Dun &

Bradstreet (D&B) Data Universal Numbering System (DUNS) number and; (2) file with the CCR system. CCR is a secure, federally controlled database of all non-Federal persons, companies, or other entities that do business with the Federal Government. After the initial CCR registration, reviewers are required to update their registration annually.

Important Information to Know Before Registering in DUNS and CCR:

According to Federal Acquisition Regulations, reviewers must be registered in DUNS and CCR as individuals. **Institutional or corporation tax ID information cannot be used for registration.** For tax and reimbursement purposes, the reviewer must be the person to receive the reimbursement for peer review services.

Each reviewer must complete the registration process using his/her **legal name**. As of October 30, 2005, the CCR will begin validating the Taxpayer Identification Number (TIN) (the TIN is the Social Security number) and Taxpayer Name of each new, updating, or renewing CCR registrant with the Internal Revenue Service (IRS) records. The TIN and Taxpayer Name combination reviewers provide in the IRS Consent Form must match exactly to the TIN and Taxpayer Name used in Federal tax matters.

Please follow the instructions and enter only the information requested. Leave all other fields blank.

To help reduce the processing time, reviewers should create a Point of Contact (POC) template. After reaching the General Information screen, find and click on the green "Create a POC template" button above the Physical Address field and enter the Point of Contact information (enter the same information used in DUNS—legal name, address, phone, fax, and e-mail). Complete all fields and click on "Save." Reviewers should use the "Paste POC Template" button any time they are asked to enter point of contact information in the required fields throughout the registration process.

The following instructions will help reviewers with the DUNS and CCR registration processes:

1. **Obtain a DUNS number by phone or online:**
   - **Apply by phone** by calling 866-705-5711. The process takes 5 to 10 minutes. Reviewers will receive a DUNS number at the end of the phone call. Please note that reviewers **must** make the call themselves.
   - **Apply online** at the D&B DUNS Number Guide for Government Contractors & Grantees Web site at *https://eupdate.dnb.com/requestoptions/government/ccrreg/* Reviewers will receive their DUNS number via e-mail within 48 hours and the DUNS number will be effective 24 hours after it is received. Once reviewers access the Web site, they should follow these instructions:
     - Under "Web Registration," click on the "click here" link.
     - Select reviewer's country from the pulldown menu.
     - Under "Business Name," enter reviewer's legal name—enter as last name, first name, middle initial.

       IMPORTANT: Reviewers should not enter the university or other institutional name.
     - Enter reviewer's office address and telephone number.
     - Click on "Submit."
     - Click on "Request a New DUNS Number."

       IMPORTANT: Reviewers should keep this information because they will need to enter the exact name and address information in the CCR registration process.

     Company Name:
     - Legal Name: Name will populate.
     - Legal Structure: Select "Proprietorship."

     Organization Information:
     - Telephone: Number will populate.
     - Executive Name: Enter reviewer's legal name.
     - Executive Title: Select title from pulldown menu.
     - Primary SIC Code: Enter "8621."
     - Description of Operations: Enter Grant Reviewer.
     - Socioeconomic Date: Select "No Special Ownership Status."

- Number of Employees: Enter "1."

Physical Address:

- Information will populate.
- Click on "Submit Your Request."

Contact:

- Enter reviewer's legal name, title, phone number, and e-mail address.
- Click on "Submit Your Request."

This completes the DUNS registration.

Removal from Marketing Mailing Lists

As a result of registering for a DUNS number, a reviewer's basic information (i.e., name, address, and phone number) may be included on a marketing mailing list.

Reviewers who want their information removed from the D&B marketing list should make sure they have their DUNS number on hand, call D&B Customer Service at 800-234-3867, and follow these steps:

- Select "5" from the menu options.
- Wait for a customer service representative.
- Tell the representative that he or she would like to be removed from D&B's marketing list.
- Give the representative his or her DUNS number.
- The representative will ask the reviewer to verify their company name. Reviewers should give the name they used when registering for a DUNS number (should be the reviewer's legal name).
- Next, the representative will ask the reviewer to verify his or her phone number.
- Request from the representative an e-mail confirmation that the removal has been processed.

Reviewers who register for DUNS numbers by phone can request at that time to not be included on marketing lists.

2. Complete the CCR registration process:

If reviewers collect the necessary information before registering, the process should take about 30 minutes to complete. Reviewers may reference the CCR Handbook on the CCR Homepage at *http://www.ccr.gov* for additional guidance, including a blank registration template and screen shots. Please contact the CCR Assistance Center at 888-227-2423 (within the U.S.) or 269-961-5757 (internationally) for help completing the registration process.

The following is a list of information reviewers will need before starting CCR registration**:**

- **DUNS Number** (see Step 1).
- **DUNS format for legal name and address must be used in CCR** (i.e., the exact way the information was entered in DUNS must be used in CCR).
- **Social Security number (SSN)**.
- **Financial institution name and telephone number:** Federal regulations require Federal payments to be made via electronic funds transfer (EFT) whenever possible. Reviewers must have a U.S. bank account to receive payments. Reviewers without U.S. bank accounts must read the note below for "Reviewers Living Outside the U.S."
- **Bank routing number:** Reviewers can find this nine-digit number on their checks (not on checking account deposit slips) in the lower left corner before the account number. Reviewers can also contact their banks for this information.
- **Account number**.
- **Account type** (checking or savings).

Reviewers Living Outside the U.S.

For reviewers who do not have U.S. bank accounts, a check will be mailed to them at the address entered in the Financial Information Section/Remittance Information section of the CCR. Foreign reviewers must have a North Atlantic Treaty Organization (NATO) Commercial and Governmental Entity (NCAGE) code. To obtain this number, go to the CCR Web site, look under "Search CCR," and click on "Find my CAGE." Then click on the link to "Tips for Companies Located Outside

the U.S." This section gives reviewers information on obtaining NCAGE numbers.

Access the CCR online registration at http://www.ccr.gov:

- Click on "Start New Registration."
- Look for the popup box, "Note to Registrants."
- Click on "Continue."
- Enter reviewer's DUNS Number. Type numbers only. Do not include dashes.
- Legal Business Name: Enter reviewer's legal name (last name, first name, and middle initial) and office address, city, state, ZIP code, and country.

Reviewers will be taken to a screen that compares the legal name and address just entered with the information entered during DUNS registration. They will then be asked to confirm that the Dun and Bradstreet information is correct. Clicking "Yes" will take reviewers to a screen that provides a CCR confirmation number.

IMPORTANT: Reviewers **must keep the CCR confirmation number**. If a reviewer cannot complete the registration in one session, he or she should click "validate/save" to save incomplete registration. To resume registration, the DUNS number and the CCR confirmation number will be required.

Enter the following information:

General Information Section

- DUNS: Enter reviewer's DUNS Number. Type numbers only. Do not include dashes.
- CAGE/NCAGE Code: U.S. Registrants—leave blank, a CAGE code will be assigned; foreign registrants must enter an NCAGE code. See instructions above.
- Legal Business Name: Enter reviewer's legal name (enter as last name, first name, middle initial).
- SSN: Reviewer's Social Security number—type numbers only. Do not include dashes.
- Physical Street Address: Enter reviewer's complete office address, which must match the one submitted to DUNS.
- Click on "Create a POC (Point of Contact) Template." Use the "Paste POC Template" to copy this information to the other required fields.
- Mailing Name: Enter reviewer's legal name (Enter as first name, middle initial, last name; must match DUNS).
- Mailing Address: Enter information or click "Paste POC Template."
- Business Start Date: Enter the reviewer's registration date.
- Number of Employees: Enter "1."
- Fiscal Year End Date: Enter "12/31."
- Annual Revenue: Enter "$1.00."
- Company Security Level: Leave default as "Not Applicable."
- Highest Employee Security Level: Leave default as "Not Applicable."
- Click on "Validate/Save Data" to move to the next section.

Corporate Information

- Type of Relationship with U.S. Federal Government: Select "Both (Contracts & Grants)."
- Type of Organization: Select "Sole Proprietorship."
- Sole Proprietorship Point of Contact: Enter information or click "Paste POC Template."
- Click on "Validate/Save Data" to move to the next section.

Goods/Services

- North American Industry Classification System (NAICS) Code: Enter "541690."
- Standard Industrial Classification (SIC) Code: Enter "8999."
- Click on "Validate/Save Data" to move to the next section.

Financial Information*

** Must be a U.S. bank. Foreign registrants without U.S. banks must complete Remittance Information Section only.*

- Electronic Funds Transfer (EFT): Enter reviewer's U.S. bank name, bank routing number (the nine-digit number in bottom left corner of check before account number; **do not** take the routing number from a deposit slip), bank account number, and bank account type.
- Automated Clearing House (ACH): Enter telephone number of reviewer's bank.
- Remittance Information: Enter information or click "Paste POC Template."
  - Foreign Registrants without a U.S. bank account: Enter the address to which the check should be mailed.
- Accounts Receivable Point of Contact: Enter information or click "Paste POC Template."
- Does the Company Accept Credit Cards as a Method of Payment: Select "No"
- Click on "Validate/Save Data" to move to the next section.

Points of Contact

- CCR POC (Registrant Name) Primary: Enter information or click "Paste POC Template."
- CCR POC Alternate: Enter information or click "Paste POC Template."
- Government Business POC—Primary: Enter information or click "Paste POC Template."
- Government Business POC—Alternate: Enter information or click "Paste POC Template."
- Electronic Business POC—Primary: Enter information or click "Paste POC Template."
- Electronic Business POC—Alternate: Enter information or click "Paste POC Template."
- Marketing Personal Identification Number (MPIN): Create and enter a nine-character/number access code that contains at least one alpha character, one number, and no spaces or special characters.
- Click on "Validate/Save Data" to move to the next section.

IRS Consent

- Taxpayer Name: Enter reviewer's legal name.
- Taxpayer Identification Number: Social Security number will be generated from the General Information section.
- Taxpayer Street Address: Information will be generated from the General Information section.
- Taxpayer City: Information will be generated from the General Information section.
- Taxpayer State: Information will be generated from the General Information section.
- Taxpayer ZIP+4/Postal Code: Information will be generated from the General Information section.
- Taxpayer Country: Information will be generated from the General Information section.
- Type of Tax: Insert applicable Federal tax.
- Tax Year: Insert most recent tax year.
- Name of Individual Executing Consent: Enter reviewer's legal name.
- Title of Individual Executing Consent: Enter reviewer's title.
- Signature (enter reviewer's MPIN here): Enter the MPIN number created for the CCR Points of Contact section.
- Date: Current date.
- Click on "Validate/Save Data."

EDI Information

It is not necessary to complete this screen.

- Click on "Validate/Save Data" at the end of this section.

At this point, the CCR registration process is complete. If the registration was submitted successfully, the reviewer will receive a letter via U.S. Postal Service or an e-mail message welcoming the reviewer to CCR. The letter or message will include a copy of the reviewer's registration. Reviewers should make sure all of the information is accurate.

Reviewers will also receive guidance on obtaining a Trading Partner Identification Number (TPIN). The TPIN is a confidential password provided upon CCR activation. When used in conjunction with a DUNS number, the TPIN gives reviewers access to their entire registration, including EFT information. The TPIN is mailed to reviewers via the U.S. Postal Service, or access to the TPIN is provided via e-mail notification. Reviewers need the TPIN to update and/or renew their registration. Reviewers who do not receive a TPIN or have lost their TPIN should contact the CCR Assistance Center at 888-227-2423 (U.S.) or 269-961-5757 (internationally).

CCR Security Issues

The CCR TPIN is a confidential password that the reviewer should not disclose to anyone under any circumstances. The reviewer should safeguard this number just as he or she would any sensitive password. CCR will never ask reviewers for their TPIN. Reviewers should not respond to any e-mails or written documents requesting their TPIN.

If a TPIN is lost or forgotten or a reviewer feels at any time that his/her TPIN has been compromised, he or she should immediately call the CCR help desk at: 888-227-2423 (U.S.) or 269-961-5757 (internationally).

CCR Privacy Information

Anyone can access the CCR Web site to search for a person in the CCR database. The results provide the person's DUNS number and contact information.

Private information, such as Social Security number or any type of banking information is **not** publicly available. The CCR Web site FAQ section, *http://www.ccr.gov/FAQ.asp#q21*, advises users to provide a generic e-mail address and a phone number other than their personal cell phone in the CCR registration point-of-contact field. This will reduce the risk of spam.

APPENDIX A

NIH INSTRUCTIONS TO REVIEWERS FOR EVALUATING RESEARCH INVOLVING HUMAN SUBJECTS IN GRANT AND COOPERATIVE AGREEMENT APPLICATIONS (5 APRIL 2002)

NIH INSTRUCTIONS TO REVIEWERS FOR EVALUATING RESEARCH INVOLVING HUMAN SUBJECTS IN GRANT AND COOPERATIVE AGREEMENT APPLICATIONS

April 5, 2002

Please read the instructions contained in this document, whether this is your first time as a reviewer or you have reviewed previously. **NIH has revised the reviewer responsibilities and applicant requirements with respect to the human subjects elements identified below.** Each assigned application and project within an application involving human subjects must be evaluated with respect to elements listed below.

Note: The first page of this document summarizes a reviewer's responsibilities, and the subsequent pages of the document provide additional details, explanations and guidance.

REVIEWER CRITIQUE HEADINGS AND EVALUATION CODING OPTIONS

1. **PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: (page 3)**

   Absent (no information provided in the application – Call the Scientific Review Administrator.) or
   Acceptable or
   Unacceptable or
   Exempt (see definitions)

   If the proposed research includes a clinical trial then a DATA AND SAFETY MONITORING PLAN is required and must be evaluated (page 4).
   Absent (no information provided in the application – Call the Scientific Review Administrator) or
   Acceptable or
   Unacceptable

2. **INCLUSION OF WOMEN PLAN: (required for clinical research - page 5)**

   Clinical Research Not an NIH-defined Phase III Clinical Trial:
   Absent (no information provided in the application – Call the Scientific Review Administrator) or
   Acceptable (coded 1-4 see instructions) or
   Unacceptable (coded 1-4 see instructions) or

   NIH-defined Phase III Clinical Trial: (see special analyses requirements)
   Absent (no information provided in the application – Call the Scientific Review Administrator) or
   Acceptable (representation coded 1-4, see instructions) or
   Unacceptable (representation coded 1-4)

3. **INCLUSION OF MINORITIES PLAN: (page 6)**

   Clinical Research Not an NIH-defined Phase III Clinical Trial:
   Absent (no information provided in the application – Call the Scientific Review Administrator) or
   Acceptable (coded 1-5, see instructions) or
   Unacceptable (coded 1-5, see instructions) or

   NIH-defined Phase III Clinical Trial: (see special **analyses requirements**):
   Absent (no information provided in the application – Call the Scientific Review Administrator) or
   Acceptable (coded 1-5, see instructions) or
   Unacceptable (coded 1-5, see instructions)

4. **INCLUSION OF CHILDREN PLAN: (page 9)**

   Absent (no information provided in the application – Call the Scientific Review Administrator) or
   Acceptable or
   Unacceptable

APPLICANT REQUIREMENTS (Page 2)

GLOSSARY OF TERMS (page 10)

ADDITIONAL GUIDANCE – Please refer to the Decision Trees:

Protection of Humans

Data and Safety Monitoring Plans in Clinical Trials

Women in Clinical Research

Women in NIH-Defined Phase III Clinical Trials

Minorities in Clinical Research

Minorities in NIH-Defined Phase III Clinical Trials

Children in Human Subjects Research

APPLICANT REQUIREMENTS:

The following requirements are described in detail in the PHS 398 application instructions.

1. PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK (page 3)

In the Human Subjects Research section, applicants must (1) address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or (2) provide sufficient information on the research subjects to allow a determination by peer reviewers and NIH staff that a designated exemption is appropriate.

Note: NIH policy no longer requires documentation of Institutional Review Board (IRB) approval at the time of the initial peer review.

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html.

If the application includes a clinical trial then the applicant must also include a **DATA AND SAFETY MONITORING PLAN (page 5).** This issue is evaluated as part of the protection of human subjects from research risk.

As of the October 2000 receipt date applicants must supply a general description of the Data and Safety Monitoring Plan for all clinical trials (see glossary definition) as part of the research application (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html). The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk.

2. WOMEN AND MINORITY INCLUSION (page 5)

The NIH Revitalization Act of 1993 (Public Law 103-43) requires that women and minorities must be included in all NIH-supported biomedical and behavioral clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

The most recent "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html) were published in the NIH Guide on August 2, 2000. All human clinical research (see glossary definition) is covered by this NIH policy. Each project of a multi-project application must be individually evaluated for compliance with the policy.

Since a primary aim of clinical research is to provide scientific evidence leading to a change in health policy or a standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently.

Applicants must include a description of plans to conduct valid analyses (see glossary definition) to detect significant differences (see glossary definition) in intervention effect for an NIH-defined Phase III Clinical Trial (see glossary definition).

3. INCLUSION OF CHILDREN (page 9)

NIH requires that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

This policy (http://grants.nih.gov/grants/guide/notice-files/not98-024.html) applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accord with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, applications for research involving human subjects must include a description of plan for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion. This policy applies to all initial applications (Type 1) proposals and intramural projects submitted for receipt dates after October 1, 1998.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK

REVIEWER RESPONSIBILITIES: Create a "**Protection Of Human Subjects From Research Risk**" heading in your written critique (using upper and lower case letters as shown).

Federal regulations (45 CFR 46.120) require that the information provided in the application (Human Subjects section e or other sections of the application) must be evaluated with reference to the following four criteria:

(1) Risk To Subjects; **(2)** Adequacy Of Protection Against Risks; **(3)** Potential Benefits Of The Proposed Research To The Subjects And Others; **(4)** Importance Of The Knowledge To Be Gained.

Evaluate the information provided in the application, and indicate whether the information is **"Absent"** or Protection Of Human Subjects From Research Risk is **Acceptable** or **Unacceptable** or that the proposed research is **"Exempt".**

Scoring Considerations:

If the Protection Of Human Subjects From Research Risk is **Unacceptable** it should be reflected in the priority score for scientific and technical merit assigned to the application. The negative impact on the score should reflect the seriousness of the human subjects concerns that are identified. Reviewers may also recommend limitations on the scope of the work proposed, imposition of restrictions, or elimination of objectionable (risky) procedures involving human subjects.

If the research risks are sufficiently serious and protections against the risks are so inadequate as to consider the proposed research unacceptable on ethical grounds, reviewers may recommend that no further consideration be given to the application and score the application as **NRFC** (**Not Recommended for Further Consideration**).

Your evaluation is independent of any other group who will review the research. (NIH policy no longer requires documentation of Institutional Review Board (IRB) approval at the time of the initial peer review http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html).

Absent If the applicant does not address any of the Human Subjects elements that are specifically required in the PHS 398 instructions, begin your comments in the Human Subjects section with the words **"Human Subjects Information Absent"** and call the Scientific Review Administrator. The application cannot be reviewed without this information.

Acceptable If the applicant has adequately and appropriately addressed the four Human subjects criteria and there are no concerns as defined in the glossary of terms, then, enter the words **Acceptable risks and/or adequate protections**.

Other issues related to the inclusion of human subjects, which are not concerns, may be communicated to the applicant or NIH staff in this section of your critique.

Unacceptable If the applicant has not adequately and appropriately addressed the four criteria in the application and/or you identify human subjects concerns, then, begin your comments with the words "**Unacceptable Risks and/or Inadequate Protections.**" Document and specify the actual or potential issues that constitute the unacceptable risks or inadequate protections against risks.

Human subjects concerns **(see Glossary)** should be described in your reviews, whether or not you recommend that the application be scored.

Exempt: If the application indicates that the Human Subjects research is exempt from coverage by the regulations, then determine whether the information provided conforms to one of the categories of exempt research and whether the information justifies the exemption claimed. If it is exempt, state "**Exempt**" and specify which exemption or exemptions apply (see Glossary for list of Exemption categories).

If an exemption is claimed and you determine that the information provided does not justify the exemption, then, indicate **Unacceptable** and indicate why you have determined that the information provided does not justify the exemption.

Where is the human subjects information located in an application?

The PHS form 398 grant application requires that applicants provide information about human subjects involvement and protections from research risk in the RESEARCH PLAN and the Appendices (if applicable).

See decision tree for **Protection of Humans**

http://grants.nih.gov/grants/peer/tree_protection_hs.pdf

DATA AND SAFETY MONITORING PLAN

REVIEWER RESPONSIBILITIES: The evaluation of the Data and Safety Monitoring Plan is part of the evaluation of the Protection of Human Subjects Section described previously.

If the application contains clinical trials research **(see Glossary),** evaluate the acceptability of the proposed Data and Safety Monitoring Plan provided in the application's research plan. Data and Safety Monitoring Plan are required of all applications that involve a clinical trial

On the basis of the information provided in the application, document the extent to which you judge the plan is **Absent, Acceptable**, or **Unacceptable.**

Scoring Considerations: If the Data And Safety Monitoring Plan is **unacceptable**, then, the unacceptability must be reflected in the priority score that you assign to the application.

The Data and Safety Monitoring Plan must be appropriate with respect to the potential risks to human participants, and complexity of study design.

Absent: If the applicant does not provide any information about a Data and Safety Monitoring Plan, indicate "**Absent**" in the Data and Safety Monitoring section of the critique and call the Scientific Review Administrator.

Acceptable: If the general description of the Data and Safety Monitoring Plan is adequate, (e.g. defines the general structure of the monitoring entity and mechanisms for reporting Adverse Events to the NIH, the IRB, etc.), your comments should include a statement to the effect that the plan is **Acceptable.**

Unacceptable: If the information provided about Data and Safety Monitoring is inadequate, your comments should include a statement that the plan is **Unacceptable** and subsequently specify what is unacceptable about the plan and/or what information is missing.

Components of a Monitoring Plan

NIH requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants.

(http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Generally, NIH-defined Phase III Clinical Trials require DSMBs. Smaller and earlier phase clinical trials may not require this level of oversight, and alternate monitoring plans may be more appropriate.

Applicants must submit a general description of the Data and Safety Monitoring Plan for all clinical trials. Monitoring plans are also required as part of the PHS 398 section "e. Human Subjects".

The general description of the Data and Safety Monitoring Plan should describe the entity that will be responsible for monitoring, and the policies and procedures for adverse event reporting. All monitoring plans must include a description of how Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the NIH, the Office of Biotechnology Activities (OBA) (if required), and the Food and Drug Administration (FDA) in accordance with IND or IDE regulations.

Monitoring entities may include, but are not limited to:

Principal Investigator
Independent individual/Safety Officer
Designated medical monitor
Internal Committee or Board with explicit guidelines
DSMB (required for multi-site NIH-defined Phase III Clinical Trials)
IRB (required)

A detailed Data and Safety Monitoring plan will be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to award. The detailed monitoring plan must be approved by the funding IC prior to the accrual of human participants.

(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html)

In addition applications involving human gene transfer research must comply with NIH Guidelines for Research Involving Recombinant DNA Molecules be and must submit protocols to the NIH Office of Biotechnology Activities (OBA), for review by the Recombinant DNA Advisory Committee (RAC) prior to final approval by the Institutional Biosafety Committee. OBA recommends that RAC review also occur prior to IRB review and submission to FDA for regulatory permission to proceed with the study.

See decision tree for **Data and Safety Monitoring Plans in Clinical Trials**

http://grants.nih.gov/grants/peer/tree_dsm_plans.pdf

See also:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html.

WOMEN AND MINORITY INCLUSION

REVIEWER RESPONSIBILITIES: Create two headings: "**Inclusion of Women**" and "**Inclusion of Minorities**" in your written critique (using upper and lower case letters as shown). Evaluate the assigned applications and each individual project within multicomponent applications to assess the plan for the inclusion of Women and then the plan for inclusion of Minorities or the acceptability of the justifications for exclusion of women or minorities provided in the application's research plan.

On the basis of the information provided in the application, designate that the information is **"Absent," "Acceptable"** or **"Unacceptable."**

Absent: If no information is provided about the Inclusion of Women, the Inclusion of Minorities, or both, indicate "**Absent**" in the appropriate heading section. In the absence of information or proposed plans for inclusion, reviewers should call the Scientific Review Administrator. The absence of plans are grounds for returning the application to the applicant without peer review.

Scoring Considerations: If the plans for Inclusion of Women and/or Inclusion of Minorities are unacceptable, then, the unacceptability must be reflected in the priority score that you assign to the application.

Provide a brief narrative text to answer the following **Questions** and evaluate the **Criteria for Acceptable/ Unacceptable plans** separately for women and for minorities

Questions about Inclusion- Does the applicant propose a plan for the inclusion of minorities and both genders for appropriate representation? How does the applicant address the inclusion of women and members of minority groups and their subpopulations in the development of a research design that is appropriate to the scientific objectives of the study? Does the research plan describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and does it provide a rationale for selection of such subjects.

Questions about Exclusion - Does the applicant propose justification when representation is limited or absent? Does the applicant propose exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the health of the subjects and/or with respect to the purpose of the research? Evaluate the justifications for exclusion in terms of the criteria for **Acceptable/Unacceptable** (see pages 6-8).

Questions about Analysis Plans - Does the applicant propose an NIH-defined Phase III Clinical Trial (see Glossary for definition)? If yes, does the research plan include either (a) an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect by sex/gender and/or racial/ethnic subgroups when the intervention effect(s) when prior research indicates such differences in intervention effect or (b) an adequate description of plans to conduct valid analyses (see Glossary) of the intervention effect between subgroups when there is no clear-cut scientific evidence to rule out such differences in intervention effect.

GENDER INCLUSION IN CLINICAL RESEARCH (NOT A NIH-DEFINED PHASE III CLINICAL TRIAL): Criteria for Determining Acceptable/ Unacceptable Plans

Acceptable: One or more of the following may apply:

1. Both genders are included in the study in scientifically appropriate numbers.

2. One gender is excluded from the study because:

- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one gender;
- evidence from prior research strongly demonstrates no difference between genders;
- sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.

3. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).

4. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.

Unacceptable: One or more of the following may apply:

1. Representation fails to conform to NIH policy guidelines summarized in this document and the

NIH Guidelines pertinent to the scientific purpose and type of study;
2. The application provides insufficient information;
3. The application does not adequately justify limited representation of one gender.

GENDER REQUIREMENTS FOR NIH-DEFINED PHASE III CLINICAL TRIALS: ADDITIONAL CRITERIA

Acceptable: One or more of the following may apply based on review of prior evidence:

1. Available evidence strongly indicates significant sex/gender differences of clinical or public health importance in intervention effect, and the study design is appropriate to answer two separate primary questions -- one for males and one for females -- with adequate sample size for each gender. **The research plan must include a description of plans to conduct analyses to detect significant differences in intervention effect.**

2. Available evidence strongly indicates there is no significant difference of clinical or public health importance between males and females in relation to the study variables. (Representation of both genders is not required; however, inclusion of both genders is encouraged.)

3. There is no clear-cut scientific evidence to rule out significant differences of clinical or public health importance between males and females in relation to study variables, and study design includes sufficient and appropriate representation of both genders to permit valid analyses of a differential intervention effect. **The research plan must include a description of plans to conduct the valid analyses (see glossary definition) of the intervention effect.**

4. One gender is excluded from the study because:

   - Inclusion of these individuals would be inappropriate with respect to their health;
   - Inclusion of these individuals would be inappropriate with respect to the purposes of the research (e.g., the research question addressed is only relevant to one gender).

Unacceptable: One or more of the following may apply:

1. Representation fails to conform to NIH policy guidelines summarized in this document and the NIH Guidelines pertinent to the scientific purpose and type of study;
2. The application provides insufficient information;
3. The application does not adequately justify limited representation of one gender;
4. The application fails to provide an appropriate analysis plan.

Evaluation And Coding: For single project applications, assign an overall code as described below. For multi-project applications, a code should be assigned to each individual project or subproject in an application containing multiple projects or involving distinct populations or specimen collections. If only one project in a multiproject application involves clinical research, the codes assigned to that project will apply to the overall document; if there is more than one project covered by the policy, ALSO assign an overall code to the entire application as follows:

Representation Proposed in Project. Coding should reflect the total representation proposed for all projects or subprojects, even if some are single-gender.

Gender Coding

Format. Each code is a three digit alphanumeric string:

1st character **G** (indicates gender code)
2nd character **1, 2, 3, or 4** (representation proposed in project – see below)
3rd character **A or U** (acceptable or unacceptable – see guidance below)

Representation Proposed in Project

(2nd character)

1 = both genders
2 = only women
3 = only men
4 = gender unknown

GENDER CODES

Gender Representation	Scientifically… Acceptable	Unacceptable
both included	G1A	G1U
women only	G2A	G2U
men only	G3A	G3U
Unknown	G4A	G4U

MINORITY INCLUSION

A minority group is defined as "...a readily identifiable subset of the US population which is distinguished by either racial, ethnic and/or cultural heritage." In accordance with OMB Directive No.15, the basic racial and ethnic categories are: American Indian or Alaska Native; Asian; Black or African American, Hispanic or Latino; Native Hawaiian or Other Pacific Islander and White. 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. Applications should describe the subgroups that will be included in the research.

In foreign research projects involving human subjects, the definition of minority groups may be different than in the US; if there are scientific reasons for examining minority group or subgroup differences in such settings, studies should be designed to accommodate such differences.

Reviewers should provide a brief narrative text to answer the **Questions about Inclusion, Exclusion, and Analysis Plans** (see page 5) and use the following **Criteria for Determining Acceptable /Unacceptable Minority plans**.

MINORITY INCLUSION IN CLINICAL RESEARCH; (NOT A NIH DEFINED NIH-DEFINED PHASE III CLINICAL TRIAL): Criteria for Determining Acceptable/Unacceptable Plans

Acceptable: One or more of the following may apply:

1. Minority individuals are included in scientifically appropriate numbers and recruitment/retention has been realistically addressed.

2. Some or all minority groups or subgroups are excluded from the study because:

- Inclusion of these individuals would be inappropriate with respect to their health;
- The research question addressed is relevant to only one racial or ethnic group;
- Evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- A single minority group study is proposed to fill a research gap;
- Sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.

4. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:

- The size of the study;
- The relevant characteristics of the disease, disorder or condition;
- The feasibility of making a collaboration or consortium or other arrangements to include representation.

Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited minority representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).

5. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Unacceptable: One or more of the following may apply:

1. Minority representation fails to conform to NIH policy guidelines summarized in this document and in the NIH Guidelines pertinent to the scientific purpose and type of study;
2. Insufficient information is provided;
3. The application does not adequately justify limited representation of minority groups or subgroups.
4. The application does not adequately address recruitment/retention of some or all minority groups or subgroups.

MINORITY REQUIREMENTS FOR NIH-DEFINED PHASE III CLINICAL TRIALS : ADDITIONAL CRITERIA

Acceptable: One or more may apply:

1. Available evidence strongly indicates significant racial or ethnic differences in intervention effects, and the study design is appropriate to answer separate primary questions for each of the relevant

racial or ethnic subgroups, with adequate sample size for each. **The research plan must include a description of plans to conduct analyses to detect** significant differences **in intervention effect.**

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

3. There is no clear-cut scientific evidence to rule out significant differences of clinical or public health importance among racial or ethnic groups or subgroups in relation to the effects of study variables, and the study design includes sufficient and appropriate representation of minority groups to permit valid analyses (see note below) of a differential intervention effect. **The Research Plan in the application or proposal must include a description of plans to conduct the** valid analyses **(see Glossary definition) of the intervention effect in subgroups.**

4. Some minority groups or subgroups are excluded from the study because:

- Inclusion of these individuals would be inappropriate with respect to their health; or
- Inclusion of these individuals would be inappropriate with respect to the purposes of the research (e.g., the research question addressed is not relevant to all subgroups).

Unacceptable: One or more of the following may apply:

1. Minority representation fails to conform to NIH policy guidelines summarized in this document and in the NIH Guidelines pertinent to the scientific purpose and type of study;
2. Insufficient information is provided;
3. The application does not adequately justify limited representation of minority groups or subgroups;
4. The application fails to provide an appropriate analysis plan.

Minority Codes

Format. Each code is a three digit alphanumeric string:

1st character **M** (indicated minority code)
2nd character **1, 2, 3, 4, or 5** (representation proposed in project – see below)
3rd character **A or U** (scientifically acceptable or unacceptable – see below)

Representation Proposed in Project (2nd character)

1 = minority and nonminority
2 = only minority
3 = only nonminority
4 = minority representation unknown
5 = only foreign subjects in study population (no U.S. subjects). If the study population includes both foreign and U.S. study subjects then use codes 1 thru 4 to describe the U.S. component (do not use code 5).

MINORITY CODES

Minority Representation	Scientifically… Acceptable	Unacceptable
minorities and non-minorities included	M1A	M1U
minorities only	M2A	M2U
non-minorities only	M3A	M3U
Unknown	M4A	M4U
Foreign	M5A	M5U

Additional Information on the Inclusion of Women and Minorities

See decision trees for:

Women in Clinical Research

http://grants.nih.gov/grants/peer/tree_women_clinical_research.pdf

Women in NIH-Defined Phase III Clinical Trials

http://grants.nih.gov/grants/peer/tree_women_clinical_trials.pdf

Minorities in Clinical Research

http://grants.nih.gov/grants/peer/tree_minorities_clinical_research.pdf

Minorities in NIH-Defined Phase III Clinical Trials

http://grants.nih.gov/grants/peer/tree_minorities_clinical_trials.pdf

Answers to Frequently asked questions:

http://grants1.nih.gov/grants/funding/women_min/women_min.htm

INCLUSION OF CHILDREN IN HUMAN SUBJECTS RESEARCH

REVIEWER RESPONSIBILITIES: Create an "**Inclusion of Children Plan**" heading in your written critique (using upper and lower case letters as shown)

Evaluate the acceptability of the proposed plan for the inclusion of children or the acceptability of the justifications for exclusion provided in the application's research plan.

On the basis of the information provided in the application document the extent to which you judge the plan is "**Absent",** "**Acceptable**," or "**Unacceptable.**"

Scoring Considerations: If the Inclusion Plan is unacceptable, then, the unacceptability must be reflected in the priority score that you assign to the application.

Reviewers are asked to evaluate the appropriateness of the population studied in terms of the aims of the research and ethical standards, the expertise of the investigative team in dealing with children at the ages included, and the appropriateness of the facilities. Evaluate and code (see instructions below) each project and subproject separately for inclusion of children.

The PI must describe in the application, under a section "Participation of Children," the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children. Additional information is provided in the Human Subjects section.

Absent: If no information is provided about the Inclusion of Children, indicate "**Absent**" in the heading section.

In the absence of information on the proposed plans for inclusion, reviewers should call the Scientific Review Administrator.

An **Acceptable** plan is one in which the representation of children is scientifically appropriate and recruitment/retention has been realistically addressed, or an appropriate justification for exclusion has been provided.

For those plans, which are "**Acceptable**" provide one of the following codes:

C1A Both children and adults are included (e.g. inclusion is scientifically acceptable).

C2A Only children are represented in the study (e.g. inclusion is scientifically acceptable).

C3A No children included (e.g. acceptable justification for exclusion is provided).

C4A Representation of children is not known (e.g. The information on age of individuals providing specimens or in existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens), and this does not compromise the scientific objectives of the research).

An **Unacceptable** plan is one, which fails to conform to NIH policy guidelines in relation to the scientific purpose of the study; or fails to provide sufficient information; or does not adequately justify that children are not included; or does not realistically address recruitment/retention

For those plans that are **Unacceptable** provide one of the following codes**:**

C1U Both children and adults are included; (e.g. no rationale is provided for selecting or excluding a specific age range of children).

C2U Only children are represented in the study (e.g. but age range is too restricted to be scientifically acceptable, such as including only children of ages 18-21).

C3U No children included (e.g. acceptable justification for exclusion is not provided).

C4U Representation of children is not known (e.g. the application does not provide sufficient information about the age distribution of the study population. the application does not comply with requirements and is unacceptable).

In all cases explain the basis for your judgment.

ADDITIONAL GUIDANCE – Please refer to the Decision Tree:

Children in Human Subjects Research

and NIH Policy:

http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Answers to Frequently asked questions:

http://grants2.nih.gov/grants/funding/children/pol_children_qa.htm

GLOSSARY OF TERMS

AMERICAN INDIAN OR ALASKA NATIVE:

A person having origins in any of the original peoples of North, Central, or South America and maintains tribal affiliation or community

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

BLACK OR AFRICAN AMERICAN:

A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”

CHILD:

For purposes of this policy, a child is an individual under the age of 21 years. This policy and definition do not affect the human subject protection regulations for research on children 45 CFR 46) and their provisions for assent which remain unchanged.

It should be noted that the definition of child described above will pertain notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states. Generally, state laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, state laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on state definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under state law. For example, some states consider a person age 18 to be an adult and, therefore, one who can provide consent without parental permission (see also http://grants.nih.gov/grants/guide/notice-files/not98-024.html).

CLINICAL RESEARCH:

The NIH definition of clinical research is based on the 1997 Report of the NIH Director's Panel on Clinical Research that defines clinical research in the following three parts:

(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.

Note: Autopsy material is not covered by the policy. When the research under review is essentially a service (e.g., statistical center or analysis laboratory) in support of another activity already found to be in compliance with this policy, a second review is not necessary.

Training grants (T32, T34, T35) are exempt from coding requirements but a term or condition of award will specify that all projects to which trainees are assigned must already be in compliance with the NIH policy on inclusion of women and minorities in clinical research.

CLINICAL TRIAL:

For purposes of reviewing applications submitted to the NIH, a clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is 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 clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (e.g. < 80) for the first time to evaluate safety (e.g. determine a safe dosage range, and identify side effects).

Phase II clinical trials are done to study the biomedical or behavioral intervention in a larger

group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III studies are done to study 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.

Phase IV studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

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 NIH-defined Phase III 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, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

EXEMPTION CATEGORIES:

The six categories of research that qualify for exemption from coverage by the regulations include activities in which the only involvement of human subjects will be in one or more of the following six categories:

The six categories of research that qualify for exemption from coverage by the regulations include one or more of the following six categories:

Exemption 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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.

Exemption 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 (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 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.

Exemption 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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and 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.

GENDER:

Refers to the classification of research subjects into either or both of 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).

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 (45-CFR-46) defines human subjects as follows:

Human subject means 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 (see also the decision charts provided by the Office of Human Research Protection)

Legal requirements to protect human subjects apply to a much broader range of research than many investigators realize, and researchers using human tissue specimens are often unsure about how regulations apply to their research. Legal obligations to protect human subjects apply, for example, to research that uses–

Bodily materials, such as cells, blood or urine, tissues, organs, hair or nail clippings, even if you did not collect these materials

Residual diagnostic specimens, including specimens obtained for routine patient care that would have been discarded if not used for research

Private information, such as medical information, that can be readily identified with individuals, even if the information was not specifically collected for the study in question.

Research on cell lines or DNA samples that can be associated with individuals falls into this category.

HUMAN SUBJECTS CONCERN:

A human subject concern is defined as any actual or potential unacceptable risk, or inadequate protection against risk, to human subjects as described in any portion of the application.

HUMAN SUBJECTS RISK AND PROTECTION CRITERIA:

The PHS 398 application instructions require that applicants address the following four criteria in the Research Plan – Section e of their applications:

1. **RISKS TO THE SUBJECTS**

   Human Subjects Involvement and Characteristics: The applicant must describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

   Sources of Materials: The applicant must identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

   Potential Risks: The applicant must describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Where

appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. **ADEQUACY OF PROTECTION AGAINST RISKS**

   Recruitment and Informed Consent: The applicant must describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document need not be submitted to the PHS unless requested.

   Protection Against Risk: The applicant must describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve clinical trials (biomedical and behavioral intervention studies), describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

3. **POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS**

   The applicant must discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. **IMPORTANCE OF THE KNOWLEDGE TO BE GAINED**

   The applicant must discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

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.

MINORITY GROUPS:

A minority group is a readily identifiable subset of the U.S. population, which is 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 than in the US.

NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER:

A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

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 NIH-defined Phase III 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, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

OUTREACH STRATEGIES:

These are outreach efforts by investigators and their staff(s) to appropriately recruit and retain populations of interest into research studies. Such efforts should represent a thoughtful and culturally sensitive plan of outreach and generally include involvement of other individuals and organizations relevant to the populations and communities of interest, e.g., family, religious organizations, community leaders and informal gatekeepers, and public and private institutions and organizations. The objective is to establish appropriate lines of communication and

cooperation to build mutual trust and cooperation such that both the study and the participants benefit from such collaboration.

RACIAL AND ETHNIC CATEGORIES:

The Office of Management and Budget (OMB) Directive No. 15 defines the minimum standard of basic racial and ethnic categories, which are 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.

RESEARCH PORTFOLIO:

Each Institute and Center at the NIH has its own research portfolio, i.e., its "holdings" in research grants, cooperative agreements, contracts and intramural studies. The Institute or Center evaluates the research awards in its portfolio to identify those areas where there are knowledge gaps or which need special attention to advance the science involved. NIH may consider funding projects to achieve a research portfolio reflecting diverse study populations. With the implementation of this new policy, there will be a need to ensure that sufficient resources are provided within a program to allow for data to be developed for a smooth transition from basic research to NIH-defined Phase III clinical trials that meet the policy requirements

SCIENTIFICALLY ACCEPTABLE OR UNACCEPTABLE:

A determination, based on whether or not the gender or minority representation proposed in the 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 merely being clinical research.

SIGNIFICANT DIFFERENCE:

For purposes of the NIH policies, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

SUBPOPULATIONS:

Each minority group contains subpopulations, which are delimited by geographic origins, national origins and/or cultural differences. It is recognized that 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.

VALID ANALYSIS:

The term "valid analysis" means an unbiased assessment. Such an assessment 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 both small and large studies. A valid analysis does not need to 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 (males and females) 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.

APPENDIX B

INTERNET ASSISTED REVIEW REVIEWER USER GUIDE (1 AUGUST 2003)

National Institutes of Health/Office of Extramural Research

Electronic Research Administration

Internet Assisted Review Reviewer User Guide

Version 2.2.3.0—August 01, 2003

Table of Contents

Introduction

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).

Summary of Capabilities

IAR allows for:

- critique and preliminary score submission and modification
- acceptance of critiques in Microsoft Word (*.doc) or plain text (*.txt) format
- streamline voting

IAR Phases

The following phases are listed in IAR:

- Submit phase—Time period when you submit critiques for your assigned applications. During this phase you only see your assigned applications. The phase end date is the Critique due date.
- Read phase—Time period after the Submit phase (the Submit phase end date determines the start of the Read Phase). 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 phase—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.

Logging In and Out

Introduction

IAR is accessed through the NIH eRA Commons, a web-based system that allows principal investigators (PIs) and central research administration offices to communicate and send information electronically. To be able to use 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 in. Other Web browsers are also supported, but some functionality may be lost.

Special Notes Regarding the Web Browser

You must enable Cookies and JavaScript on your browser and use the navigation buttons and hyperlinks provided on the system pages instead of the browser buttons to move through the pages. Additionally, make sure that the browser is *not* set for automatic password completion. For instructions on making these changes, check your browser's Help text.

Please use the navigation buttons and hyperlinks provided in the IAR interface instead of the browser buttons to move through the module pages.

Session Expiration

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.

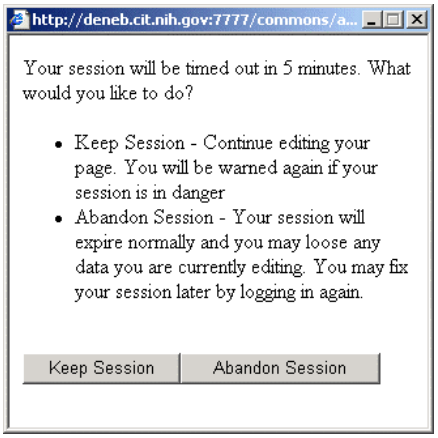

Figure 1 Session Expiration Warning

If you know you won't need to use the system for an extended period of time, you should use the Logout hyperlink located at the top of every page to log out. If your session expires while the NIH eRA Commons is still open (if you don't 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.

Logging In to IAR

Figure 2 NIH eRA Commons Home Page Before Logging In

1. Launch your Web browser.
2. Enter the following URL in your browser's Address/Location field:
   https://commons.era.nih.gov/commons/ and press **Enter**.
   The eRA Commons Home page opens.
3. In the Username field, type your username and press **Tab** to move to the Password field.

4. Type your password and press **Enter** or click **Login**.
5. If this is the first time you are logging in, the Change Password page (FRW0015) opens:

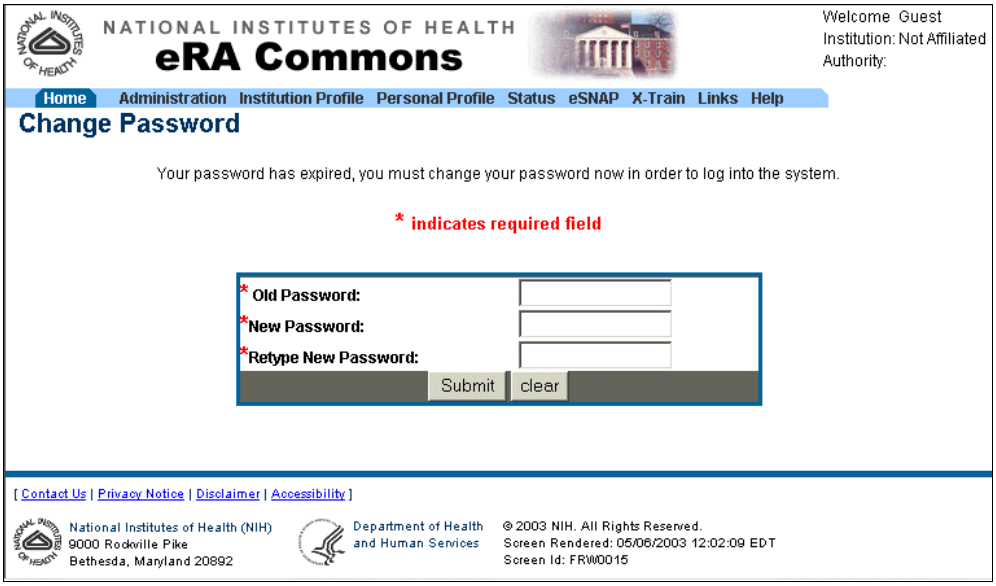

Figure 3 Change Password Page (FRW0015)

   a. Enter your old password, and then enter and retype a new password.
   b. Click **Submit** to update the new password information.

The system returns you to the Home page with your login information displayed in the upper right corner of the page. A logout hyperlink is located directly beneath your login information.

6. Click the **IAR** tab to open the IAR List of Meetings page (IAR0001). See *Viewing Meeting Information* on page 4 for more information.

Concurrent Log Ins

You may be logged in to the eRA Commons for only 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.

Password Expiration Notification

For security purposes, eRA Commons user passwords expire and must be reset. If your password is about 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.

Printing Screens

All web pages in IAR can be printed using your browser's standard print feature in order to provide a hard copy report of what you see on the screen.

Logging Out

Logging out of the eRA Commons ends your current session. The top of each page contains a Logout hyperlink.

Creating/Accessing an IAR Account

Your SRA/GTA grants you access to use IAR to submit and view critiques for applications in meetings. When this happens, you receive an email informing you of your ability to access IAR. If you do not yet 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.

To access IAR if you already have an IAR account or once you receive the notification email:

1. Click the hyperlink in the email to open the eRA Commons Login page.
2. Log in as described in Logging In to IAR on page 2.
3. Select the **IAR** tab to open the List of Meetings page (IAR0001)

Viewing Meeting Information

The List of Meetings page shows all the meetings where you have assignments and the meeting is in the Read, Submit, or Edit Phase. This is a display-only page; none of the information can be edited.

- Log in as described in Logging In to IAR on page 2.

Table 1 List of Meeting Page Information

Column	Description
Meeting	Includes the meeting identifier and the meeting title. 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. An example of an SRG Meeting is 2002/10 PC-1 (01) An example of a SEP Meeting is 2002/10 ZRG1 SRG-F (GC) X 001 The title indicates the title of the meeting or the panel name if the meeting is a SEP.
Meeting Dates/Location	The dates that the actual meeting starts and ends and the hotel name, city, and state where the meeting is being held.
SRA Name	The first and last names, the work telephone number, and the work email address of the SRA. The latter is in the form of a hyperlink so that an email can be sent to the SRA.
Phase	The current IAR phase for the meeting.
Critique Due	The date and time critiques are due. This is also known as the Submit phase end date.

Read Phase End	The Read phase end date and time.
Edit Phase End	The Edit phase end date and time.
Action	Area that provides a hyperlink to open the List of Applications page.

Viewing Application Information

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.

1. From the List of Meetings page, click the **View List of Applications** hyperlink (in the Action column) to open up the List of Applications page (IAR0007) with your assigned applications.

When the meeting is in the Submit phase:

- Each application has a link for submitting a critique. If you have already submitted a critique, there are also links for deleting and viewing the critique.

When the meeting is in the Read phase:

- Based on the whether or not you have been permitted by your SRA/GTA to view the critiques of other reviewers, the list of available applications with either list only assigned applications or will list all reviewed applications.
- If you have not yet submitted a critique on an application and are blocked from reading the critiques of other reviewers, only the Submit option will be available for blocked applications.
- The other applications will each have a link for viewing critiques.

When the meeting is in the Edit phase:

- Each application has a link for submitting a critique. If you have already submitted a critique, there are also links for deleting and viewing the critique.
- If you have not yet submitted a critique on an application and are blocked from reading the critiques of other reviewers, only the Submit option will be available for blocked applications.

List of Applications Page—Meeting Information

Meeting information, listed in Table 2, is displayed on the top of the page and is the same for any of the IAR phases.

Note: All times are listed according to Eastern Standard/Daylight Savings Time.

Table 2 List of Applications Page—Meeting Information

Column	Description
Meeting Title	The title of the meeting or the panel 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. An example of an SRG Meeting is 2002/10 PC-1 (01) An example of a SEP Meeting is 2002/10 ZRG1 SRG-F (GC) X 001
Meeting Phase	The current IAR phase for the meeting; Submit, Read, or Edit.
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 Page—Link Information

The links at the top of the application list table provide ways to navigate in IAR and various ways to view the application information. The links are described in Table 3.

Table 3 List of Applications Page—Link Information

Link	Description	Viewed in IAR Phase
Back to List of Meetings	Returns you to the List of Meetings page. Use this link instead of using the browser's Back button.	All
Show All Applications	Shows all applications for the meeting, including those with conflicts.	All
Show Assigned Applications	Shows all the applications that are assigned to you. This is the default view when you first access the List of Applications page.	Submit
View My Critiques	Opens Adobe Acrobat with a PDF file of all critiques that you have submitted so far.	All
List My Assignments Only	Shows the applications that have been assigned to you.	Read, Edit
View Score Matrix	Shows the score matrix for applications in the meeting. See *Viewing the Score Matrix* on page 8 for more information.	Read
View All Meeting Critiques	Opens Adobe Acrobat with a PDF file of all critiques for all applications in a meeting.	Read, Edit
View all Critiques for Assigned Applications	Opens Adobe Acrobat with a PDF file of all critiques you have submitted for your assigned applications in a meeting.	Read, Edit
View All Critiques	Opens Adobe Acrobat with a PDF file of all critiques submitted for a specific application in a meeting.	Read, Edit

List of Applications Page—Application Information

The information listed in the table of applications is sorted by last name of the PI with a secondary sort by application number (Activity Code/IC/Serial Number). Table 4 describes the information available in the application list.

Table 4 List of Applications Page—Application Information

Column	Description
Application	Lists the full application number. This column also provides a link to view all critiques. During the Submit phase, only a PDF link is available. If the Submit phase end date has passed, a link to a Microsoft Word format pre-summary statement body is listed (if a summary statement exists for the application).
PI Name	Lists the last name, first name of the principal investigator.
New PI	Indicates (Y/N) if the application is from a new investigator.
Title	Lists the project title of the grant application.
Reviewer (Role)	Lists the last name, first name of the reviewer and indicates the reviewer's role (primary, secondary, etc.).
Score	The preliminary score for the application. If available, an average score for each application is listed.
Submitted Date	If a critique has been submitted, indicates the date and time that the critique was submitted. **Note**: All times are listed according to Eastern Standard/Daylight Savings Time.
Action	Lists the various options available for the specific application (Submit, View, Delete)

Viewing SRA/GTA Contact Information

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

1. Click the SRA/GTA hyperlink located at the bottom of the List of Applications page to open the SRA/GTA Name and Contact Information page (IAR0010). The page displays SRA/GTA name, telephone number and email address.
2. The email address is in the form of a hyperlink so that an email can be sent to the SRA/GTA. Click the hyperlink to open your default email program.

Submitting Critiques/Scores

You can 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 or β) insert them as symbols within the Microsoft Word document.

Unassigned reviewers can not submit scores for any applications.

1. Log in to IAR as described in Logging In to IAR on page 2.
2. From the List of Meetings page, click the **View List of Applications** hyperlink (in the Action column) to open the List of Applications page (IAR0007).

3. Click the **Submit** hyperlink in the Action column for the desired application to open the Submit Critique and Preliminary Score page (IAR0011).
4. Enter the full path and filename (including extension) of the critique or click **Browse** button to locate the file.
5. If applicable, either a numeric score or a score code can be entered (see *Submit Critique and Preliminary Score Page Information* for more information about the score code). A numeric score must be within a range of 1.0–5.0.
6. Click **Submit** to upload the file. The file is checked for the proper file type and is virus-checked.
7. IAR displays a validation message with an option to cancel or submit critique and score. Click **Submit** to finalize the submission and view a confirmation message that your critique and score were updated.

Special Considerations for 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.

Submit Critique and Preliminary Score Page Information

Table 5 describes the information included on the Submit Critique and Preliminary Score page.

Table 5 Submit Critique and Preliminary Score Page Information

Field	Description
Application	A display-only field that lists the application number (activity code/IC/serial)
Title	A display-only field that lists the project title of the grant application.
PI Name	A display-only field that lists the last name, first name of the principal investigator.
Assignment Role	A display-only field that lists the reviewer's role (primary, secondary, etc.).
Critique File	The field where you enter the full path and filename of the critique file on your computer.
Score	The field where you enter either the numeric score (from 1.0–5.0) or a score code of NR (not recommended), UN/NC (unscored/not competitive), or DF (deferred). Only one option is permitted.

Viewing Critiques

Your ability to view critiques depends upon the type of reviewer that you are and the current IAR phase that the meeting is in. Critiques cannot be modified during the Read Phase and you will not be able to view critiques and

scores for applications where you have conflicts of interest. 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.

1. From the List of Meetings page, click the **View List of Applications** hyperlink (in the Action column) to open the List of Applications page (IAR0007).
2. To view an individual critique (during all IAR phases):
   - Click the **View** hyperlink in the Action column for the desired application. The critique is usually viewed in Adobe PDF, but may be displayed in the original Word/text format if the conversion hasn't yet occurred.
3. To view critiques for all applications in a meeting (during the IAR Read/Edit phases only):
   - Click the **View All Meeting Critiques** hyperlink. An Adobe PDF document of all critiques for all applications is created. The critiques are listed in order of application number with a secondary sort on the reviewer assignment role. Critiques for applications where there are conflicts of interest are omitted from the document.
4. To view all critiques that you have submitted (during all IAR phases):
   - Click the **View My Critiques** hyperlink. An Adobe PDF document of all your critiques is created.
5. To view all critiques that you have submitted for your assigned applications (during the IAR Read/Edit phases only):
   - Click the **View All Critiques for Assigned Applications** hyperlink. An Adobe PDF document of all your critiques is created.
6. To view all critiques submitted for a specific application (during the IAR Read/Edit phases only):
   - Click the **View All Critiques** hyperlink that appears under the Application column for the desired application. An Adobe PDF document of all critiques for the application is created. The critiques are listed in order of reviewer assignment role.

Viewing the Score Matrix

The Score Matrix page is used by the SRA/GTA during the Submit and Read phases to designate which applications should be categorized as lower half. Your ability to view the Score Matrix page depends upon the type of reviewer that you are and the current IAR phase that the meeting is in. The Score Matrix is available in two views—Show All Applications (the default view) and Show Lower Half Applications Only.

Regular reviewers—The score matrix page is available (display-only) during the Read phase, but only for applications where there is no conflict of interest. If you are blocked by your SRA/GTA from reading critiques for applications where you haven't yet submitted a critique, you are also blocked from seeing scores for those applications.

Telephone reviewers—The score matrix page is available (display-only) during the Read phase, but only for applications where there is no conflict of interest.

Mail reviewers—You do not have access to the Score Matrix page at all.

Note: Subprojects are sorted under the parent application (the applications are grouped by the parent PI name). The subproject itself lists the Core Leader name and not the parent PI name.

To access the Score Matrix page:

1. Log in to IAR as described in Logging In to IAR on page 2.
2. From the List of Meetings page, click the **View List of Applications** hyperlink in the Action column to open up the List of Applications page (IAR0007).
3. Click the **View Score Matrix** hyperlink located below the meeting information at the top of the page. The View Score Matrix page (IAR0008) opens. By default, all applications are listed and sorted PI name.
4. To view lower half applications only:
   - Click the **Show Lower Half Applications Only** hyperlink.

Table 6 describes the information included on the View Score Matrix page.

Table 6 Score Matrix Page Information

Column	Description
Application Number	Lists the full application number. This column can be sorted by either activity/IC/serial number or by IC/serial number.
PI Name [Conflicts]	Lists the PI last name, first name with an indication if the PI has at least one conflict of interest. This column can be sorted by activity/PI name or by PI name.
Lower Half	Indicates (by an X) if the application is marked for inclusion into the lower half. The column can be sorted either by: • **LH/ACT/PI/AVG** (lower half/activity code/PI name/average)—lists applications without lower half designation and without an average score first, then the lower half applications, then average score in descending order. • **LH/PI/AVG** (lower half/PI name/average)—lists applications without lower half designation and without an average score first, then the lower half applications, then average score in descending order.
AVG	Lists the average score for applications that are scored with numeric scores only. The column can be sorted by applications with no average and no lower half designation first, then the average score in ascending order, and then all applications designated as lower half.
Scores	Lists the individual preliminary scores submitted for the applications.

APPENDIX C: USEFUL WEB SITES

General Information

- NCI DEA Web Site
  http://deainfo.nci.nih.gov
- NCI Web Site
  http://www.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
- OER: Peer Review Policy and Issues
  http://grants.nih.gov/grants/peer/peer.htm
- NCI Research and Funding – General Information
  http://www.nci.nih.gov/researchfunding/
- PHS 398 Form and Instructions
  http://grants2.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://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
- Center for Scientific Review Policy, Procedure, and Review Guidelines
  http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/
- 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
- Decision Tree for Protection of Human Subjects From Research Risk
  http://grants.nih.gov/grants/peer/tree_protection_hs.pdf
- NIH Policy for Data and Safety Monitoring
  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
- Guidance on Research Involving Coded Private Information or Biological Specimens
  http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf
- 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
  https://commons.era.nih.gov/commons/
- ERA Home Page
  http://era.nih.gov
- NIH Commons Support Page
  http://era.nih.gov/commons/

Vertebrate Animals

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

APPENDIX D: GLOSSARY OF TERMS

Accelerated Peer Review (APR): A mechanism for accelerated re-review of P01 applications that are rated highly meritorious but fall outside the P01 payline.

Amendment (Amended or Revised 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.

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.

APR – see Accelerated Peer Review.

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.

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.

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.

Board of Scientific Advisors (BSA): The BSA advises the Director of each NCI Division, and the NCI Director and Deputy Director, on matters concerning scientific program policy and the progress and future direction of extramural research programs. This includes the evaluation of NCI awarded grants, cooperative agreements, and contracts. The BSA’s advisory role is scientific and does not include deliberation on public policy.

Board of Scientific Counselors (BSC): The BSC advises the Director of each NCI Division, and the NCI Director and Deputy Director, on matters concerning scientific program policy and progress and future direction of research programs. This includes the evaluation of performance and productivity of staff scientists through periodic site visits to intramural laboratories and evaluation and advice on the course of each Division's programs. The BSC’s advisory role is scientific and does not include deliberation on public policy.

BSA – see Board of Scientific Advisors.

BSC – see Board of Scientific Counselors.

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): The NCI Cancer Center Support Grants support research programs in approximately 60 institutions across the United States.

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

CCSG – see Cancer Center Support Grants.

Center Grants: Financial assistance awards to institutions on behalf of program directors 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.

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.]

Cluster Review Panel: An advisory group of scientific experts typically including representatives of an SRG subcommittee plus ad hoc members. These panels perform the initial technical review of P01 applications and provide comments in a draft review report to the chartered SRG.

CO – see Contracting Officer/Contract Specialist.

COI – see Conflict of Interest.

Comment: In the context of research involving human subjects and/or vertebrate animals, a comment is an issue that needs to be addressed/resolved by the applicant before the research is conducted.

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.

Competing Applications: Applications that are either new or recompeting. 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.

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 (COI): 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 an Initial/Integrated Review Group (IRG) 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. For IRG committees, this reviewer is invited initially to attend meetings as a temporary member, but subsequently may be invited to become a regular member of the review group for a term of 1 year. Each 1-year term would be a term of "availability" to participate in review meetings, with actual service at each meeting based on the need for the reviewer's experience/expertise. For SEP meetings, this person serves as a regular SEP member.

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 used when substantial Federal programmatic involvement with the recipient during performance is anticipated by the NIH Institute or Center.

Core: A separately budgeted P01 component 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 P01 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.

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 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.

DEA – see Division of Extramural Activities.

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.

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.

Division of Extramural Activities (DEA): The DEA administers the NCI's grant application and contract proposal processes, from advising potential applicants and administering peer review to coordinating and administering advisory committees and activities, such as the National Cancer Advisory Board.

Double-Blind Study: A clinical trial 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.

Electronic Research Administration (ERA): As part of NIH's reinvention initiative, the ERA sets up an electronic dialogue between NIH and its grantees covering the entire life cycle of the grant.

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

ER – see Electronic Review.

ERA – see Electronic Research Administration.

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.

FACA – see Federal Advisory Committee Act.

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 Advisory Committee Act (FACA): The U.S. Congress passed the FACA in 1972 to ensure that advice rendered to the executive branch by advisory committees, task forces, boards, and commissions formed by Congress and the President, be objective and accessible to the public. The Act formalized a process for establishing, operating, overseeing, and terminating these advisory bodies. NCI advisory committees, such as the NCAB, were formed in accordance with the FACA

Federal Register Notice (FRN): Published by the *Office of the Federal Register*, National Archives

and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and **notices** of Federal agencies, including the NIH and its Institutes. It also publishes executive orders and other presidential documents.

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.

FRN – see Federal Register Notice.

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 grantee institutions to appeal 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 procedure before appealing to the DHHS Appeals Board.

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.

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 Concern: Any actual or potential unacceptable risk, or inadequate protection against risk, to human subjects as described in any portion of a grant application or contract proposal.

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: Grant and contract applicants are required to address the following items in their proposed plans: 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.

IAR – see Internet Assisted Review.

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

Individual Evaluation Workbook: Technical Evaluation Panel members use these workbooks before and during SBIR contracts peer review meetings to document their critiques of the Technical Evaluation Criteria in individual proposals.

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/Integrated 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 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 to protect the rights of human subjects.

Internet Assisted Review (IAR): Internet Assisted Review gives reviewers a way to submit their preliminary critiques and preliminary scores before the review meeting. At a time determined by the SRA, reviewers will be able to view not only their own preliminary critiques and scores, but also those of other reviewers (provided the reviewer is not in conflict with an application). By having a chance to view the critiques of other reviewers early on, reviewers can come to the review meeting better prepared either to defend their own positions or modify their opinions based on the comments of other reviewers.

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

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.

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 one 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 unscored or not recommended for further consideration), a minority report may be prepared by the dissenting member(s).

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. Web address: *http://grants.nih.gov/grants/funding/modular/modular.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.

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

NIH – see National Institutes of Health.

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.

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): If an application raises substantial concerns that would prevent it from being funded (e.g., concerns regarding human subjects, animal welfare, or biohazards), the review committee may elect to rate it not recommended for further consideration (NRFC). This action is made by majority vote. For any NRFC motion that does not pass unanimously, the full action of the review committee must be recorded: Number of votes for, number against, and number of abstentions. Any dissenting committee member may provide a minority report.

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.

NRFC – see Not Recommended for Further Consideration.

NRSA – see National Research Service Award.

OER – see Office of Extramural Research

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

Office of Extramural Research (OER): The OER administers medical and behavioral research grant policies, guidelines, and funding opportunities for the NIH.

Organ Site: One specific organ (breast) or group of related organs (gastrointestinal) as the focus of cancer research.

Outreach Strategies: Efforts by investigators and their staff(s) to appropriately recruit and retain populations of interest into research studies. Such efforts should represent a thoughtful and culturally sensitive plan of outreach and generally include involvement of other persons and organizations relevant to the populations and communities of interest (e.g., family, religious organizations, community leaders and informal gatekeepers, and public and private institutions and organizations). The objective is to establish appropriate lines of communication and cooperation to build mutual trust and interaction such that both the study and the participants benefit from the collaboration.

P01 – see Program Project Grant.

P30 – see Cancer Center Support Grant.

P50 – see Specialized Center Grants.

PA – see Program Announcement.

PAR – see Program Announcement Reviewed in an Institute.

Parent Committee: The review committee responsible for scientific peer review and final merit scoring of multicomponent (e.g., P01, Centers) 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.

PD – see Program Director.

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.]

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 .5 to 99.5.

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 (generally 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. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.

PO – see Project Officer.

Principal Investigator: The one person designated by, and responsible to, the applicant/awardee institution for the scientific and administrative direction and proper conduct of all aspects of the project or activity supported by the grant. He or she is responsible for the scientific and technical direction and day-to-day management of the project or program, and is accountable to the grantee for the proper conduct of the project or activity.

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): A PAR is a PA for which special referral guidelines apply, as described in the announcement.

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 (PD): 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 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 P01 research project.

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

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.

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.*

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, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Programs Review Branch (RPRB): Staff within the NCI's Division of Extramural Activities assigned to coordinate the peer review of grants, contracts, and cooperative agreements.

Research Projects: Projects that are primarily investigator initiated and involve basic scientific research.

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, A2). NIH limits applicants to two resubmissions.

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.

RFA – see Request For Applications.

RFP – see Request For Proposals.

RPG (Research Project Grant) – see Research Projects.

RPRB – see Research Programs Review Branch.

SBIR – see Small Business Innovation Research.

Scientific Review Administrator (SRA): 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.

Scientific Review and Evaluation Award (SREA): SREAs are used to reimburse non-Federal reviewers for travel, lodging, per diem, and other expenses associated with attending scientific review meetings. The SREA program is administered by the NIH Center for Scientific Review.

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. For P01 applications, Subcommittees C (Basic and Preclinical), D (Clinical Studies), and E (Cancer Epidemiology, Prevention and Control) of the NCI IRG are responsible for review of grant applications. [See *http://deainfo.nci.nih.gov/Advisory/irg/sub-cmte/index.htm*.]

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 study section 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.

SEP – see Special Emphasis Panel.

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

Significant Difference: For the purposes of NIH policies, a significant difference is one that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant but clinically small difference that is of very little clinical importance. Conversely, with less information, one could find a large difference of potential importance that is not statistically significant.

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*

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. Membership is fluid with individuals designated to serve for individual meetings rather than for fixed terms of service. SPORE mechanisms are reviewed by a standing SEP whose members serve terms of up to four years. 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 Grants (P50): SPOREs fall under this grant mechanism category.

Specialized Programs of Research Excellence (SPORE): SPOREs support translational cancer research focused on a single organ site or a related group of organ sites. The purpose of the SPORE program is to move basic research discoveries into human applications and/or determine the underlying biological mechanism responsible for a clinical or population observation.

Specimen Core: Also known as Tissue Core, a Specimen Core is a separately budgeted component of a research application focused on collecting, providing, and maintaining human specimens/tissue essential to the proposed research program.

SPORE – see Specialized Programs of Research Excellence.

SRA – see Scientific Review Administrator.

SREA – see Scientific Review and Evaluation Award.

Statement of Work (SOW): In a contract proposal, the detailed description of the work to be performed under the contract.

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.

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. Also known as a type 3 application/award, a supplement can be either non-competing (administrative) or competing (subject to peer review).

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.

Tissue Core: Also known as Specimen Core, a Tissue Core is a separately budgeted component of a research application focused on collecting, providing, and maintaining human

specimens/tissue essential to the proposed research program.

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).

Translational Research: Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer.

Triage – see Streamlining.

Unscored: In the peer review process, applications that are judged by a study section to be non-competitive (i.e., generally in the lower half of the applications to be reviewed) are unscored. These applications are not given a priority score, although they are reviewed and applicants do receive a summary statement.

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 P01s. 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
BSA	Board of Scientific Advisors
BSC	Biological Safety Cabinet or Board of Scientific Counselors
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
COI	Conflict of Interest
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
DEA	Division of Extramural Activities (NCI)
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)
FACA	Federal Advisory Committee Act
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
FRN	Federal Register Notice
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

IAR	Internet Assisted Review
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
PD	Program Director
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
SREA	Scientific Review and Evaluation Award
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