REVIEW PROCEDURES FOR SCIENTIFIC REVIEW GROUP MEETINGS

REVIEW PROCEDURES

The guiding principles for the initial review of research project grant applications are based on the Public Health Service (PHS) Scientific Peer Review Regulations that state that peer review groups are to make recommendations concerning the scientific and technical merit of applications. The specific criteria used to assess the merit of research project grant applications will vary with types of applications reviewed, such as Investigator Initiated Research Project Grants (R01), Academic Research Enhancement Awards (R15), the Ruth L. Kirschstein National Research Service Awards (F32, F33, etc.), Small Business Innovation Research Grants, etc.

For the review of investigator-initiated research grant applications (e.g., R01, R15 and R21), a streamlined procedure will be employed to determine whether the assigned applications are in the upper or lower half of all applications being considered at the scientific review group (SRG) meeting, with respect to scientific and technical merit. This procedure is described in the document CSR Streamlined Review Procedures. Applications not in the upper (more meritorious) half are identified as candidates for unscoring. Each application that has received a recommendation for unscoring is introduced by the Chair, and the committee is asked if anyone would like to have the application discussed. If any SRG member so desires, the application will be brought to full discussion during the review meeting.

The Chair of the SRG introduces each application designated for discussion, that is those that are not unscored, and calls upon the reviewers assigned by the SRA to present their evaluations. The assigned discussants are then called upon for their comments and group discussion follows. If, prior to substantial discussion, the SRG determines that the application being discussed should not be placed in the upper half, they may recommend that the application be unscored. Such a designation requires unanimous agreement of the SRG. Otherwise, after sufficient discussion of the application in terms of review criteria, human subjects, vertebrate animals and biohazards has ensued, the Chair calls for a priority score rating for the application. Ratings are assigned by regularly appointed members of the SRG and by those serving as temporary members.

If there are serious concerns regarding the participation of human subjects, vertebrate animal welfare or potential biohazards, to reflect these concerns a motion may be initiated that the application should be coded (human subjects or animals) or flagged with a biohazard header. A summary of this discussion will be included in the summary statement.

If additional information is needed before the SRG can make a

recommendation, a motion for **deferral** may be entertained. The review group may, by majority vote, defer an application for additional information or, if information necessary to evaluate the application can be obtained only by visual inspection of the facilities, for a project site visit. Any member may nominate an application for deferral.

Whether the review meeting involves streamlining or not, if in the course of discussion, an application is found to lack significant and substantial scientific merit, it may be "not recommended for further consideration (NRFC)". This action may also be recommended when serious hazards or unethical procedures are involved. No priority score rating is recorded, and the budget is not discussed. The "not recommended for further consideration" judgment results in an application's being ineligible for funding. As is the case for deferrals, if an application is not to be recommended for further consideration, the SRG must make a formal motion and vote.

NUMERICAL RATING

Each application that is discussed is assigned a single, global score that reflects the overall impact that the project could have on the field, based on consideration of the five review criteria (Significance, Approach, Innovation, Investigator, and Environment), with the emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. The degree to which the participation of human subjects and vertebrate animals and safeguards against biohazards have been satisfactorily addressed will also be factored into the priority score. The best possible priority score is 1.0 and the worst is 5.0. Individual reviewers mark scores to two significant figures, e.g., 2.2; the individual scores are averaged and then multiplied by 100 to yield a single overall score, e.g., 253. Those members who are not present during the discussion do not assign a numerical rating and are not counted in calculating the average of the individual ratings. Reviewers are asked to spread final scores to achieve a median score of 300. The scoring range is dependent on the number of unscored applications. If half of the applications are unscored, then the remaining applications should be scored from 1.0-3.0. If only 25% of the applications are not scored then the remaining applications should be scored from 1.0-4.0.

BUDGET

For applications with modular budgets (presented in $25,000 modular increments up to $250,000), the SRG may recommend either the elimination of specific budget items - not necessarily in $25,000 modules - or elimination of one or more $25,000 modules. Documents relevant to modular grants can be found at http://grants.nih.gov/grants/funding/modular/modular.htm.

In the case of non-modular budgets, the SRG may recommend that positions or other requests be deleted from the budget if they do not appear necessary to conduct the research, or that the percent effort devoted to the project be reduced if judged to be excessive for the needs of the project. Recommendations to reduce a budget should be clearly justified. The budget recommendation should be based upon the appropriateness of direct costs for the proposed research for each year of support requested. In view of the

principal investigator's ability to reallocate funds, the appropriateness of the total budget and the requested duration of support in relation to the research proposed should be emphasized.

Reviewers may identify areas of potential overlap with other supported research. However, potential overlap should be neither a reason for altering the budget nor should it affect the priority score. Information regarding potential overlap is included in the Scientific Review Administrator's note at the end of the summary statement.

FOREIGN ORGANIZATIONS

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of unique talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the foreign country that are not readily available in the United States, or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a foreign component.

RESEARCH INVOLVING HUMAN SUBJECTS

Applicant organizations have the primary responsibility for safeguarding the rights and safety of individuals who participate as subjects in research activities supported by the NIH. The NIH also relies on its scientific review groups and National Advisory Councils or Boards to evaluate applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subjects regulations.

The review of applications involving human subjects requires several considerations that can be clustered into two broad areas: Protection of subjects from research risks and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

Assessment of scientific and technical merit of applications involving human subjects must include an evaluation of the proposed composition of the study population and its appropriateness for the scientific objectives of the study. If representation of women, minorities, or children in the study design is inadequate to answer the scientific question(s) addressed and justification for the selected study population is inadequate, reviewers should consider this to be a scientific weakness or deficiency in the study design and are required to consider this weakness in assigning a priority score.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL:

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

Definitions:

When considering applications that involve human subjects it is important for reviewers to keep a number of definitions in mind:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. Some research projects involving human subjects may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy material is governed by state and local law and is not directly regulated by the Federal human subject regulations.

Guidance from the Office for Human Research Protections in 2004 has refined the definition of what constitutes research involving human subjects by expanding upon the definition of what constitutes "identifiable private information". According to this guidance, human subjects are **not** considered to be involved if the research uses **only coded private information or specimens** and this information meets two conditions:

1) the private information or specimens are not collected specifically for the proposed research and

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

Clinical research, http://www.nih.gov/news/crp/97report/execsum.htm, is defined as:

1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin, such as tissues, specimens and cognitive data) for which an investigator (or colleague) directly interacts with human subjects. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; or

2) Epidemiologic and behavioral studies; or

3) Outcomes research and health services research.

A Clinical Trial is operationally defined as a prospective biomedical or behavioral study of human subjects that is designed to answer specific

questions about biomedical or behavioral interventions.

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

An application for a phase III clinical trial must include ***valid analysis*** (an appropriate data analysis plan) as part of the study design and proposed onduct of the study. This requires that the applicant must present the most appropriate assessment of the results of the trial by which they will determine whether the clinical trial has shown a positive or negative result. The analysis plan should discuss the critical issues which the investigators have determined will provide the most appropriate analysis of the difference in outcomes between two or more groups in the clinical trial. The analysis plan for the trial must be as comprehensive as possible, irrespective of the size of the clinical trial. It is expected that the investigators will discuss such statistical issues as Type 1 error, Type 2 error, power, sample size and confounding issues that affect the study design. The analysis plans should contain, but not be limited to, the following:

1) Discussion of the method of allocation of study participants, such as randomization, to assure that participants will be appropriately allocated with respect to such issues as gender, race/ethnicity, and any other appropriate variables.

2) Presentation of an analysis plan that describes the evaluation of the outcomes of the clinical trial to assure that the evaluation is as unbiased as possible.

3) Presentation of an appropriate statistical analysis plan that will discuss methods of inference to estimate and compare intervention effects among different genders, races/ethnicities, ages and other appropriate subgroups.

Human Subjects Research Conducted in a Foreign Country: For awards to a foreign institution and awards to a domestic institution for a project with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is a scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

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

permission, and consent, which remain unchanged by the 2004 OHRP Guidance. State laws define who constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

EXEMPTION FROM HUMAN SUBJECTS REGULATIONS

If the applicant designates one of six possible exemptions from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, reviewers need not evaluate questions related to research risks or the inclusion of women, children and minorities.

PROTECTION OF HUMAN SUBJECTS

If the proposed research involves human subjects, and does not qualify for an exemption, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

1) ***Risks to the subjects:*** discussion of human subject involvement and characteristics, source of material, and potential risks. This includes discussion of the likelihood and seriousness of potential risk to subjects including, as applicable, risks to special populations. Where appropriate, alternative treatments and procedures, including risks and benefits should be considered. If a test article (Investigational New Drug, device, or biologic) is involved, or if the applicant proposes using a drug or device in a method that may not have FDA approval, the test article must be named and the status with regard to FDA submission/approval must be stated.

2) ***Adequacy of protection against risks:*** discussion of plans to protect against or minimize potential risks and assessment of their likely effectiveness. Where appropriate, this section should include discussion of plans for ensuring necessary medical or professional intervention in the case of adverse effects. Also to be included are recruitment plans and description of the process for obtaining informed consent. The information to be provided to subjects should be specified.

3) ***Potential benefit of the proposed research to the subjects and others:*** discussion of why the anticipated risks are reasonable in relation to the anticipated benefits to the subjects and to others.

4) ***Importance of the knowledge to be gained:*** discussion of why the risks to subjects are reasonable in relation to the importance of the knowledge to be gained.

There is a fifth level of protection involving data and safety monitoring, if a clinical trial is proposed. All applications proposing an NIH defined Phase III clinical trial (see definition above) should include plans for Data and Safety

Monitoring that describe the establishment of a Data and Safety Monitoring Board to be responsible for the monitoring and for the policies and procedures for adverse event reporting. Reviewers should look for this information within the applicant's Protection of Human Subjects section and evaluate it accordingly.

Based on the evaluation of whether the applicant has adequately addressed Human Subjects Protection according to these criteria, the study section may score the application with no concerns, or with concerns that may affect the score to a level commensurate with the seriousness of the concern. A "concern" is a scientific review group finding regarding human subjects that requires resolution by program staff prior to an award; no awards will be made until all identified concerns about human subjects have been resolved to the satisfaction of the NIH.

Inclusion of Women and Minorities as Subjects in Clinical Research

It is the policy of the NIH that women and members of minority groups and their subpopulations **must** be included in all NIH-funded clinical research (see definition above), 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. Cost is not an acceptable reason for exclusion, except when the study would duplicate data from other sources. Women of childbearing potential should **not** be routinely excluded from participation in clinical research. The inclusion of women and members of minority groups, and their subpopulations, must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. The objective should be to actively recruit and retain the most diverse study population consistent with the purposes of the research project.

When an NIH-defined Phase-III clinical trial (see definitions above) is proposed, the Research Plan must include a description of plans to conduct valid analysis (see definition above) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable.

Accordingly, reviewers should consider these inclusion criteria in their evaluations and:

1) Evaluate the proposed plan for the inclusion of minorities and both genders for appropriate representation or evaluate the proposed justification when representation is limited or absent (e.g., inclusion is inappropriate with respect to the health of the subjects, or the purpose of the research);

2) Determine whether the design of clinical trials is adequate to measure differences when warranted;

3) Evaluate the plans for analysis (for NIH-defined Phase III clinical trials);

4) Evaluate the plans for recruitment/outreach for study participants; and

5) Include these evaluations as part of the scientific assessment and priority score.

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research is available at:http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Inclusion of Children as Participants in Research

It is the policy of NIH that children (i.e., individuals under the age of 21) **must** be included in all human subjects research supported by the NIH, unless there are scientific or ethical reasons not to include them. If children will be excluded from the research, the application must present an acceptable justification for the exclusion.

The section in the application titled "Inclusion of Children" should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation for excluding children as participants in the research. When children are included, the plan **must** also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Reviewers should assess each application as being "acceptable" or "unacceptable" in regard to the age-appropriate inclusion or exclusion of children in the proposed research project. Specific exclusionary circumstances and other pertinent information on the inclusion of children in NIH-supported research may be found at: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

RESEARCH INVOLVING VERTEBRATE ANIMALS

Although the recipient institution and applicant bear the major responsibility for the proper care and use of animals, NIH staff, scientific review groups, and Councils and Boards share this responsibility. Care and use of vertebrate animals in research must conform to applicable law and Public Health Service policy, including U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. These principles can be summarized as follows:

1) Any proposal to involve animals in procedures that may cause pain and suffering must adhere to the highest ethical standards and be well justified in terms of advancing knowledge to improve human health. Research involving animals should also be justified with respect to the extent that it is not possible to gain the information without animal experimentation. The applicant should

be aware that, when animals used as human companions are involved, the application must present adequate justification that a species lower on the animal hierarchy will be inadequate. Research involving non-human primates, particularly chimpanzees, needs to be thoroughly justified and specifically discussed during the review meeting.

2) All persons involved in the use of animals in research must be appropriately qualified by training and experience to conduct animal experiments, or be under the direct supervision of such a person. A person qualified to conduct animal experiments would normally have an advanced degree in the life sciences. All animals must be housed and cared for in an accredited facility that complies with PHS standards, with appropriate attention to cleanliness, including protection from pathogens as indicated, nutrition and water quality, air quality, lighting, and veterinary care and supervision.

The evaluation by SRG members is to take into consideration how the investigator has addressed the following five points as required by the PHS 398 application instructions:

1) Provide a **detailed description of the proposed use of the animals** in the work previously outlined in the experimental design and methods section. Identify the species, strains, ages, sex and numbers of animals to be used in the proposed work.

2) **Justify the use of animals**, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their numbers.

3) Provide information on the **veterinary care** of the animals involved.

4) Describe the procedures for **ensuring that discomfort, distress, pain, and injury will be limited** to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain, and injury.

5) Describe any **euthanasia method** to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Research involving nonhuman primates or chimpanzees requires special attention by Review and Institute staff, so their use must be identified during review and in the vertebrate animal section of the summary statement.

Reviewers should consider animal welfare issues **prior** to scoring. This is based on the consideration that animal care and use issues are integral to the science (e.g., the choice of an inappropriate animal model is a scientific issue; unnecessary or unacknowledged pain or distress in animals can introduce variables having an impact on the quality of the science). Any concerns that SRG members may wish to express regarding the appropriateness of the choice

of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note **(ANIMAL WELFARE)** in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; other SRG observations about vertebrate animal welfare will be communicated in the summary statement as a suggestion to the principal investigator.

No award will be made unless the applicant institution has given the NIH Office of Laboratory Animal Welfare an acceptable assurance of compliance with the PHS policy, verification of Institutional Animal Care and Use Committee (IACUC) approval has been provided, and all concerns raised by the scientific review group have been resolved to the satisfaction of the NIH.

BIOHAZARDS

The investigator and the sponsoring institution are responsible for protecting research personnel, the public and the environment from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the SRG in identifying potential hazards, such as inappropriate handling of select biological agents and toxins, oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

Although issues relating to biohazards are not scorable, they can affect a reviewer's assessment under the review criteria. If the principal investigator appears to lack knowledge about appropriate methods for working with biohazardous agents, that could affect the evaluation under "Investigator". If appropriate containment is not proposed, that could affect "Environment" (as well as "Investigator"); inappropriate plans could affect the evaluation under "Approach". If the proposed project is egregiously hazardous, NRFC should be considered.

If applications pose serious hazards, these hazards should be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement. No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

AVOIDING CONFLICTS OF INTERESTS DURING SCIENTIFIC REVIEW GROUP MEETINGS

At the beginning of each meeting, the Scientific Review Administrator orients the members by explaining the NIH conflict-of-interest policy. A member must leave the room when an application submitted by his/her own organization is being discussed or when the member, his/her immediate family, or close professional associate(s) has a financial or vested interest, even if no significant involvement is apparent in the proposal being considered. If the member is available at the principal investigator's institution for discussion; is a provider of services, cell lines, reagents, or other materials, or writer of a letter of reference, the member must be absent from the room during the review.

Members are also urged to avoid any actions that might give the **appearance** that a conflict of interest exists, even though he or she believes there may not be an **actual** conflict of interest. Thus, for example, a member should not participate in the review of an application from a recent student, a recent teacher, or a close personal friend. Judgment must be applied on the basis of recency, frequency, and strength of the working relationship between the member and the principal investigator as reflected, for example, in publications. Other examples are a project that closely duplicates work ongoing in the member's laboratory, or an application from a scientist with whom the member has had longstanding differences that could reasonably be viewed as affecting the member's objectivity.

If an application is submitted naming an SRG member as a participating individual from another institution, the SRG member is not considered to have a relationship with the applicant institution that constitutes a conflict of interest. Consequently, (1) that SRG member may review other applications from the applicant institution; and (2) other individuals from the institution of the SRG member may be used as reviewers for the submitted application, ***so long as any real or apparent conflict of interest is resolved***. The SRA will document that there is no conflict of interest.

For peer review consultants who are not federal employees, all separate organizational components/schools of multi-component academic institutions, hospitals, health centers, and research institutes may be considered to be sufficiently independent such that an employee of one component can review an application from another component without a conflict of interest, so long as any other real or apparent conflict of interest is resolved. In practice, for example, this means that:

1) the separate campuses of the California State system are considered separate components in the same way that the separate campuses of the University of California system are so noted in the Federal Register citation above;

2) the separate campuses of the Harvard system are considered separate components;

3) the Johns Hopkins Bayview Medical Center and the School of Arts and Sciences, Homewood Campus, are separate components;

4) the Johns Hopkins Schools of Arts and Sciences and of Engineering, Homewood Campus, are separate components;

however,

5) for purposes of this blanket waiver, the Departments of Biology and Chemistry within the School of Arts and Sciences are NOT separate components.

In addition, ***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 SRG, 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 multi-center network (e.g., sites for a multi-center 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.

A reviewer must leave the room during discussion of an application if he/she is a member of, or has a financial interest in a for-profit organization submitting the application. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be, an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

Prior to the scientific review group meeting, each reviewer will sign a certificate of Conflict of Interest and Confidentiality and provide a list of applications that are in conflict. Reviewers must notify the Scientific Review Administrator of any conflict of interest prior to the meeting and certify that the confidentiality of the review procedures will be maintained.

At the SRG meeting, the SRA will obtain written certification from all members that they have not participated in any reviews of applications when their presence would have constituted a real or apparent conflict of interest and that the confidentiality of actions will be maintained. In addition, for each SRG meeting a log is kept of which members left the room because of potential conflict of interest and for which applications.

CONFIDENTIALITY AND COMMUNICATIONS WITH INVESTIGATORS

All materials pertinent to the applications being reviewed are privileged communications prepared for use only by consultants and NIH staff, and should not be shown to or discussed with other individuals. Review group members must not independently solicit opinions or reviews on particular applications or parts thereof from experts outside the SRG. Members may, however, suggest scientists from whom the SRA may subsequently obtain advice. Consultants are required to leave all review materials that are not in the public domain with the

SRA at the conclusion of the review meeting. Privileged information in grant applications should not be used for the benefit of the reviewer or shared with anyone.

Under no circumstances shall consultants advise investigators, their organizations, or anyone else, of recommendations or discuss the review proceedings. The investigator 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 fellow consultants serving on review committees and site visit teams. A breach of confidentiality could deter qualified consultants from serving on review committees and inhibit those who do serve from engaging in free and full discussion of recommendations.

Except during site visits, there must be no direct communications between consultants and investigators and then only in the presence of the SRA. Consultants' requests for additional information and telephone inquiries or correspondence from investigators must be directed to the SRA, who will handle all such communications.

SCIENTIFIC 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 that are 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.

Review of grant/cooperative agreement applications and contract proposals for scientific merit will ordinarily not be delayed by pending or ongoing inquiry or investigation. To avoid influencing the review process, HHS awarding units will not inform members of scientific review groups about instances of possible misconduct or the status of ongoing investigations. However, if certain instances have received such extensive publicity that the review may be compromised, the CSR Research Integrity Officer (RIO) will discuss the matter with the Agency Research Integrity Liaison Officer (ARILO). Findings from completed investigations should be shared with scientific review groups when an accurate disclosure of the facts in the case is necessary for an objective and thorough review.

The scientific review group should not review an application about which an allegation of misconduct has surfaced from one of its members. The SRA should report the allegation to the CSR RIO. The RIO will involve appropriate CSR staff and the ARILO to determine the manner in which the allegation will be treated

In all cases of suspected misconduct, it is essential that the SRA stress to the reviewers the seriousness of such allegations and the potential harm that may result if confidentiality is not strictly maintained. In addition, it is important for the SRA to assure the reviewers that the suspicions identified will be taken seriously and pursued by the HHS. In no instance shall the SRA or a reviewer communicate the scientific review group's concerns to the principal investigator

or applicant institution.

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