

Tahoe Science Advisory Council Guidance for External Peer Review

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Table of Contents

Tahoe Science Advisory Council Guidance for Independent Peer Review.....	1
Introduction	1
Principles Guiding Peer Review.....	2
Factors Critical to Effective Peer Review	2
Peer Review Services Provided by the TSAC.....	4
Review Approach	5
Types of Peer Review	7
Pre-Review Responsibilities	7
Review Processes	8
A. Independent peer review.....	8
B. Engaged review	9
C. Colleague review.....	10
Response to a Peer Review	11
Dissemination of Review Results.....	11
Transparency in the Peer Review Process	11
Conflict of Interest, Confidentiality and Non-disclosure Rules.....	13
Literature Cited	13
Appendix A Example Independent Peer Review Charge	15
Appendix B Conflict of Interest, Confidentiality and Non-Disclosure Rules and Information for Reviewers	17

Introduction

Peer review is an objective process used to evaluate proposals for new projects and results from completed projects. The practice of peer review is used in many types of business, technology, and enterprise activities where there is an interest in maximizing cost effectiveness, credibility, and success. Peer review practices are often thought of in the context of science activities; however, rigorous peer review has been a hallmark of the modern scientific method only since the middle of the twentieth century.

The classical definition of a *peer* is “a person who has equal standing with another or others” (American Heritage, 1992). A *peer review*, then, is a review of one or more person’s work by others of equal standing. In the areas of science and engineering, someone of equal standing is generally considered to have an equivalent level of experience, and recognized expertise in the subject research area. Although peer reviews are critical in nature, the process is intended to improve the quality, certainty, and credibility of the work product. Independent peer review is considered one of the best ways to identify oversights, mistakes, or flaws in a proposal or completed project. The complexities of scientific endeavors often mean that opportunities for improvement are apparent only to someone with specialized expertise or experience. Thus, allowing others to review the work of their peers increases the probability that strengths will be identified and supported, or that weaknesses will be identified and corrected.

In scientific work, the peer review process is most commonly associated with the publication of manuscripts or journal articles. However, the peer review of research proposals is often a required step in the decision-making processes used to determine and/or direct funding for new science activities. Used in this manner, the review process works to directly increase the confidence of funding decisions. Today, many consider independent and unbiased peer review of both proposed and completed scientific work an essential component of the scientific process. For example, the Federal Office of Management and Budget produced a final bulletin (OMB 2004), which “establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government.”

Principles Guiding Peer Review

The procedures described in this document are based on the principle that effective peer review improves the analysis, interpretation, and reporting of scientific information. However, to ensure the credibility of the peer review process itself, the process must be

- **Unbiased.** The reviewers and those managing the review process cannot have conflicts of interest that prevent them from providing objective information.
- **Fair and ethical.** All parts of the review process must ensure the fair and ethical treatment of the participants and the products undergoing review.
- **Transparent.** Regular and broadly-disseminated communication about the review process must be shared in a timely manner with all interested parties to ensure a complete understanding of the process.

These guiding principles direct the peer review processes described in this document.

Factors Critical to Effective Peer Review

Kostoff (1997) identified eight factors critical to an effective peer review program. These factors are listed below in order of priority. All of the factors must be addressed in order to maintain a successful peer review program on a sustained basis:

1. High-level commitment from the organization(s) requesting the review, to follow processes that will obtain high-quality reviews. It is a waste of effort and funds to conduct a peer review unless senior management: a) supports the time and expense to conduct rigorous reviews, and b) is fully committed to using the review results in subsequent management decisions.
2. Commitment of the review manager or review committee to administer a credible and transparent peer review process. The review manager or committee oversees implementation of the peer review process. This can include development of the review charge or criteria, guiding the questions and discussion in a panel review, synthesizing and summarizing the reviewers' comments, and recommending follow-on actions. Often the review manager has the latitude to select the review process and criteria,

- and generally has the latitude to select reviewers by a non-random process. The review outcome can be substantially influenced before the process begins, if the review manager or committee does not follow the highest standards in establishing the review process and selecting reviewers.
3. Obtain highly competent and objective reviewers. Each reviewer must be technically competent in his or her subject area, and the competence of the total review group for any specific document should cover the multiple facets of research issues identified in the product submitted for review. In addition, the review group's expertise should not be limited to sub-disciplines of the specific research area under review (which addresses the question of whether the job is being done right), but should be broadened to the area covered by the highest-level objectives of the research (which addresses the question of whether the right job is being done). This will help insure that outmoded but prolific and well-cited research is not promulgated in perpetuity, and that the fresh perspectives of new paradigms are considered equitably.
 4. Maximize normalization and standardization across panels and disciplines. For disciplines which have some similarities, use of common reviewers among the panels can provide some degree of standardization. For very disparate disciplines, some allowances need to be made for the relative strategic value of each discipline to the organization, and arbitrary corrections applied for scoring differences and biases. Even in the case of disparate disciplines, some normalization is possible by having some common reviewers with broad backgrounds evaluating the diverse programs and projects. The use of a technical synthesis panel also can help to normalize the results of individual review panels.
 5. Select relevant evaluation criteria. In evaluating basic research proposals, the four main criteria are research merit, research approach, realistic budget, and team quality. The evaluation of research approach and team quality together provides insights into the likelihood of success. Use of a fifth criterion: research relevance is often essential in evaluating applied research proposals.
 6. Maintain reviewer anonymity. If honest and frank viewpoints on the intrinsic quality of the research under review are desired, the reviewer

- must remain anonymous to all but the review manager. Rewards are few for a reviewer making strong negative statements about a proposal (or research paper or program), and resulting retributions and resentments to the reviewer may far outweigh the intrinsic benefits to science of honest and forthright statements.
7. Maintain high ethical standards. Using peers to conduct reviews does present an inherent conflict: peers may be in a position to compete for future research funding or positions. This raises the potential for several ethical conflicts including scientific fraud, scientific misconduct, betraying confidential information, and unduly profiting from access to privileged information. To mitigate ethical conflicts, it is increasingly common to request reviewers to sign documents agreeing to maintain high ethical standards and confidentiality as a condition of their participation in the review process.
 8. Be prepared for the full cost of peer review. The true total costs of peer review can be considerable, but tend to be ignored or understated. The major contributor to total cost is the time of all individuals involved in executing the review, including staff and reviewers. There are also costs associated with the synthesis and reporting of review results. Costs must be considered carefully in designing a high quality peer review process.

Peer Review Services Provided by the TSAC

The Tahoe Science Advisory Council (TSAC) was formed in February 2015 through a memorandum of understanding (MOU) between the States of Nevada and California¹. The aim of the TSAC is to

“Provide objective research and scientific analysis that will help support decision-makers of both states meet their obligations to advance attainment of environmental thresholds, as provided in the Bi-State compact, and take any other action to promote awareness of sound science consistent with existing law of both the states and the Compact.”

The MOU identifies the promotion of independent peer reviews, workshops, and panels as a primary duty of TSAC. Following models employed by the National Institutes of Health and the Health Effects Institute, the TSAC established a

¹ The TSAC memorandum of understanding is available at www.tahoesciencecouncil.org.

standing Peer Review Committee (PRC) in 2017 to oversee independent peer reviews requested of the TSAC. Upon request, the PRC is prepared to administer the peer review of scientific products or technical programs following the processes described in this document.

Several different types of work products and situations may necessitate a peer review. Often the scientists and engineers from the member organizations of the TSAC may produce products that need to be peer-reviewed, or may need to peer-review existing standards or practices. Other potential situations where peer review should be considered is when changes to existing standards or practices are sought, or when controversial science-based questions are raised in the Basin. Peer reviews requested directly by member organizations of TSAC will be discussed by the council and PRC, but in general will be accomplished within one calendar year of request (unless exception can be justified). In this case, the outside organization would be primarily responsible for providing the work product to review (with some coordination with PRC) and may need to financially contribute to the costs of peer review. The council also reserves the discretion to request peer-review for other science-based topics it feels would reduce expenses to outside organizations or allay concerns of stakeholders. These topics would be discussed and voted on by the council and would be supported by the PRC with internal TSAC budgets. All peer reviews will follow the same approach and standards that assures a credible, transparent, and unbiased process.

Review Approach

The Peer Review Committee (PRC) will oversee and administer independent peer reviews requested of the TSAC.

The independent peer review of technical products will generally require the PRC to oversee and/or participate in an independent technical review, followed by the synthesis and reporting of review results. Typically, the PRC will select one of its members to oversee/administer the review. This individual may or may not serve as the review chairperson.

Since the technical products submitted for review may only comprise a portion of the complete product, a review charge specific to each technical product must be developed to ensure a properly focused peer review. Generally, reviews

undertaken by the PRC are not anonymous reviews. The names and affiliations of the reviewers will be provided by the PRC upon request.

Three critical elements must exist before a technical product review can occur:

- 1) A well-defined product (e.g., a complete report or manuscript, or a functioning model with documentation) amenable to review by someone who has relevant expertise, but is not associated with the specific project.
- 2) A clearly described review charge that documents the scope of the review and reviewer's tasks (see Appendix A for an example review charge). Peer review is most powerful when the charge is specific and steers the reviewers to specific technical questions, while also directing reviewers to offer a broad evaluation of the product (OMB 2004).
- 3) A clear understanding of how the review results will be used. Specifically, the agency or entity requesting the review must identify in advance of the review the types of actions that may occur in response to the review. Appropriate actions may include: (1) a simple response to comments; (2) revision of the science product to address errors and/or omissions; (3) completion of additional analyses or studies deemed critical to verifying an underlying assumption or addressing remaining uncertainties; (4) reconsideration of the results and conclusions after addressing flaws identified through the peer review; or (5) some combination of these or other actions (OMB 2004).

The PRC member overseeing a review will ensure the three critical elements are in place. This PRC member will also oversee selection of the reviewers.

Funding for those directly involved in the review (e.g., the PRC member(s), the review chairperson, and the technical reviewers) is required to support each review. All or some portion of the required funding may come from the TSAC budget, but additional outside funding also may be required. The amount of funding and funding source(s) will depend on the kind of review and the review approach.

Compensation for the review of technical products will vary depending on the type and complexity of the review. Normal compensation for an individual review may range from \$200 to \$2,000 per reviewer, depending on the length and complexity of the review document and the scope of the review charge.

Compensation for each member of a review panel may range from \$200 to \$1,000 per day plus travel expenses for their participation in a panel review

meeting. Compensation will cover preparation time, panel meeting participation, and panel report preparation.

Types of Peer Review

The PRC is responsible for recommending an appropriate review format based on the specific technical document and review charge. Three types of review formats are available:

- (1) Independent peer review – A traditional technical peer review in response to a review charge. The peer reviewers have relevant, established expertise, and have no contact with the authors. The reviewers have no conflicts of interests, and have no affiliations with the authors of the document subjected to review. Those overseeing the review as part of the PRC will also have no conflicts of interests.
- (2) Engaged peer review – The technical experts selected by the PRC will have relevant, established expertise. The reviewers will have no affiliation with the documents' authors, and will not be directly involved in the production of the document. However, the reviewers will engage with the authors during the production process, and may be asked to provide early feedback and direction.
- (3) Colleague review – The reviewers selected will have relevant expertise and may have affiliations with the document authors. However, colleague reviewers will not have made a substantial contribution to the document subjected to review.

After receiving a recommendation for the type of review considered appropriate by the PRC, the entity requesting the review (hereafter 'the entity') will have five business days to respond to the PRC either affirming the recommended format, or providing an alternative option and accompanying explanation. No peer review will occur if the PRC and the entity cannot reach agreement on the peer review format.

Pre-Review Responsibilities

The PRC will review each review request and appoint a member to oversee/administer the review. In the rare case where all PRC members are determined to have significant conflicts of interest, an alternate, independent

individual, chosen by the TSAC co-chairs will be appointed to oversee the peer review.

For the independent and engaged peer review options, the entity will be responsible for preparing the first draft of the review charge. For a colleague peer review, the documents' authors will be responsible for preparing a first draft of the peer review charge. Where the document authors prepare the draft review charge, the authors may provide it to other relevant parties (e.g., a funding agency) for review and comment. In all cases, the review charge will describe the scope of the review, the reviewer's tasks (e.g., questions to be answered), and describe how the review results will be used by the entity. The PRC will review and comment on all draft review charges, and it will offer suggestions to clarify and refine the review charge. The review will not occur if the entity and PRC members are unable to reach agreement on the review charge.

No review will be scheduled until the review charge and all review materials are complete and ready to distribute to the review panel. For the independent and engaged peer review options, the entity will have full responsibility for providing complete versions of the documents submitted for review and for transmitting complete electronic copies of the documents to the PRC. For a colleague peer review, the lead author will be responsible for preparing complete versions of the documents submitted for review, and for transmitting complete electronic copies of the documents to the PRC. Review documents will not be transmitted to the reviewers until complete electronic copies of all documents have been provided.

Review Processes

The PRC will have full authority and discretion to select the reviewers, based in part on the type of review (see below). The entity requesting the review can provide the names of recommended reviewers, but the PRC will make the final determination of reviewers. The selection of the reviewers will occur once the PRC has an opportunity to examine the technical document to be reviewed, and once the review charge is complete.

A. Independent peer review

Independent peer review is the standard approach for the review of technical products. Reviewers may complete their work individually (i.e., a mail review), or they may complete the review as a group (i.e., a panel review). Panel reviews

will typically include an in-person meeting among the reviewers, author(s) of the report, and the entity.

Three to five technical experts will be selected as reviewers based on relevant expertise, availability, and ability to work within the available funding and timeline. The PRC member overseeing the review will send the technical product and review charge to selected reviewers. Each reviewer will prepare a written review that responds to the review charge. The PRC will work with reviewers to select a chairperson. One or more members of the PRC may serve as a reviewer or chairperson, but other selected reviewers may serve as the chairperson. The chairperson will be the primary point of contact, and will be responsible for preparing a synthesis of the individual reviews, with a summary of the major findings and recommendations.

Completion of an independent peer review may take up to five weeks (35 days), unless otherwise determined in advance by the PRC. The technical experts will be expected to complete their individual reviews within three weeks of receipt of the technical documents. The review synthesis will be completed by the chairperson within two weeks of receipt of the individual reviews. The PRC will examine the review responses to ensure they are clear and fully respond to the review charge. Incomplete or inferior reviews will be returned to the reviewer for revision. The complete peer review package will be transmitted to the entity upon acceptance by the PRC.

B. Engaged review

The purpose of an engaged review is to provide outside input on the approach and methods used in the development of a technical document or product, or to engage reviewers (using a workshop setting) in the review of a complex program. An engaged review should be considered for documents that include development of a model or new application of an existing model, or for review of a technical document that considers other efforts which are part of a complex program (e.g., the Lake Tahoe Total Maximum Daily Load program).

The document authors and/or the entity will recommend three to five technical experts to participate in the engaged review. The PRC will select at least three reviewers based on relevant expertise, availability, and ability to work within the available funding and timeline. Direct engagement of the reviewers and document authors is expected, which will usually occur in a meeting. A review charge (prepared in advance) will identify the questions or issues addressed

during the meeting, but relevant issues identified during the meeting also will be considered. After the meeting, each reviewer will prepare a written review that responds to the review charge. The PRC will identify a chairperson for the review. The chairperson will be the primary point of contact and will be responsible for preparing a synthesis of the individual reviews, with a summary of the major findings and recommendations.

Completion of an engaged review may take up to four weeks (28 days) after the meeting has occurred, unless otherwise determined in advance by the PRC with the entity's concurrence. The reviewers will be expected to complete their individual reviews within two weeks of the meeting. The review synthesis will be completed within a week of receipt of the individual reviews from the individual reviewers. The PRC will have one week to examine the review responses to ensure they are clear and fully respond to the review charge. Incomplete or inferior reviews will be returned to the reviewer for revision. Final review results will be transmitted to the document authors, and to the authors and/or the entity upon acceptance by the PRC.

C. Colleague review

A colleague review may be requested by the document authors, or by the PRC. Colleague reviews may involve reviewers who are not completely independent. The aim of the colleague review is to obtain outside expert input to help improve the veracity and utility of the final product. Colleague reviews are intended to occur more expeditiously than independent or engaged peer reviews, and may be best suited for interim or draft products.

For colleague reviews, the document authors will recommend three to five technical experts to review the product. The PRC will select two to three reviewers based on relevant expertise, availability, and ability to work within the available funding and timeline. Each reviewer will prepare a written review that responds to the review charge. The PRC will identify a chairperson for the review. The chairperson will be the primary point of contact and will be responsible for preparing a synthesis of the individual reviews, with a summary of the major findings and recommendations. Completion of a colleague review may take 3.5 weeks (25 days), unless otherwise determined in advance by the PRC. The technical experts will be expected to complete their individual reviews within 1.5 weeks of receipt of the technical documents. The review synthesis will be completed within one week of receipt of the individual reviews from the technical experts. The PRC will have one week to examine the review responses to ensure

they are clear and fully respond to the review charge. Incomplete or inferior reviews will be returned to the reviewer for revision. Final review results will be transmitted to the document authors, upon acceptance by the PRC.

Response to a Peer Review

The entity requesting the review and/or the document authors will have two weeks to review the complete peer review package. The entity will have the option to ask questions about the reviews. These questions should focus on points where further clarification is desired, or where additional information may be needed. The questions will be provided in writing to the PRC within the two-week review period. The PRC will transmit the questions to the reviewers after examining the questions to ensure they are clear and complete. The reviewers will have complete discretion in developing responses to these questions, including the choice of not preparing a response to a question. At their discretion, the entity or the document authors can prepare a written response to the review. At their discretion the entity, the PRC, or the chairperson of the review may request a meeting or conference call between the reviewers and the entity to provide a forum for direct discussion of the questions, and reviewer responses to those questions.

Dissemination of Review Results

The complete final review package (charge, document reviewed, individual reviews, review summary, questions to reviewers, and any responses) will be made available to the public two weeks after delivery of the package to the entity requesting the review. The review package may be posted on the Council's web site, the entity's website, and/or other document sharing platforms (e.g., Laketahoeinfo.org). In some cases, the entity may request the review chair provide an oral presentation of the review findings to agency representatives or elected officials. The entity shall cover the cost for this presentation.

Transparency in the Peer Review Process

An open and transparent review process is critical to the sustained success and credibility of any peer review program (OMB 2004). Effective communication is essential during all phases of a review to ensure transparency in the review process. Details are provided below about the types of information that will be communicated during the three major review phases.

- i. Communications at the initiation of the review. Once the Peer Review Committee (PRC) accepts responsibility for administering a review, it will upon request disseminate an announcement identifying the member of the PRC overseeing/administering the review, describing the type of review the PRC will oversee, the major steps in completing the review, and the associated timeline. For proposal reviews, initial communications may include general statistics on the number and topical categories of the proposals received, and results of the administrative review (i.e., the number of proposals meeting the RFP requirements). For the review of science products or technical programs, communications also will include identification of the documents to be reviewed and a description of the review charge.
- ii. Communications during the review. The PRC is responsible for all communications during the review. The PRC is the only entity that will communicate with individual reviewers during a review. Outside communications by the PRC during the review will consist of updates on the status of the review.
- iii. Communications at the conclusion of the review. The PRC is responsible for transmitting the final results of any review it oversees. In all cases, review results will be transmitted to the entity that requested the review. The PRC will transmit the results of the individual reviews and its synthesis, or the final report from a peer review panel to any member of the public requesting the review results two weeks after delivery of the review package to the entity requesting the review.

Review results also will be posted on the TSAC web site. It is increasingly common for entities to provide communications about a peer review process via an internet web page. Using a web page to disseminate review information has greatly enhanced the ability to provide interested parties with the same information in a timely manner. For example, using electronic review forms that individual reviewers can download and complete on their computer helps contribute to a more efficient and consistent process. The TSC intends to make use of web-based tools to identify potential reviewers, disseminate review information, and to support the completion of individual reviews. Regular communication during all phases of a review combined with the dissemination tools available through an internet web page can go a long way to ensuring any review process remains transparent and timely.

Conflict of Interest, Confidentiality and Non-disclosure Rules

Maintaining high ethical standards throughout the peer review process is critical to the overall credibility and success of the review. The National Academy of Sciences defines “conflict of interest” as any financial or other interest that conflicts with the service of an individual reviewer, because it could impair the individual’s objectivity, or it could create an unfair advantage for a person or organization (NAS 2003). Thus, a breach of ethics or conflict of interest can arise for several reasons, so care must be exercised to consider all potential sources. The review processes described in this document are patterned after national programs, and similarly the ethic standards and conflict of interest provisions follow those used by the National Institutes of Health. The PRC shall use the forms in Appendix B to ensure no conflicts of interest exist and ensure confidentiality. All individual reviewers and PRC participants will be required to complete these forms. The peer review processes described in this document require the full integrity of all participants, which is ultimately the basis for maintaining high ethical standards and avoiding conflicts of interest.

The PRC will have initial responsibility to determine if a reviewer or PRC member has a substantial conflict of interest that would prevent participation in a review. If one member of the PRC is deemed to have a conflict of interest, then the remaining two members will make the conflict of interest assessment of those selected to participate in a review. If two members of the PRC are deemed to have a conflict of interest, then the remaining PRC member and TSAC co-chairs will make the conflict of interest assessment of those selected to participate in a review. If all members of the PRC members are deemed to have a conflict of interest, then the full TSAC will consider whether it is appropriate for the TSAC to take on the review. If the TSAC accepts the review responsibility, then it will identify the appropriate individual(s) to oversee/administer the review.

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Appendix A

Example Independent Peer Review Charge

Background:

Environmental Threshold Carrying Capacities Standards (hereafter standards) are Tahoe’s shared vision for environmental quality and restoration. TRPA is currently leading the review and update of the standards, to ensure that the standards used to guide millions of dollars of public and private investment in the basin are representative, relevant, and scientifically rigorous. Constructive feedback and critical review of technical products used to inform changes to the threshold evaluation system or the standards themselves is essential to ensuring those changes are based on sound, well-reasoned information.

Most of the current standards were adopted in 1982, and are based on science that is now over 35 years old. Past efforts to review and revise the standards, including a four-year stakeholder engagement process, and more than 90 modifications recommended in the 2011 threshold evaluation report, have not resulted in significant revisions. In 2015, the TRPA governing board identified the review and update of the standards and the associated evaluation system as a strategic initiative for the agency. The science and best practices for establishing environmental goals, identifying indicators, and integrating reporting into adaptive management have all advanced since the establishment of the standards.

Goals of the peer review:

The goal of the peer review is to ensure the scientific rigor of the evidence used to inform review and revision of the threshold standards and the associated evaluation system.

Scope of the peer review:

Each reviewer’s charge is to provide a critical evaluation that identifies deficiencies, errors, and positive aspects of the content reviewed. Reviewers are expected to provide sufficient detail in their comments, so that the document authors, TRPA staff, and partners can fully understand the concern or comment expressed and recommend a remedy. Like a peer review for a scientific journal, the goal of the review is to strengthen the document. Simple yes or no answers are not sufficient. Where possible, reviewers are asked to provide solutions or recommendations to address any identified deficiencies or errors. Commentary provided by reviewers should be objective and not indicate the reviewer’s personal values or preferences.

Potential Review Questions

- Is the document consistent with best scientific practices in the field and technically sound?
- Is there additional science or research that should have been considered, used, or referenced in the technical document you reviewed? Please provide full citations.
- Does the document identify assumptions? If so, are the assumptions reasonable? If not, are there assumptions that should be included?
- If the document draws conclusions or makes recommendations, are those conclusions/recommendations supported by the analysis and results provided, and do they logically draw from the information presented?
- Please answer the following questions if a new threshold standard is proposed:
 - Does the document provide a clear rationale for the proposed standard and is that rationale supported by sound science?
 - Is the proposed standard specific and measurable?
- Is there strong support for the selection of the indicator as a measure for what the standard is intended to achieve?
- Are the suggested indicators likely to be responsive to change over timeframes that are meaningful for management?

Appendix B

Conflict of Interest, Confidentiality and Non-Disclosure Rules and Information for Reviewers²

As reviewers themselves are most familiar with their own situations, it is their personal responsibility to: (1) alert the Peer Review Committee (PRC) to any possible conflict of interest situation, whether real or apparent, that may impact the review, and (2) identify and certify on the pre-meeting and post-meeting Conflict of Interest Certification Forms associated with this information sheet, (a) any application where they have a conflict of interest, and (b) that they will not be, and have not been, involved in the review of any application where their participation constitutes a conflict of interest. Reviewers must also certify that they will maintain the confidentiality of the proceedings and associated materials and that they will not disclose to another individual any matter or information related to the review proceedings. In addition, the PRC may determine that a particular situation involves a conflict of interest and require that the potential reviewer not be involved in the review of the application(s) or proposal(s) in question. All reviewers are covered by this information sheet and associated Certification Forms.

There are several bases for a conflict of interest: employment, financial benefit, personal relationships, professional relationships or other interests. If applicable, any one condition may serve to disqualify a reviewer from participating in the review of an application or proposal. A **conflict of interest may be real or apparent.**

The following guidance and definitions, derived from federal regulations governing the Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects (42 CFR Part 52h), will assist you in determining whether you are faced with a real or apparent conflict of interest. The guidance is not all-inclusive, due to the variety of possible conflicts of interest. Therefore, it is important that you should consult the PRC when there is any question about your participation in a review.

GUIDANCE AND DEFINITIONS

A **Conflict Of Interest** in scientific peer review exists when a reviewer has an interest in a proposal that is likely to bias his or her evaluation of it. A reviewer who has a real conflict of interest with a proposal may not participate in its review.

Real Conflict Of Interest means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in a proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that proposal as follows:

A reviewer shall have a real conflict of interest if he/she or a close relative or professional associate of the reviewer: (1) has received or could receive a direct financial benefit of any amount deriving from funding a proposal under review; (2) has received or could receive a financial benefit from the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year; 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 (3) has any other interest in the proposal that is likely to bias the reviewer's evaluation of that application or proposal.

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 application or proposal at issue. The peer review system relies on the professionalism and integrity of each

²Documents in this appendix follow forms and guidelines used by the National Institutes of Health, Office of Extramural Research.

reviewer to identify to the PRC any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

Employment: A reviewer who is a salaried employee, whether full-time or part-time, of the applicant institution, offeror, or principal investigator, or is negotiating for employment, shall be considered to have a real conflict of interest with regard to an application/proposal from that organization or principal investigator. The PRC may determine there is no real conflict of interest or an appearance of a conflict of interest where the components of a large or multi-component 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.

Financial Benefit: See definition of Real Conflict of Interest above.

Personal Relationships (Relatives): A close relative means a parent, spouse, sibling, son or 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. In such case, it will be treated as the reviewer's financial benefit.

Professional Associates: Professional associate means any colleague, scientific mentor, 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 three years of the date of the review.

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

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

Multi-Site Or Multi-Component Project: An individual serving as either the principal investigator or key personnel on one component of a multi-site or multi-component 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): Persons serving as the principal investigator or key personnel on an application submitted in response to an RFA or on a proposal in response to an RFP are 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 PRC that will permit an individual to review only those applications or proposals with which he/she has no conflict of interest that is likely to affect the integrity of the advice to be provided by the reviewer.

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 PRC and would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review. The PRC will evaluate the appearance of a conflict of interest and determine whether or not the interest would likely bias the reviewer's evaluation of the proposal. Where there is an appearance of conflict of interest, but not sufficient grounds for disqualifying the reviewer, the PRC will document: (1) that there is no real conflict of interest; and (2) that, at the time of the review, no practical alternative exists for obtaining the necessary scientific advice from the reviewer with the apparent conflict.

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Waivers If no other reviewer is available with the expertise necessary to ensure a competent review, a waiver may be granted by the PRC to allow participation in the review.

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CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIALS AND PROCEEDINGS

The applications and proposals and associated materials made available to reviewers, as well as the discussions that take place during review meetings are strictly confidential and must not be disclosed to or discussed with anyone who has not been officially designated to participate in the review process. In addition, disclosure of procurement information prior to the award of a contract is prohibited by the Procurement Integrity Act.

CERTIFICATION

All reviewers must certify that they have read the Conflict of Interest, Confidentiality, and Non-Disclosure Rules.” The reviewer must certify that, to the best of his/her knowledge, he/she has disclosed all conflicts of interest that he/she may have with the proposal or its authors and he/she fully understands the confidential nature of the review process and agrees: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the review, their evaluation, or the review meeting with any other individual except as authorized by the PRC; (3) not to disclose procurement information prior to the award of a contract; and (4) to refer all inquiries concerning the review to the PRC.

DRAFT

PRE-REVIEW CERTIFICATION FORM REGARDING CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE FOR REVIEWERS

Name [Last, First]: _____
(Please print)

Address:

Other Employers (if applicable)

Title of Document Reviewed: _____

Date(s) of review: _____

Check only one (and provide any comments or explanations on reverse side):

I have read the attached "Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and hereby certify that, based on the information provided to me, **I do not have a conflict of interest in the document listed above or the proposal authors.**

OR

I have read the attached "Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and hereby certify that based on the information provided, **I have a conflict of interest in the specific document or document authors listed above** and hereby recuse myself from the review of this proposal.

Certification

I certify that I have read the attached "Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers." I certify that to the best of my knowledge I have disclosed all conflicts of interest that I may have with the document or document authors and I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the review, my evaluation, or the review meeting with any other individual except as authorized by the Peer Review Committee (PRC); (3) not to disclose procurement information prior to the award of a contract; and (4) to refer all inquiries concerning the review to the PRC.

Signature: _____ Date: _____



POST-REVIEW CERTIFICATION FORM

REGARDING CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE OF INFORMATION FOR REVIEWERS

Title of Proposal Reviewed:

Date(s) of review: _____

A. Confidentiality and Non-Disclosure: I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials related to the evaluation; (2) not to disclose or discuss the materials associated with the review, my evaluation, or the review meeting outside of that meeting or with any other individual except as authorized by the Peer Review Committee (PRC); (3) not to disclose procurement information prior to the award of a contract; and (4) to refer all inquiries concerning the review to the PRC.

CERTIFICATION

I fully understand the confidential nature of the review process and agree to confidentiality and non-disclosure (Paragraph A).

Printed Name

Signature

Date Signed

