

The National Academies

National Academy of Sciences
National Academy of Engineering
Institute of Medicine
National Research Council

POLICY ON

COMMITTEE COMPOSITION AND BALANCE

AND

CONFLICTS OF INTEREST

FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS

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Introduction

The National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council -- collectively the *National Academies* -- accord special importance to the policies and procedures established by the institution for assuring the integrity of, and hence the public confidence in, the reports of the institution. The work of the institution is largely done by volunteer committees appointed for their special expertise in the area of study. Each year roughly 10,000 scientists, engineers, and other professionals working on such committees contribute their knowledge and experience to the solution of national problems, the identification of new scientific and technical goals and opportunities, and other forms of national service. These men and women are drawn from every part of the nation and from every sector of society -- academia, industry, government, nonprofit and public interest groups, and so on. The technical skills and perspectives of this distinguished and diverse group of individuals are essential to the ability of the institution to consistently produce accurate and objective assessments of national problems, needs, and opportunities.

Extensive efforts are made by the institution to assure the soundness of reports issued by the institution by selecting highly qualified committee members. Yet, if a report is to be not only sound but also effective as measured by its acceptance in quarters where it should be influential, the report must be, and must be perceived to be, not only highly competent but also the result of a process that is fairly balanced in terms of the knowledge, experience, and perspectives utilized to produce it and free of any significant conflict of interest. Conclusions by fully competent committees can be undermined by allegations of conflict of interest or lack of balance and objectivity.

The federal charter of the National Academy of Sciences, which establishes the Academy as a federally chartered corporation and under which the entire institution (i.e., the *National Academies*) operates, provides in part that "[o]n request of the United States Government, the corporation shall investigate, examine, experiment, and report on any subject of science or art." 36 U.S.C. 150303. Pursuant to this charge to "investigate, examine, experiment and report," the

institution convenes and operates hundreds of committees annually that are used by the institution in the development of reports to be provided by the institution to sponsoring Government agencies and other sponsors. The development of such reports for the U.S. Government and other sponsors is subject to the institution's various policies and procedures for the preparation and review of reports, including this Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports.

Federal Advisory Committee Act

Since 1997 the Federal Advisory Committee Act ("FACA"), 5 U.S.C. App., has contained certain specific requirements regarding work performed by this institution for the United States Government, including certain requirements relating to **committee composition** and balance and conflict of interest. Section 15 of FACA provides that an agency of the U.S. Government may not use any advice or recommendation provided by the National Academy of Sciences that was developed by use of a committee created by the Academy under an agreement with a Federal agency unless (1) the committee was not subject to any actual management or control by a Federal agency or officer, (2) the committee was appointed in accordance with the requirements contained in subsection 15(b)(1) of FACA (discussed below), and (3) the Academy has complied with various other requirements regarding public access to committee meetings (including public summaries of certain committee meetings not open to the public) and written materials presented to the committee, as well as public access to completed reports provided to the sponsor by the Academy and the identities of the principal Academy reviewers of such reports. These requirements apply to the work of the National Academy of Sciences as a corporation, and therefore to the *National Academies* as a whole, including the National Academy of Engineering, the Institute of Medicine, and the National Research Council.

Subsection 15(b)(1) of FACA requires that during the committee appointment process the institution must determine and provide public notice of the names and brief biographies of individuals that the institution appoints or intends to appoint to serve on a committee to which Section 15 of FACA applies. The institution must also determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the institution determines that such prior comment is not practicable, in the period immediately following the appointments.

Subsection 15(b)(1) of FACA further requires that the institution must "make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable, (B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and (C) and the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed." This Policy on **Committee Composition** and Balance and Conflicts of Interest describes the institution's policy and procedures for meeting these requirements. It shall apply to committees of the *National Academies* (other than certain privately funded National Academy of Engineering committees) used in the development of reports for sponsors, regardless of whether or not the particular committee is subject to the requirements of Section 15 of FACA.

Questions of Committee Composition and Balance

All individuals selected to serve on committees to be used by the institution in the development of reports must be highly qualified in terms of knowledge, training, and experience -- often highly specialized and particularized -- to properly address the tasks assigned to the committee. The institution identifies such individuals by drawing upon a vast network of national and international

contacts and resources, including in particular the distinguished memberships of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, as well as thousands of other highly qualified scientists, engineers, public health professionals, and others who have contributed their talents and services to the national interest through the National Research Council.

Suggestions of potential committee members may also come from sponsors, from groups that have an interest in the underlying subject matter of a particular study, from professionals with knowledge and expertise in relevant disciplines who have an interest in the scientific and technical questions to be addressed, and from members of the general public who may have a special interest or concern regarding a particular study or the underlying issues involved in the study. In every case, the assessment of the qualifications of potential candidates for committee membership and the final determination of the individuals to be selected for membership on a committee rest *solely* with the institution.

Individual qualifications are not the only determinant in this process. Having a committee of highly qualified and capable individuals is a necessary but not sufficient condition for success. It is also essential that the knowledge, experience, and perspectives of potential committee members be thoughtfully and carefully assessed and balanced in terms of the subtleties and complexities of the particular scientific, technical, and other issues to be addressed and the functions to be performed by the committee. For example, if a particular study requires the expertise of microbiologists, epidemiologists, statistical experts, and others with broader public health expertise, the significant omission of any required discipline from the committee might seriously compromise the quality of the committee's analysis and judgments, even though it is clear to all that the committee is composed of highly qualified and distinguished individuals. Even within a particular discipline, there may be very important differences and distinctions within the field, or regarding the particular subject matter to be addressed, that require careful consideration in the **committee composition** and appointment process.

The assessment of the necessary perspectives required for a particular study committee may also involve considerations that go beyond specific disciplinary scientific or technical concerns. For some studies, for example, it may be important to have an "industrial" perspective or an "environmental" perspective. This is not because such individuals are "representatives" of industrial or environmental interests, because *no one is appointed by the institution to a study committee to represent a particular point of view or special interest*. Rather it is because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee.

Finally, it is essential that the work of committees that are used by the institution in the development of reports not be compromised by issues of bias and lack of objectivity. (Questions of conflict of interest are separately addressed below.) Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group.

Potential sources of bias are not necessarily disqualifying for purposes of committee service. Indeed, it is often necessary, in order to ensure that a committee is fully competent, to appoint members in such a way as to represent a balance of potentially biasing backgrounds or professional or organizational perspectives. For example, an individual may be selected to serve on a committee conducting a broad study of proposed new scientific missions in space, although the individual is a consultant or an employee of an aerospace company that has a general business interest in such matters. Or an individual may be selected to serve on a committee conducting a general study of research alternatives and funding priorities and opportunities in a particular scientific field, although the individual is a faculty member or research scientist at an

institution that conducts research in that field. In either case, while the factual circumstances might suggest the existence of a possible bias, this would not ordinarily disqualify an individual from service but would be a factor to be taken into account by the institution in the overall composition of the committee. Some potential sources of bias, however, may be so substantial that they preclude committee service (e.g., where one is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary).

Questions of Conflict of Interest

It is essential that the work of committees of the institution used in the development of reports not be compromised by any significant conflict of interest. For this purpose, **the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.** Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports if the individual has a conflict of interest that is relevant to the functions to be performed.

General Principles

The term "conflict of interest" means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the committee.

Conflict of interest requirements are *objective* and *prophylactic*. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest. The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of such conflicting interests.

The term "conflict of interest" applies only to *current interests*. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is not a current interest.

The term "conflict of interest" applies not only to the personal financial interests of the individual but also to the *interests of others* with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and minor children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

Financial Interests

The term "conflict of interest" as used herein ordinarily refers to *financial* conflicts of interest. In assessing potential conflicts of interest in connection with an individual's service on a committee of the institution used in the development of reports for sponsors, particular attention will be given to the following kinds of *financial interests* if they are relevant to the functions to be performed: employment relationships (including private and public sector employment and self-employment); consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, and serving as an expert witness in litigation); stocks, bonds, and other financial instruments and investments including partnerships; real estate investments; patents, copyrights, and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.

Access to Confidential Information

The opportunity to have access to confidential information during the course of committee activities at the institution, if abused or misused, may confer an unfair competitive advantage. If an individual during the course of participating in a program activity of the institution obtains and uses, or intends to use, confidential information not reasonably available to the public for the individual's own direct and substantial economic benefit, such conduct constitutes a conflict of interest. The same rule applies if the individual discloses, or intends to disclose, such information (albeit not unlawfully) to other individuals or to organizations in such a manner that a direct and substantial economic benefit may be conferred on such individuals or organizations. These restrictions do not apply to information once it has entered the public domain.

In some situations -- for example, access to classified information, medical records, etc. -- special limitations on access to and use of such information will be imposed. Substantial legal penalties may apply for noncompliance. In addition, an individual employed by or associated with a particular organization or enterprise should not be given access to proprietary information of a competitor or potential competitor unless appropriate safeguards have been established that reasonably protect the interests of all parties. Otherwise, such access may create an unfair competitive advantage, as well as possible liability for improper disclosure and use. For further guidance regarding access to confidential information, contact the Office of the General Counsel.

Reviewing One's Own Work

It is not uncommon for individuals serving on committees of the institution being used in the development of reports for sponsors to find that their own published and professional work, in common with others in the field, is part of the technical basis and literature for the committee. This ordinarily would not constitute a conflict of interest. However, an individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is the central purpose of the activity, because that would constitute a conflict of interest, although such an individual may provide relevant information to the program activity.

Public Statements and Positions

An individual may have become committed to a fixed position on a particular issue through public statements (e.g., testimony, speeches, interviews, etc.), through publications (e.g., articles, books, etc.), through close identification or association with the positions or perspectives of a particular group, or through other personal or professional activities. This would ordinarily constitute a potential source of bias but not a conflict of interest. However, in situations where there is some significant, directly related interest or duty of the individual -- e.g., where the

individual is currently president of a professional society that espouses the same fixed position on the issue -- the situation may constitute a conflict of interest.

Employees of Sponsors

There are special rules for employees of sponsors. *An individual who is employed by the agency or other entity which is sponsoring the study or other activity in which a particular committee is engaged ordinarily cannot be a member of that committee (although the individual can be an agency liaison representative) because the institution provides independent reports and other services to sponsors, and it would generally constitute a conflict of interest for sponsor employees to serve on such committees.* However, in special circumstances and to the extent not prohibited by federal or state laws or regulations, such an individual may serve as a member of such a committee where the following requirements are met: (1) the service of the individual on the committee must be based upon the unique scientific or technical expertise which the individual brings to the committee; (2) the individual must not be involved in any way within the agency in any deliberative or decision-making process or any policy-making or similar process relating to the study or other activity or the expected or intended results of the study or other activity; and (3) it must be specifically determined during the committee appointment process that service by the individual will not compromise, or appear to compromise, the independence or objectivity of the particular study or other activity in which the committee is engaged. In the work of the institution, scientists, engineers, health specialists, and others working at national laboratories often meet the above requirements, while senior government officials and government officials in policy-making roles do not.

Categorizing Program Activities for Conflict of Interest Purposes

At any given time, committees of the *National Academies* are engaged in hundreds of studies and other activities involving thousands of volunteers working on topics that range across the entire spectrum of science, technology and public policy. The diversity and complexity of this undertaking make it difficult to state complete, all-encompassing rules that will anticipate and address every possible situation involving a potential conflict of interest. However, APPENDIX A to this Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports, incorporated herein and made a part hereof, contains guidelines applying conflict of interest principles to some commonly occurring categories of program activities. These guidelines are provided as an aid to defining and identifying possible conflicts of interest for committees engaged in such program activities.

Implementation of this Policy Statement

Background Information and Confidential Conflict of Interest Disclosures

To address questions of **committee composition** and balance and conflict of interest, individuals being selected to serve and serving on committees used by the institution in the development of reports for sponsors are required to submit certain background information, and certain information regarding conflicts of interest, to the institution to be reviewed and acted on by the institution in making committee appointments. These "Background Information and Confidential Conflict of Interest Disclosure" forms are prepared and distributed by the National Research Council Executive Office.

In order to facilitate the identification and disclosure of relevant information, different types of forms may be used for different types of committee activities, in accordance with instructions issued from time to time by the NRC Executive Office. For example, there may be separate "Background Information and Confidential Conflict of Interest Disclosure" forms for studies involving program reviews and evaluations and for studies relating to government regulation.

In addition to the submission of these forms, committees are asked to discuss the issues of **committee composition** and balance and conflict of interest, and the relevant circumstances of their individual members, at the first committee meeting, and annually thereafter. Moreover, disclosure of relevant information is a *continuing obligation* for the duration of the committee activity for which the "Background Information and Confidential Conflict of Interest Disclosure" form was prepared. If during an individual's period of service on the committee it becomes apparent to the individual that there have been changes in the information disclosed, or that there is new information that needs to be disclosed, such information must be reported promptly to the responsible staff officer for the project for which the form was completed.

Except as otherwise provided herein, *specific conflict of interest information obtained by the institution from the "Background Information and Confidential Conflict of Interest Disclosure" forms, from the confidential committee discussion of **committee composition** and balance and conflict of interest at the first committee meeting and annually thereafter, from amended disclosures, and from the public and other sources will be held in confidence by the institution.* Access to such information within the institution will be limited to those offices whose proper business requires access to such information. It is the policy of the institution that such information may be released, on a privileged basis, to the head of an agency sponsoring the program activity in which a committee is engaged, if that official so requests in writing and the chair of the National Research Council concurs. Such information is not otherwise released by the *National Academies* or the agency except with the approval of the individual to whom the information pertains, unless release is required by law.

Public Notice and Public Comments

For committee activities that are subject to the institution's procedures for compliance with the requirements of Section 15 of the Federal Advisory Committee Act ("FACA") (either as a matter of law or of institutional policy), the institution will determine and provide public notice on the institution's web site of the names and brief biographies of individuals that the institution appoints or intends to appoint to serve on the committee. The institution will also determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the institution determines that such prior comment is not practicable, in the period immediately following the appointments.

Institutional Determinations on Composition and Balance and Conflicts of Interest

The specific factors to be considered by the institution in assessing questions of **committee composition** and balance for committees used in the development of reports will generally depend in each case upon the particular facts and circumstances involved. The resolution of these matters will be based in the final analysis upon the independent judgment of the institution in discharging its responsibility for the character and quality of its committees and reports, to ensure that such reports meet the institution's standards of quality and represent the institution's independent judgment on the issues addressed. Final authority over committee appointments rests with the chair of the National Research Council.

Information obtained from the "Background Information and Confidential Conflict of Interest Disclosure" forms, from confidential committee discussions of **committee composition** and balance and conflict of interest at the initial committee meeting and annually thereafter, and from other sources including the public will be used by the institution in addressing and resolving questions of conflict of interest. Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports for sponsors if the individual has a conflict of interest that is relevant to the functions to be performed.

A particular individual's conflict of interest may be determined to be unavoidable if, for example, the individual's qualifications, knowledge, and experience are particularly valuable to the work of the committee and if the institution is unable to identify another individual with comparable qualifications, knowledge, and experience who does not also have a conflict of interest. Determinations that a conflict of interest exists and that a conflict of interest is unavoidable are made jointly by the NRC Executive Office and the General Counsel's Office.

For certain projects involving committee review of multiple applications for fellowships, grants, etc., and recommendations to sponsors who make the awards, an alternate conflict of interest procedure may be used with the advance approval of the NRC Executive Office. This alternate procedure may be particularly appropriate in the following situations: the pool of available experts is unusually small; the volume of applications to be reviewed is particularly large; the potential pool of applicants is largely unknown at the time of committee formation and conflict of interest determinations and disclosures must be made shortly before the applications are reviewed; special and particularized expertise is needed on the committee.

Under this alternate procedure, the following requirements will apply for each individual appointed to serve on the committee: (1) any relevant factual information regarding the individual's conflicts of interest as defined herein must be disclosed in the individual's Confidential Conflict of Interest Disclosure, as submitted or as amended prior to the actual reviews; (2) the NRC Executive Office and the General Counsel's Office must determine that under the circumstances such conflicts of interest among members of the committee are unavoidable; (3) the conflicts of interest must be promptly and publicly disclosed; and (4) the individual, although appointed to serve on the committee, must be excluded from all deliberations and decisions on applications for which the individual has a conflict of interest. A public written record of the deliberations and decisions from which an individual has been excluded must be maintained by the responsible staff officer.

Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports -- APPENDIX A

Categorizing Program Activities for Conflict of Interest Purposes

At any given time, committees of the *National Academies* are engaged in hundreds of studies and other activities involving thousands of volunteers working on topics that range across the entire spectrum of science, technology and public policy. The diversity and complexity of this undertaking make it difficult to state complete, all-encompassing rules that will anticipate and address every possible situation involving a potential conflict of interest. However, the following guidelines in this Appendix apply the conflict of interest principles in the Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports to some commonly occurring categories of program activities and are provided as an aid to defining and identifying possible conflicts of interest for committees engaged in such program activities.

1. *General Scientific and Technical Studies and Assistance*. Much of the work of the institution involves scientific and technical studies and assistance for sponsors across a broad range of activities including, for example, the following: defining research needs, priorities, opportunities and agendas; assessing technology development issues and opportunities; addressing questions of human health promotion, protection, and assessment; providing scientific and technical assistance, assessments, and supporting services for government agency program development; providing international and foreign country science and technology assessments, studies and assistance. Such activities frequently address scientific, technical, and policy issues that are sufficiently broad in scope that they do not implicate specific financial interests or conflict of interest concerns. However, where such activities address more specific issues having significant financial implications -- e.g., funding telescope A versus telescope B, government development or evaluation of a specific proprietary technology, promotion or endorsement of a specific form of

medical treatment or medical device, connecting foreign research facilities to specific commercial interests, etc. -- careful consideration must be given to possible conflict of interest issues with respect to the appointment of members of committees that will be used by the institution in the development of reports to be provided by the institution to sponsoring agencies.

The overriding objective of the conflict of interest inquiry in each case is to identify current, directly affected financial interests, and other interests as described herein, which conflict with the committee service of the individual because they could impair the individual's objectivity or could create an unfair competitive advantage. The application of these concepts to specific scientific and technical studies and projects must necessarily be addressed in each case on the basis of the particular facts and circumstances involved. However, in every case the underlying issue is whether an individual, or others with whom the individual has substantial common financial interests, has identifiable interests that could be directly affected by the outcome of the project activities of the committee on which the individual has been invited to serve.

2. Program Reviews and Evaluations. This institution is frequently called upon by sponsors to provide an independent review and evaluation of a particular program or programs of the sponsor. For any committee that will be used by the institution in the development of reports to be provided by the institution to a sponsoring agency for use as an independent review and evaluation of one or more programs of the sponsor, *the focus of the conflict of interest inquiry is on the identification and assessment of relationships to the program or programs to be reviewed and evaluated, as well as on other interests that might be directly affected by the review and evaluation.* For example, if the institution were conducting an independent review and evaluation of a particular research program of a sponsor, the focus of the conflict of interest inquiry would be on the identification and assessment of existing interests in that program which could be directly affected if the institution's report were to provide the basis for action or inaction with respect to changes in that program. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has current interests that could be directly affected by the review and evaluation process, the individual's objectivity while participating in the review and evaluation process could be impaired.

Such interests could include existing research grants or contracts under the program being reviewed and evaluated held by the individual (or by others with whom the individual has substantial common financial interests) if, for example, the current grants or contracts might be modified or terminated, or if there is a current expectation of continuing research funding that could be enhanced or lost. Other interests that might be directly affected might include, for example, possible impact on one's employment or the financial interests of one's employer, one's self-employment or the financial interests of one's clients, interests in partnerships and commercial ventures arising out of or related to the research, interests in relevant patents and other forms of intellectual property related to the research, and interests in various forms of substantial non-financial research support.

Certain relationships to the sponsor may also raise issues of conflict of interest. For example, serving as a consultant to the sponsor could constitute the basis for a conflict of interest if the consulting relationship could be directly affected or is directly related to the subject matter of the program review and evaluation.

3. Studies Related to Government Regulation. For any committee that will be used by the institution in the development of one or more reports to be provided by the institution to a sponsoring agency for use in a government regulatory process, *the focus of the conflict of interest inquiry is on the identification and assessment of any interests that may be directly affected by the use of such reports in the regulatory process.* For example, if the institution were conducting a study of proposed modifications in the government regulation of a particular application of biotechnology, the focus of the conflict of interest inquiry would be on the identification and assessment of any interests that would be directly affected by that regulatory process if the

institution's report were to provide the basis for regulatory action or inaction. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has specific interests (primarily financial) that could be directly affected by the regulatory process, the individual's objectivity could be impaired.

Such interests would include, for example, an individual's significant stock holdings in a potentially affected biotechnology company, or being an officer, director, or employee of the company. Serving as a consultant to the company would constitute such an interest if the consulting relationship with the company could be directly affected, or is directly related to the subject matter of the regulatory process. Other possible interests might include, for example, interests in relevant patents and other forms of intellectual property or serving as an expert witness in litigation directly related to the subject matter of the regulatory process. Receiving current research funding from a party that would be directly affected by the regulatory process would constitute a conflict of interest (1) if the research funding could be directly affected by the outcome of the regulatory process or (2) the research is directly related to the subject matter of the regulatory process and the investigator's right to independently conduct and publish the results of the research is limited or controlled by the sponsor. Consideration would also need to be given to the interests of others with whom the individual has substantial common financial interests -- particularly spouses, employers, clients, and business or research partners.

4. Advice and Assistance Regarding Contract, Grant, Fellowship, etc. Awards. This institution routinely provides reviews of specific applications and proposals for contract, grant, fellowship, etc., awards to be made by sponsors. In doing so, the institution is guided by the principle that *an individual should not participate in any decision regarding the award of a contract or grant or any other substantial economic benefit to the individual, or to others with whom the individual has substantial common financial interests or a familial or substantial professional relationship.* Other current directly affected financial and competitive interests that may be disqualifying because they could be directly affected by the work of the committee -- e.g., providing advice regarding possible awards to one's existing substantial competitors -- also need to be considered in assessing potential conflicts of interest for individuals selected to serve on committees making award decisions and recommendations.

This institution also routinely participates in projects involving the development of work statements and requests for proposals for sponsor procurements and financial assistance projects. When a project involves the design of a specific procurement or grant program activity (including the development of requests for proposals, work statements, and/or specifications, etc.), an unfair competitive advantage could arise if committee members were to design the program to favor their own proposals or those of others with whom they have common financial interests. To address this concern, any committee member who is interested in seeking a procurement or grant award under the program -- or who is employed in any capacity by, or has a financial interest in or other relationship with, any person or organization that to the best of the committee member's knowledge has an interest in seeking such an award under the program -- must disclose that fact in the individual's Confidential Conflict of Interest Disclosure. As a limited exception to the confidentiality rules that otherwise apply to information on the Background Information and Confidential Conflict of Interest Disclosure form, the sponsor will be informed of such information. In order to avoid creating an unfair competitive advantage, the sponsor may limit the subsequent eligibility of the committee member, or any person or organization identified by the committee member as described in the preceding sentence, to seek an award under the program. Such information would not, however, necessarily disqualify an individual from serving on the committee.

5. Other Activities. Some program activities may not be easily assigned to one of the four categories described above and may present conflict of interest considerations that range from substantial to negligible. Such projects will be addressed by the institution on an *ad hoc*, case-by-

case basis by the NRC Executive Office utilizing the general principles and concepts outlined above.