



Date: June 14, 2005

To: Addressees

From: Director, Office of Federal Advisory Committee Policy, OD, NIH

Subject: OFACP Policy Announcement 2000-01 (**REVISED**): Working Groups at the National Institutes of Health (NIH)

**PLEASE NOTE: The June 3, 2003 policy has been REVISED to reflect changes in conflict of interest information for working group participants (Attachment IV) and, accordingly, to update the Confidentiality Certification for working group participants (Attachment V). This guidance supersedes all previous issuances related to Working Groups at the NIH.**

**Background:** NIH chartered advisory committees often need to assemble and convene groups of outside experts to provide advice or to serve as fact-finding bodies to gather information, analyze relevant issues and facts, and draft proposed position papers for final deliberation by chartered advisory committees. At NIH, these groups are referred to as “Working Groups.”

This policy was originally issued August 12, 1998, and was revised November 21, 2000. It is being updated to reflect the General Services Administration’s (GSA) August 20, 2001, revision of the Federal Advisory Committee Act (FACA) Regulation, 41 CFR Parts 101-6 and 102-3, concerning the definition of “utilized” within the meaning of FACA. The new FACA Regulation de-emphasizes the concept of “consensus advice” as a barometer for determining whether a committee is subject to the FACA. It also clarifies the applicability of the FACA to “subcommittees.”

**Policy Statement:** Chartered Federal advisory committees may create working groups to provide recommendations, gather information, or provide assistance on a specific, limited project. They are, temporary in nature. NIH working groups are generally not subject to the FACA under GSA Regulation, 41 CFR Part 102-3, §'102-3.25 and §'102-3.35, if they meet the subcommittee definition provided in the current Rule.

**§102-3.25** “Subcommittee means a group generally not subject to the [FACA], that reports to an advisory committee and not directly to a Federal officer or agency, whether or not its members are drawn in whole or in part from the parent advisory committee.”

**§102-3.35** “In general, the requirements of the [FACA] and the policies of this Federal Advisory Committee Management part do not apply to subcommittees of advisory committees that report to a parent advisory committee and not directly to a Federal officer or agency.”

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**Discussion:** NIH uses the term “working group” to define groups that are convened by and report to a chartered advisory committee to conduct research, gather information, analyze relevant issues and facts, and to draft position papers. These groups satisfy the definition of a “subcommittee” under the FACA regulation since they do not report directly to a Federal officer.

Many of NIH's chartered advisory committees have formal, standing subcommittees that report directly to a Federal official and follow the requirements of the FACA. Because the HHS FACA Handbook includes such groups with the definition of a subcommittee, we will continue to refer to groups that report to chartered committees as working groups. HHS's FACA Handbook requirements should continue to be followed for formal, standing subcommittees that report directly to a Federal official. For your reference, Attachments I and II are charts that provide major distinctions between a chartered advisory committee, a subcommittee, and a working group.

The FACA Rule de-emphasizes consensus advice as a criterion for determining whether a group is subject to the FACA. Instead, it encourages agencies to apply an actual management or control test to determine if a group is subject to the Act. The test for whether a committee is “utilized” for purposes of FACA, is whether an agency either has actual management of the committee or, in some fashion other than management, exercises actual control over the committee. The agency must determine whether or not its relationship with a group created by non-Federal entities (such as a contractor or private organization) constitutes actual management or control within the meaning of FACA. NIH working groups are exempt from the FACA since the agency does not have actual management or control of the working group and the agency does not manage or control the groups for the purpose of obtaining advice or recommendations. Working groups are convened by the chartered advisory committee and report directly to the committee, not Federal officials.

The chartered advisory committee to which the working group reports, will have the necessary expertise to deliberate the working group's recommendations, reports, and research. The committee may not simply “rubber-stamp” the information provided. Working group meetings are not required to be open to the public or announced in the Federal Register. However, it is strongly encouraged that these meetings be open to the public and announced in the Federal Register. It is also highly recommended that working groups include ethnic and gender diversity, as well as balanced geographic representation among the participants, as appropriate. Additionally, these groups should include the term, “Working Group” as part of their name, to distinguish them from advisory committees chartered under the FACA.

The manner in which a working group functions, not the number of times it meets, determines whether or not it is exempt from the FACA. These groups are temporary in nature. Given the complexity of the exemptions to the applicability of the FACA, and the fact that the statute on which they are based continues to be interpreted by the courts, the Office of the General Counsel (OGC) and the Office of Federal Advisory Committee Policy (OFACP) should be consulted, as appropriate, before a working group is convened. Attachment III includes two court cases that illustrate key points regarding the manner in which working groups function and their

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relationship to chartered Federal advisory committees.

**Special Concerns:** The role of the working group is to serve as a fact-finding body that gathers information, analyzes relevant issues and facts, and drafts proposed positions for final deliberation by a chartered advisory committee. The working group does not participate in decisions regarding funding of grants. However, many working group participants are directly involved in research that could be the subject of working group activities. Effort should be made to select working group participants who are free of conflicts.

While working groups are not bound by the Office of Government Ethics Criminal Conflict of Interest statutes, working group participants must manage all potential for allegations of bias or inappropriate influence. The working group's Federal official must have the opportunity to consider whether a working group member's input might be influenced by the interests of their employer, or their own financial, equity, or patent interests. Attachment IV provides conflict of interest information for working group participants. Attachment V, "*Conflict of Interest and Confidentiality Certification for Working Group Participants*" must be completed by all participants in advance of the meeting.

Provided below are four specific examples of potential concern:

- When a working group participant or immediate family member holds financial, equity, or a patent or other proprietary interest in an organization whose product or product concept is subject of the deliberations.
- When a working group participant or immediate family member holds financial, equity, or a patent or other proprietary interest in an organization whose product or product concept competes with a product or product concept being discussed.
- When a working group participant or immediate family member is seeking employment in an organization or serves as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is subject of the deliberations, or would benefit from research in a defined area.
- When a working group participant or immediate family member holds financial, equity, or a patent or other proprietary interest in an organization whose product or product concept would uniquely benefit from research emphasis in a defined area.

Each working group participant should be advised to keep in mind these potential concerns while pursuing their working group responsibilities and bring any issues to the attention of the chartered committee's Federal official. At NIH, this is usually the committee's Executive Secretary or Scientific Review Administrator. Full disclosure should be reflected in the minutes.

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There are some suggested actions that should be taken in cases where concern is raised about conflict of interest. Full disclosure, as reflected in the meeting minutes of financial, equity, or patent interests by the participants involved in the deliberation will allow the Federal official and the working group to determine whether a concern exists and whether any additional actions are warranted. In most instances, knowledge of the interests will be sufficient to allow the working group to carry on its deliberations, while taking into account those interests as recommendations are made. Another possible action is that participants recuse themselves from making recommendations in matters related to a concern.

**Confidentiality:** Material made available to working group participants, as well as the discussions that take place during closed meetings, are strictly confidential and may not be disclosed or discussed with anyone who has not been officially designated to participate in the working group meeting. Participants must certify that they will maintain the confidentiality of the meeting materials and discussions and not disclose this information to any other individual, except as authorized by the NIH advisory committee to which the group reports.

**Record Keeping and Retention:** Proper record keeping procedures should be followed, as described below:

- *Individual Meeting Records.* These records are maintained by the appropriate Institute and Center (IC) managing the operations of the working group and/or the chartered advisory committee. Records include membership lists, visitor lists, agendas, transcripts and/or minutes of meetings. Meeting records should be destroyed six years after the working group has terminated.
- *Certifications.* Certifications should be filed separately from other working group documents, in confidential binders by working group. When a participant submits an updated certification, previous ones should be filed alphabetically by name in separate confidential folders. These records should be destroyed six years after the participant completes working group responsibilities, except that documents needed in an on-going investigation will be retained until no longer needed in the investigation.

Any information obtained or prepared in connection with the certifications (for example, reports of telephone conversations and notes) should be filed in a secure place to ensure confidentiality and security of these records as required by the Privacy Act.

- *Working Group Recommendations.* Reports, draft position papers, letters and/or memorandum documenting the working group's recommendations to the chartered advisory committee should be filed in the chartered advisory committee's individual committee meeting file with the meeting where the recommendations were discussed. Other copies may be destroyed when no longer needed, or when the working group terminates.

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For further information concerning this policy, please call the Office of Federal Advisory Committee Policy at (301) 496-2123.

/s/

LaVerne Stringfield

Issuing Office: OFACP (301/496-2123)

Attachments:

Comparison Chart for Chartered Committees, Subcommittees & Working Groups  
Comparison Chart - FACA Committee vs. Working Group  
Court Cases Relating to Working Groups and the FACA  
Conflict of Interest and Confidentiality Information for Working Group Participants  
Conflict of Interest and Confidentiality Certification for Working Group Participants

Addressees:

Dr. Zerhouni  
Dr. Kington  
EPMC Members  
CMOC Members & Liaisons  
OGC  
OGC/Ethics Division

Addendum to OFACP Policy Announcement 2000-01 Dated June 14, 2005:  
[Working Groups at the National Institutes of Health \(NIH\)](#)

**ATTACHMENT I**

**COMPARISON CHART for CHARTERED FACA COMMITTEES, SUBCOMMITTEES & WORKING GROUPS**

	Chartered FACA Committees	Subcommittees	Working Groups
<b>Definition</b>	<p>An advisory committee subject to the Federal Advisory Committee Act means “any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other similar group, which is established by statute, or established or utilized by the President or by an agency official for the purpose of obtaining advice or recommendations for the President or on issues or policies which are within the scope of an agency official’s responsibilities” (41 CFR 102-3.25). NIH utilizes five types of advisory committees: <b>National Advisory Councils, Program Advisory Committees, Boards of Scientific Counselors, Initial/Integrated Review Groups and Special Emphasis Panels.</b></p>	<p>Subcommittees may be used by any type of chartered advisory committee to subdivide a workload or to address issues in specific substantive areas. Continuing subcommittees are termed standing subcommittees; subcommittees that meet and subsequently disband are considered ad hoc subcommittees.</p>	<p>Working groups are exempt from the Federal Advisory Committee Act under General Services Administration Regulations 41 CFR 102-3.35 and 102-3.25. Working groups are groups of individuals assembled and convened by chartered Federal advisory committees to provide advice or serve as fact-finding bodies that gather information, analyze relevant issues and facts, and draft proposed position papers for final deliberation by chartered advisory committees. Working groups are <u>not</u> to be established or “<i>utilized</i>” to provide advice or recommendations directly to a Federal official.</p>
<b>Membership</b>	<p align="center"><b><u>National Advisory Councils</u></b>            Scientific and public members appointed as Special Government Employees by the President or Secretary. May obtain advice from special consultants who may attend subcommittee meetings, but these non-member attendees may not vote on subcommittee actions or count toward the quorum.</p> <p align="center"><b><u>Program Advisory Committee</u></b>            Scientific and public members are appointed as Special Government Employees by the President, Secretary, Director, NIH, or in a few cases the IC Director. May obtain advice from special consultants who may attend subcommittee meetings, but may not vote on subcommittee actions or count toward the quorum.</p> <p align="center"><b><u>Board of Scientific Counselors</u></b>            Scientific members appointed as Special Government Employees by Director, NIH, or NCI Director for NCI’s BSC. May obtain advice from special consultants who may attend subcommittee meetings, but may not vote on subcommittee actions or count toward the quorum.</p> <p align="center"><b><u>Initial/Integrated Review Group</u></b>            Scientific/technical/public peer review members appointed by the Director, NIH, or in a few cases the IC Director.</p> <p align="center"><b><u>Special Emphasis Panel</u></b>            Scientific/technical peer review members selected to serve by the Designated Federal Official in charge of the meeting. Membership is fluid and individuals are designated to serve for only the meeting(s) they are requested to attend.</p>	<p>Subcommittees are composed of selected members of the chartered advisory committee.</p> <p align="center"><b><u>National Advisory Councils, Program Advisory Committee, &amp; Board of Scientific Counselors</u></b>            Subcommittees may obtain advice from special consultants who may attend subcommittee meetings, but may not vote on subcommittee actions or count toward the quorum.</p> <p align="center"><b><u>Initial/Integrated Review Group</u></b>            IRG subcommittees may include Temporaries. They may vote but do not count toward the quorum.</p> <p align="center"><b><u>Special Emphasis Panel</u></b>            No subcommittees for SEPs.</p>	<p>Participants may be selected by the chartered advisory committee and Federal official. It is recommended that a Federal official attend all meetings.</p>

<b>Reports To</b>	The President, Secretary, Director, NIH, the IC Director, the Scientific Review Administrator, and the Designated Federal Official in the case of SEPs.	Chartered committee or a Federal official if designated in the charter.	Chartered advisory committee
<b>Type of Advice</b>	Group advice or recommendations	Group advice or recommendations.	Advice of attendees, findings
<b>Meeting Notification</b>	Each meeting must be advertised in the Federal Register at least 15 calendar days in advance of the meeting.	Meetings must be advertised in the Federal Register 15 calendar days in advance of the meeting.	Meetings may or may not be advertised in the Federal Register.
<b>Conflict of Interest</b>	Conflict of interest rules as prescribed for Special Government Employees and scientific and technical peer reviewers of grant applications or contract proposals.	Conflict of interest rules for Special Government Employees and members of scientific and technical peer review groups apply to all subcommittee members, as appropriate.	NIH Conflict of Interest and Confidentiality Certification required. If a participant has a question about a potential concern/interest involving the working group function, he or she should bring it to the attention of the group and Federal official. Full disclosure and the group's response should be reflected in the minutes.

\* “*Utilized*” for the purpose of FACA, does not have its ordinary meaning. A committee that is not established by the Federal Government is *utilized* within the meaning of FACA when the President or a Federal office or agency exercises actual management or control over its operations.

**ATTACHMENT II**

**FACA COMMITTEE vs. WORKING GROUP**

<b>Issue</b>	<b>Federal Advisory Committee</b>	<b>Working Group</b>
Subject to FACA Laws and Regulations	Yes	No
Provides direct advice to the Government	Yes	No
Federal official present at all meetings	Yes	Highly Recommended
Participates in decisions for recommending the funding of grants	Yes	No
Reports to a Federal advisory committee	No	Yes
Temporary in nature	No	Yes
Must have an open public session	Yes, except when authorized to close the meeting	Highly Recommended
Must be published in the Federal Register	Yes	Highly Recommended
Appropriate geographic, ethnic, gender representation	Yes	Highly Recommended
Use appropriate record keeping procedures, i.e., meeting file, roster, agenda, minutes	Yes	Yes

**COURT CASES RELATING TO WORKING GROUPS AND THE FACA**

In the case National Anti-Hunger Coalition v. Executive Comm. of the President=s Private Sector Survey on Cost Control, 557 F. Supp. 524 (D.D.C. 1983) it was argued successfully that a task force, co-chaired by members of an Executive Committee (itself subject to FACA), is not an advisory committee within the meaning of the statute. The court found that the task force was merely providing information and recommendations for consideration by the FACA Committee. Consequently, it was not directly established or utilized by the Federal agency for the purpose of obtaining advice or recommendations. Even though the task force was directly involved in the gathering of information and the formulation of recommendations, the court viewed these as staff functions not covered by FACA. The task force could perform various functions including the gathering of information, the development of work plans, the performance of studies, the drafting of reports and even the discussion of preliminary findings with agency employees without being subject to FACA. However, if it provided advice directly to the agency or an agency official, then it would be viewed as an advisory committee within the meaning of FACA. The decision of the district court was affirmed on appeal, National Anti-Hunger Coalition v. Executive Comm. of the President=s Private Sector Survey on Cost Control, 711 F.2d 1071 (D.C. Cir. 1983). The Court of appeals noted that the outcome might have been different if the plaintiff could have proved that the Executive Committee was merely “rubber stamping” recommendations of the task force or that the task force reports were transmitted directly to Federal officials before they were made publicly available.

In the March 10, 1993, decision, Association of American Physicians & Surgeons v. Clinton 997 F.2d (D.C. Cir. 1993), Judge Lamberth relied on the National Anti-Hunger Coalition decision in holding that the interdepartmental working groups, including their cluster groups, were exempt from FACA, because they were gathering information and formulating proposals to be reported to the task force. On appeal, the Court of Appeals held that the FACA did not apply because the task force was comprised entirely of Federal employees. However, the Court of Appeals held that this did not resolve the issue of whether the cluster groups were subject to FACA. Rather, the Court distinguished the holding in the National Anti-Hunger Coalition case because there the parent committee of the working group was subject to the FACA. The Court reasoned that where the Task Force was considered part of the Government, because it was comprised entirely of Federal officials, “we must consider more closely FACA’s relevance to the working group.” (Association of American Physicians & Surgeons v. Clinton, 997 F.2d at 913) “For it is the working group now that is the point of contact between the public and the government.” (Id.) The Court of Appeals concluded that it could not determine if the working groups were subject to FACA on the record before it and remanded the issue to the district court. This issue was never determined on the remand of the case, because the district court determined the case had become moot. Thus, the holding in National Anti-Hunger Coalition remains in effect.

## **CONFLICT OF INTEREST AND CONFIDENTIALITY INFORMATION FOR WORKING GROUP PARTICIPANTS**

### **Conflict of Interest**

It is essential that the business of the working group 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. A conflict of interest exists when a participant has a financial interest that may bias the participant’s opinion regarding the charge of the working group or an item on the agenda of a working group meeting. Working group participants are most familiar with their own situation, and it is their personal responsibility to bring to the attention of the working group and its Federal official any conflict of interest that may pertain to the agenda items. The Federal official and the working group will respond to the concern by taking the conflict into account either before the meeting, by recusing the participant with the conflict from all discussion or by disqualifying the participant from a recommendation or vote on the issues to be discussed.

In addition, the Federal official may make determinations regarding conflicts of interest and require that a participant not be involved in the discussion of an item that presents a potential conflict of interest.

The overriding objective of the conflict of interest inquiry in each case is to identify whether there are interests - primarily financial in nature - that conflict with the committee service of the individual because they could impair the individual’s objectivity or could create an unfair competitive advantage for any person or organization. The fundamental question in each case is does the individual, or others with whom the individual has substantial common financial interests, have identifiable interests that could be directly affected by the outcome of the project activities of the working group on which the individual has been invited to participate.

The following guidance will assist in determining whether a conflict of interest exists.

## **BASES FOR CONFLICTS OF INTEREST**

- When a working group participant or a member of that individual's immediate family holds financial, equity, or proprietary interest in, or receives research support from, an organization whose product or product concept is involved in the deliberations;
- When a working group participant or a member of that individual's immediate family holds financial, equity, or proprietary interest in, or receives research support from, an organization whose product or product concept competes with a product or product concept being discussed;
- When a working group participant or a member of that individual's immediate family is seeking employment in an organization or serves as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations of, or would benefit from research in an area that is on the agenda...(for example, when a participant or spouse is negotiating for employment with a company whose product is being considered or participant or spouse works for a company that has a competing product from the product being considered);
- When a working group participant or a member of that individual's immediate family holds financial, equity, or proprietary interest in, or receives research support from, an organization whose product or product concept would substantially benefit from research emphasis in a defined area (for example, when a participant holds stock in a company that is one of a very few companies conducting a certain type of vaccine research and the research area being discussed is that type).

### **Confidentiality**

**Closed sessions and confidential documents** - Materials made available to working group participants as well as the discussions that take place during closed sessions are strictly confidential and may not be disclosed to or discussed with anyone who has not been officially designated to participate in the meeting. Participants will be asked to return or destroy all confidential materials at the conclusion of the working group's business. Working group participants must certify on the Conflict of Interest and Confidentiality Certification form that they will maintain the confidentiality of the materials and discussions and not disclose this information to any other individual, except as authorized by the NIH advisory committee to which the group reports.

**Open sessions and public documents** - Discussions and documentation distributed during an open session are not considered confidential. Discussions involve

information that is a matter of public record or general in nature. Documentation provided to working group participants in an open session may be freely distributed, copied or made available to the public.

OFACP  
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**ATTACHMENT V**

**CONFLICT OF INTEREST AND CONFIDENTIALITY CERTIFICATION  
FOR WORKING GROUP PARTICIPANTS**

Working Group Name: \_\_\_\_\_

Date(s) of Meeting: \_\_\_\_\_

Name of Participant: \_\_\_\_\_

Check only one:

- I have read the attached "Conflict of Interest and Confidentiality Information for Working Group Participants" and have examined the group's charge and the meeting agenda. I have also read the below statements, and I hereby certify that I do not have a potential or actual conflict of interest in relation to any agenda item.
  
- I have read the attached "Conflict of Interest and Confidentiality Information for Working Group Participants" and have examined the group's charge and the meeting agenda. I have also read the below statements, and I hereby certify that I have a potential or actual conflict of interest with an item on the agenda. I will disclose the conflict to the working group and the Federal official managing the group prior to any discussion of that item so it can be reflected in the minutes along with the group's determination of how to handle the conflict.

Statements:

The central purpose of the project for which this disclosure form is being prepared is not a critical review and evaluation of my work or that of my employer.

I do not have an existing professional obligation that effectively requires me to publicly defend a previously established position on an issue that is relevant to the functions to be performed in this working group activity.

To the best of my knowledge, my participation in this working group activity will not enable me to obtain access to a competitor's or potential competitor's confidential proprietary information.

As a current, or former, U.S. Government employee (either civilian or military), there are no federal conflict of interest restrictions that may be applicable to my service in connection with this working group activity.

As a current U.S. Government employee, I am not currently employed by a federal agency that is sponsoring this project; OR, as a non-U.S. Government employee, I am not employed by any other sponsor (e.g., a private foundation) of this project.

I am not interested in seeking an award under the program for which the working group is developing the request for proposals, work statement, and/or specifications – and, I am not employed in any capacity by, or have a financial interest in or other economic relationship with, any person or organization that to the best of my knowledge is interested in seeking an award under this program

Neither I nor any member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is involved in the deliberations of this working group.

Neither I nor any member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is competing with a product or product concept being discussed by this working group.

Neither I nor any member of my immediate family is seeking employment in an organization or serve as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations of, or would benefit from research in an area that is on this working group's agenda.

Neither I nor any member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept being discussed by this working group would substantially benefit from research emphasis in a defined area.

*I fully understand the confidential nature of the discussions held during closed sessions of the working group and agree: (1) to destroy or return all materials related to the meetings; (2) not to disclose or discuss the materials associated with the meetings or my evaluations with any other individual except as authorized by the NIH advisory committee to which the group reports; and (3) to refer all inquiries concerning the meeting to the Federal official managing the working group.*

Signature: \_\_\_\_\_  
(Participant's Name)

Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_  
(Federal Official)

Date: \_\_\_\_\_