MANAGING
NATIONAL INSTITUTES OF HEALTH
FEDERAL ADVISORY COMMITTEES

An Overview

August 2012
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INTRODUCTION

The purpose of this orientation guide is to provide an overview of some of the basic principles and major functions required to manage Federal advisory committees at the National Institutes of Health (NIH). Federal advisory committees provide expert advice, ideas, and diverse opinions to officials and agencies in the Executive Branch of the Federal Government. NIH has the most extensive and complex advisory committee system of any other Government agency in the Executive Branch of the Federal Government. Coordination and collaboration among NIH staff in various positions are essential to successfully manage these committees in compliance with the laws, regulations, and policies governing Federal advisory committees.

We hope you will find this overview beneficial in understanding the basic principles and major functions required to manage NIH advisory committees chartered under the Federal Advisory Committee Act, Public Law 92-463. This guide will also facilitate your understanding of the significant role NIH staff play in the successful management of these committees.

Office of Federal Advisory Committee Policy
Office of the Director
National Institutes of Health
August 2012
The Federal Advisory Committee Act (FACA) became Federal law (Public Law 92-463) on October 6, 1972. It provides a system for governing the creation and operation of advisory committees in the Executive Branch of the Federal Government. Through enactment of the FACA, Congress formally recognized the merits of seeking advice and assistance from public participants in the Federal decision-making process. Congress also sought to assure that these committees provided advice that was relevant, objective, and open to the public; acted promptly to complete their work; and complied with reasonable cost controls and recordkeeping requirements. In 1977, President Carter signed Executive Order 12024, designating the General Services Administration (GSA) to monitor committee activities governmentwide.

Federal agencies sponsoring advisory committees must adhere to FACA requirements, as well as administrative guidelines provided by GSA. Agencies must also establish uniform administrative guidelines and management controls to ensure FACA compliance. Agencies are also required to maintain systematic information on the nature, functions, and operations of their advisory committees.

The FACA defines an advisory committee as “any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup which is established by (1) statute or reorganization plan, or (2) established or utilized by the President, or (3) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations, for the President or one or more agencies or officers of the Federal Government.”

The following are primary requirements of the FACA:

- All Federal advisory committees must be chartered and the charters must be renewed every two years. Section 402(b) of the Public Health Service (PHS) Act exempts NIH's Initial/Integrated Review Groups (IRGs), Special Emphasis Panels (SEPs), and Boards of Scientific Counselors (BSCs) from renewing their charters every two years.

- Memberships must be balanced in terms of points of view represented.

- Notice of all meetings must be published in the Federal Register.

- A Designated Federal Official (DFO) must attend all meetings and approve the agendas.

- Minutes of all meetings must be kept and must be certified by the Chairperson of the committee.
Financial records must be kept and each committee must report annually on activities, expenses, and membership. This requirement is accomplished by submitting two annual reports:

a) Annual Report of Closed Meetings.

b) Annual Comprehensive Review of Federal Advisory Committees.

The following are activities not covered by the FACA:

- Committees exempt by statute.
- Committees not actually managed or controlled by the Executive Branch.
- Meetings called to obtain advice from individual attendees, on an individual basis and not from the group as a whole.
- Meetings with a group initiated by Federal officials to exchange facts or information.
- Meetings composed wholly of full-time or permanent part-time officers or employees of the Federal Government.
- Meetings called to perform primarily operational as opposed to advisory functions (operational directive must be in law).
- A meeting called to obtain advice from one individual.
- Meetings initiated by a group to express their views (not to be used recurrently or as a preferred source of advice).
- Meetings of two or more advisory committee members or subcommittee members convened solely to gather information or conduct research, analyze relevant issues and facts, or draft position papers for a chartered advisory committee.
TYPES OF NIH FEDERAL ADVISORY COMMITTEES

Types of Chartered Federal Advisory Committees

NIH uses five major types of advisory committees. They are: National Advisory Councils or Boards, Program Advisory Committees, Boards of Scientific Counselors, Initial/Integrated Review Groups, and Special Emphasis Panels.

National Advisory Council or Board (NAC)

Most NIH Institutes and Centers (ICs) have a National Advisory Council or Board composed of both scientific and public members. Council members perform the second level of peer review of grant and cooperative agreement applications. They also provide advice and recommendations on matters of significance to the policies, missions, and goals of the IC they advise, as well as provide oversight of research conducted by that IC’s intramural program.

Program Advisory Committee (PAC)

These committees advise the IC on specific programs, future research needs and opportunities, management policy issues, and identify and evaluate future extramural initiatives.

Board of Scientific Counselors (BSC)

These committees review and evaluate the research programs, projects, and investigators in the intramural laboratories and programs of the NIH. In addition to the scientific merit of a laboratory or intramural program, the personal qualifications and achievements of individual scientists and the Institute’s Scientific Director are reviewed and evaluated.

Initial/Integrated Review Group (IRG)

These committees perform the first level of scientific and technical peer review of grant applications, cooperative agreements, or contract proposals. In the Center for Scientific Review (CSR), these groups are referred to as Integrated Review Groups.

Special Emphasis Panel (SEP)

These committees also function as IRGs performing the scientific and technical peer review of grant applications, cooperative agreement applications, or contract proposals.
Types of Subgroups

Subcommittee

Most NIH committee charters contain language permitting the authorized membership, commonly referred to as the parent committee, to establish standing or ad hoc subcommittees. Subcommittees may be utilized to subdivide a workload or to deal with issues in specific substantive areas. Subcommittees may be composed of non-members and selected members of the chartered or parent advisory committee.

Standing and ad hoc subcommittees at NIH must follow all applicable FACA requirements. These include balanced membership and publication of meeting notices in the Federal Register. An Executive Secretary (ExecSec) or Scientific Review Administrator (SRO) must attend all meetings, minutes must be certified by the subcommittee Chair, and financial records must be kept. In addition, record keeping procedures must be followed as defined in NIH Manual Policy 1743 - "Keeping and Destroying Committee Management Records."

Standing subcommittee: Subcommittee that meets on a continuing basis.

Ad hoc subcommittee: Subcommittee established to work on a specific project or issue for a short, usually predetermined, length of time.

Working Group

NIH chartered advisory committees often need to assemble groups of outside experts to provide individual advice or to serve as fact-finding bodies to gather information, to analyze relevant issues and facts, and to draft proposed position papers for final deliberation by chartered advisory committees. At NIH, these groups are referred to as working groups. Working groups are exempt from the Federal Advisory Committee Act under General Services Administration (GSA) Regulations 41 CFR Parts 102-3.25 and 102-3.35.

In general, the requirements of the Act and the policies of Federal Advisory Committee Management do not apply to subcommittees of advisory committees that report to a parent advisory committee and not directly to a Federal officer or agency (Part 102-3.35). The term subcommittee used in this instance refers to any group reporting directly to a chartered advisory committee rather than a Federal official.

“Utilized,” for the purpose of the Act, does not have its ordinary meaning. A committee that is not established by the Federal Government is “utilized” within the meaning of the Act when the President or a Federal office or agency exercises actual management or control over its operation. 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. NIH working groups are exempt
from the FACA since the agency does not have actual management or control of the working group. Working groups are convened by the chartered advisory committee and report directly to the committee, not Federal officials.

OFACP Policy Announcement 2000-01, revised 6/14/2005: "Working Groups at the National Institutes of Health (NIH)" provides additional guidance on the use and operation of working groups. 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 and OFACP should be consulted, as appropriate, before a working group is convened.

**Conferences and Workshops**

Conferences and workshops are convened to inform the public or scientific community on health, well-being, programmatic, and health policy issues and are not generally subject to FACA.

**FEDERAL STAFF ROLES AND RESPONSIBILITIES**

Numerous NIH staff have responsibility for the management of Federal advisory committees. However, this list is not all inclusive of staff required to fully manage an NIH Federal advisory committee. The following Federal staff and their roles and responsibilities are crucial to this process:

*Office of Federal Advisory Committee Policy (OFACP)* - responsible for the oversight of all NIH Federal advisory committees established and operated under FACA. Develops policy and provides guidance, resources, and training for the NIH.

*Institute/Center Committee Management Officer (IC CMO) and Office of the Director (OD) Liaisons* - responsible for the oversight of their IC advisory committees established and operated under FACA. Provides guidance, training, and assistance to the Designated Federal Official (DFO) and staff on various facets of managing advisory committees.

*Designated Federal Official (DFO)* - responsible for the operation of their IC’s advisory committees and must be present at each committee and subcommittee meeting. The terms Scientific Review Administrator (SRO) and Executive Secretary (ExecSec) are used at NIH to denote the DFO role.

*Grants/Contracts Technical Assistant (GTA/CTA)* - assists the ExecSec/SRO in the administration of a committee, usually a scientific and/or technical peer review committee.
ESTABLISHMENT OF FACA COMMITTEES

All advisory committees meeting the criteria specified in FACA, as amended, must be chartered in accordance with section 9(c) of the Act. FACA states, “No advisory committee may meet or take any action until a charter has been filed by the Committee Management Officer (CMO) designated in accordance with section 8(b) of the Act, or by another agency official designated by the agency head.” The charter must be prepared and filed with the agency head, the standing committees of the Senate and House of Representatives having legislative jurisdiction of the agency, and the Library of Congress. The filing date is the official date of establishment for the advisory committee.

A charter is essential for defining the structure and function of a committee. It also describes the roles and responsibilities of members and staff, and may define the quorum for meetings. A charter is a public document that is provided to the public upon request.

A great deal of thought and consideration must be given to the role of the committee prior to its establishment. If the proposed committee meets FACA criteria, several factors should be considered before establishing a Federal advisory committee:

- Are there similar committees in the agency performing the same function?
- Are there other routes available for accomplishing goals and performing functions without establishing an advisory committee? Alternate methods may include holding public hearings, utilizing an existing group, creating a working group under an existing committee, obtaining individual opinions by using a mail ballot, and other options. However, if a mail ballot is sent to more than 10 persons, the collection of information is subject to the provisions of the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

NOMINATION AND APPOINTMENT OF MEMBERS

Members of NIH advisory committees are appointed by the Director, NIH; the Secretary, Department of Health and Human Services (HHS); or the President. In a few exceptional cases, IC Directors are authorized to appoint members. Specific policies and procedures for selecting and nominating members to NIH advisory committees are outlined in the NIH Committee Management Handbook, which can be found at the following web site address: http://ofacp.od.nih.gov/index.asp.
Preparation of Nominations

The nomination of members is a major responsibility of the advisory committee’s ExecSec/SRO. This activity involves long-range planning and obtaining suggestions and information from many different sources.

Primary considerations in the nomination process for all advisory committees are the appointment of highly qualified individuals, and adherence to legislative, departmental, and NIH policies regarding the composition of all advisory committees. It is imperative that the ExecSec/SRO, IC CMO, and OFACP staff communicate and collaborate on an ongoing basis in order to accomplish both requirements.

The following must be taken into consideration when proposing candidates for membership:

- Appropriate scientific or technical expertise, interest, or knowledge;
- Committee service (current and previous service on NIH committees);
- Balance in membership (gender, ethnicity, race, and geographic distribution);
- Member's affiliation (institution, organization, or Federal Government); and
- Membership rotation.

CONFLICT OF INTEREST

A conflict of interest occurs when a Federal or non-Federal member has a personal, professional, or financial interest that could affect the member’s objectivity relating to committee matters. Every effort must be made to avoid real and apparent conflicts whenever possible. It is the responsibility of each advisory committee member, working with the ExecSec/SRO, the IC Deputy Ethics Counselor, and the IC CMO, to identify and resolve potential conflicts.

Special Government Employees (SGEs)

Criminal statute 18 U.S.C. 208(a) prohibits Federal employees, including Special Government Employees (SGEs), from participating personally and substantially in particular matters that could affect their interest or the interests of people having specific associations with the SGE (such as a spouse, minor child, close professional associate, or employers). SGEs are appointed and employed to perform temporary duties on an intermittent basis (less than 130 days in a calendar year), with or without compensation. SGE members may serve on National Advisory Councils, Program Advisory Committees, or Boards of Scientific Counselors.

All new SGE advisory committee members must file a “Confidential Financial Disclosure Report” OGE 450 form to determine actual or potential conflicts between the member’s public responsibilities and private interests and activities. If a real or potential conflict or appearance of conflict is determined to exist, the individual must recuse himself during specific deliberations. Where permissible by law, the IC Deputy Ethics Counselor may waive the requirements if the
need for a member’s service outweighs the risk of potential conflict. The member’s financial information is updated and reviewed 30 days prior to each meeting during their membership on the committee. SGE members are required to receive annual ethics training. IC CMOs maintain documentation of the annual training, as well as any additional ethics training provided.

Members may also complete a post-review certification at the committee meeting, confirming that they did not participate in any deliberations that might pose a conflict of interest. Refer to NIH Manual Policy 1810-1, "Procedures for Avoiding Conflict of Interest for NIH Special Government Employee (SGE) Advisory Committee Members" for specific guidance and procedures on these matters. The information can be found at the following web site address: http://www1.od.nih.gov/oma/manualchapters/management/1810-1/.

The Emoluments Clause of the U.S. Constitution applies to all U.S. Government employees, including SGEs. The Clause places constitutional limitations on a SGE advisory committee member's concurrent employment by a foreign government, including positions with government-operated foreign universities. The clause prohibits SGEs from receiving any gift, emolument, office, or title of any kind whatsoever from a foreign state. The Emoluments Clause applies at all times during the SGE’s advisory committee appointment. To determine if there is or could be a violation or potential violation of the Emoluments Clause, all new SGE advisory committee members must complete a "Foreign Activities Questionnaire" HHS-697 form. Current SGE members are required to complete this form yearly during their advisory committee appointment, before the first committee meeting of each calendar year.

**Initial/Integrated Review Group (IRG) Members and Special Emphasis Panel Participants**

Members and participants of IRGs must complete the NIH Pre-Review and Post-Review Conflict of Interest Certification forms. The Pre-Review form must be completed by members and reviewed by appropriate officials prior to each meeting to ensure no real or apparent conflict of interest exists. A conflict may result in a grant application being moved to another IRG or, in the case of contract proposals, a member becoming ineligible to serve for a particular meeting.

The Post-Review form certifies that members recused themselves from deliberating on a specific application contract that may have been in conflict. The appropriate staff should address each situation individually. Specific guidelines for these situations are referenced in the Scientific Review Administrator Handbook.

**MEETING REQUIREMENTS**

OFACP staff, IC CMOs and OD liaisons, ExecSecs/SROs, and other NIH staff work together to ensure NIH Federal advisory committee meetings are held in compliance with FACA requirements. There are also a number of HHS and NIH policies that must be adhered to for meetings held under FACA auspices. These requirements include:
Federal Register Notices – Notice in the Federal Register is required at least 15 calendar days prior to an advisory committee meeting. Section 10(a)(1) of FACA states that each advisory committee meeting will be open to the public. However, advisory committee meetings may be closed, or partially closed, to the public based on exemptions in the “Government in the Sunshine Act” (Public Law 94-409, September 13, 1976).

**Agenda** - In accordance with section 10(3)(f) of the FACA and HHS policy, meetings and agendas must be approved by the ExecSec/SRO. The agenda must include the following information: a) date(s), approximate time(s), and location of the meeting; b) designated open and closed portions of the meeting; c) appropriate statements concerning reasons for closing a meeting, when applicable; and, d) a list of all matters to be discussed at the meeting. An agenda must be available for public distribution.

**Meeting Management** - In accordance with section 10(3)(e) of the FACA, the ExecSec/SRO is responsible for approving or calling the meeting, approving the agenda, and attending the meeting. The ExecSec/SRO is authorized to adjourn the meeting when it is in the public interest to do so, and may chair the meeting when so directed by the agency head.

**Minutes/Summaries** - Section 10(3)(c) of the FACA and HHS policy require that meeting minutes include the following: a) time; b) date; c) location of the meeting; d) a list of advisory committee members and Federal employees in attendance; e) name of any member of the public who presents an oral or written statement; f) accurate description of matters discussed and resolutions reached, if any; g) copies of all reports received, issued, or approved by the advisory committee; and h) a designation of portions of the meeting that were open or closed to the public.

The ExecSec/SRO must ensure that minutes be prepared, reviewed, and certified by the Chair within 90 calendar days of the meeting; meeting summaries must be prepared within 14 working days.

**TRAVEL AND HONORARIUM**

NIH advisory committee members are reimbursed for travel costs and receive honoraria. The type of member or consultant attending the meeting determines the mechanism by which a member will be reimbursed for travel. The following reimbursement methods are used:

**Federal Travel Order** – Standard Form HHS-1 reimburses the cost of transportation, per diem, and miscellaneous expenses for:

- Special Government Employees serving on NACs, PACs or BSCs. Honoraria for these members are paid through the Government payroll system.
- Federal Ex Officio Members serving on NACs or PACs.
- Federal Members serving on NACs, PACs, BSCs, IRGs, or SEPs.
Scientific Review and Evaluation Activities (SREA) system was revised in 2005. The U-09 Cooperative Agreement mechanism was replaced by a flat-rate method. CSR oversees the modified SREA structure. Basic changes include:

- Reviewers will no longer need to pay for their sleeping rooms and be reimbursed for these charges. Instead, sleeping rooms will be billed to the NIH. Reviewers will still need to provide a credit card to pay for ancillary fees such as internet access, movies, or any food billed to the room.

- Reviewers will receive a "Flat-Rate" reimbursement for their meals and incidental expenses, making the need for vouchers obsolete.

- Payment of honoraria and the Flat-Rate reimbursements will be made by electronic funds transfer rather than by a paper check. This change requires reviewers to register on a U.S. Treasury Web site (Central Contractor Registration or CCR).

Further information can be found at CSR’s SREA website, located at:
http://cms.csr.nih.gov/PeerReviewMeetings/SREAProgram/.

Professional Services Contract reimburses non-member participants for cost of transportation, per diem, miscellaneous expenses, and honoraria for participation in a NAC, PAC or BSC meeting.

RECORD KEEPING

NIH Manual Policy 1743 - "Keeping and Destroying Committee Management Records" defines the disposition of Federal advisory committee records. The ExecSec/SRO, IC CMO, OD Liaison, and OFACP staff are responsible for these records. This policy is available on the OFACP web site. Each committee must maintain an official meeting file.

Official Meeting File - The official meeting file is maintained by the ExecSec/SRO, IC CMO, or OD Liaison. Each meeting file, at a minimum, should contain a membership list, agenda, reports, conflict of interest documentation (unless stored separately), minutes, and all handouts available during the open session of the meeting.
COMMITTEE REPORTS

As required by FACA, HHS, and NIH, reports are prepared through extensive analysis relating to all aspects of advisory committee operations. These reports are submitted to the President, the Congress, the Office of Management and Budget, the General Accounting Office, the Secretary of Health and Human Services, the General Services Administration, and the Department Committee Management Officer. These reports are available upon request.

Major reports include:

- **Annual Comprehensive Review of Federal Advisory Committees**
  The FACA requires that the President report to Congress annually on advisory committee membership, costs, and activities. This report identifies the activities and accomplishments of each advisory committee, dates of all meetings, membership lists, actual operating costs for the fiscal year, estimated operating costs for the next fiscal year, and other data pertaining to the activities of advisory committees.

- **Annual Report of Closed Meetings**
  Section 10(d) of the FACA requires that a written report be issued annually giving a summary of all activities and related matters of each advisory committee. HHS policy requires that the following information be included in each report: function of the committee, a list of members and their addresses, dates and places of meetings, and a summary of committee recommendations and activities. Certified meeting minutes or meeting summaries fulfill the requirements for this report.

- **Female/Minority Report**
  This report, required by HHS, includes gender, ethnicity and race distribution for all members serving on NIH advisory committees.

- **Waivers Granted Report**
  A report is made to HHS twice a year on the number and types of waivers of HHS committee membership policy issued by NIH officials. The report includes the names of individuals receiving waivers and the types of waivers approved.

- **Annual Secretarial Vacancies Report**
  A list of scheduled vacancies for each committee whose members are appointed by the Secretary, HHS. This report includes the name of the committee, date of the vacancies, and expertise required.

- **Annual Ethics Report**
  A statistical report on the number of SGEs required to file form OGE 450, “Confidential Financial Disclosure Report,” and to receive annual ethics training. Section 402(e) (1) of the Ethics in Government Act, as amended, requires this report.
In addition to the required reports, there are numerous congressional and statistical reports compiled throughout the year.

**COMMITTEE MANAGEMENT APPLICATION OF IMPAC II**

The Committee Management (CM) Application of the Information for Management, Planning, Analysis, and Coordination system (IMPAC II) is a client-server application providing data entry, basic ad hoc querying, and reporting capabilities associated with establishing, amending and re-chartering committees/subcommittees, the nomination and appointment of members to these committees/subcommittees, the managing of people data, and maintenance of the data associated with committee meetings and the Federal Register Notice.

The Committee Management application provides the following functionality:

1. Tracks the details of existing committees, creates newly chartered committees and subcommittees records, and tracks each committee’s affiliations. Tracks the committee’s status of existing nominees or currently serving members.

2. Perform a NIH wide query within the IMPAC II database to determine a person’s availability to serve on an NIH Committee and to view their person information or add the person to the database.

3. Develops committee membership by entering requests for nominations, recording the status of a nominee, and tracks the qualifications of an appointee/member through the nomination and appointment process. Tracks the reviewing process that clears financial interest documents and COI waivers for committee nominees/members and meeting attendees.

4. Prepares the nomination slate package for submission to the ICD CMO, the NIH CMO, and approving offices for clearance.

5. Sets up review meetings, meeting rosters, meeting agenda details, combining subcommittee meetings with parent meetings and facilitates the generation of the Federal Register Notice.
RESOURCES AND WEB SITES

Below is a list of useful resources and web site references related to NIH's management of Federal advisory committees.

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### IMPAC II

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### OFFICE OF EXTRAMURAL RESEARCH

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### FEDERAL REGISTER

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