

# NATIONAL INSTITUTES OF HEALTH COMMITTEE MANAGEMENT HANDBOOK

## Council Charter Establishment/Renewal

NIH Letterhead – *Times New Roman 11point*  
For charters signed by another approving official  
(use appropriate letterhead)

### Chapter III - Illustration 1

Key to text: Black text is standard text that should be followed. Red identifies text that is unique, for example IC name, expertise, or costs for this individual committee. Blue provides some explanations and reasons why certain paragraphs contains specific information.

### CHARTER (*Times New Roman 12 point*)

#### [NAME OF NATIONAL ADVISORY COUNCIL]

If amending a current charter, replace “Charter” with “AMENDED CHARTER” as the title. If the name of the committee is changing, state the new Name of Committee followed by (formerly (insert full former name).]

#### **COMMITTEE’S OFFICIAL DESIGNATION**

[Official Name of Advisory Council]

Official Name of Advisory Council should be pulled from the FACA Database.

#### **AUTHORITY**

Required by 42 U.S.C. 284a, section 406 of the Public Health Service (PHS) Act, as amended. The [insert full name of Council] (Council) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2).

The authority cited above is for most NIH National Advisory Councils. If an IC uses a different authority to establish the Council, that authority must be cited here. If the authority is not statutory, for example, NCATS Council, the council will be “*Authorized*” not Required.

#### **OBJECTIVES AND SCOPE OF ACTIVITIES**

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) and the Director, [insert full Institute/Center name] (full IC acronym), also referred to as [insert Institute or Center (as appropriate)] on matters related to the activities carried out by and through the [insert Institute or Center (as appropriate)] and the policies respecting these activities.

## **DESCRIPTION OF DUTIES**

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for study, investigation, or research on **[INSERT IC BASIC SCIENTIFIC AREAS (i.e., drug abuse)]**, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the **[insert Institute or Center]**, may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the Institute was established and, with the approval of the Director of **[insert IC ACRONYM]**, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public.

The Council will prepare triennial reports describing the manner in which the Institute has complied with section 492B of the PHS Act, as amended, which sets forth requirements addressing the inclusion of women and members of minority groups as subjects in clinical research conducted or supported by the National Institutes of Health (NIH). Each report will be submitted to the Director, **[insert IC ACRONYM]**, for inclusion in the triennial report submitted to Congress by the Director, NIH, pursuant to section 403 of the PHS Act, as amended. Each triennial report prepared by the Council shall include each of the following:

1. The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.
2. The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.
3. For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—
  - (a) have been completed during such reporting period; and
  - (b) are being carried out during such reporting period and have not been completed.
4. The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with section 492B(c)(2)(A) of the PHS Act, as amended.

This is standard language for Councils established under 42 U.S.C. 284a, section 406 of the Public Health Service (PHS) Act, as amended. Councils established under other authorities may have different language in this section.

### **AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS**

The Council will advise the Secretary and the Director, **[insert IC ACRONYM]**.

### **SUPPORT**

Management and support services will be provided by the **[Insert Office/Program]**, **[IC ACRONYM]**.

The office or program area cited here represents the area responsible for providing funds to cover the costs incurred by the operation of the Council such as travel and per diem for members and other costs associated with holding a meeting.

### **ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS**

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is **[Insert Amount]**. The estimated annual person-years of staff support required is **[Insert % of Time]**, at an estimated annual cost of **[Insert Amount]**.

When establishing a committee, a Financial Operating Plan (FOP) is developed that estimates costs on the number of members, number of meetings, and NIH staff time needed to manage the committee. The projected costs are inserted in the paragraph above.

### **DESIGNATED FEDERAL OFFICER**

The Director, **[insert IC ACRONYM]**, will assign a full-time or permanent part-time **[insert IC ACRONYM]**, employee to serve as the Designated Federal Officer (DFO) of the Council. In the event that the DFO cannot fulfill the assigned duties of the Council, one or more full-time or permanent part-time **[insert IC ACRONYM]** employees will be assigned as DFO and carry out these duties on a temporary basis.

The DFO will approve all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH or Director, **[insert IC ACRONYM]**.

The Director, **[INSERT IC ACRONYM]** shall designate a member of the staff of the Institute to serve as the Executive Secretary of the Council. The staff member assigned to serve as DFO will also be designated to serve as the Executive Secretary.

### **ESTIMATED NUMBER AND FREQUENCY OF MEETINGS**

Meetings of the full Council will be held at the call of the Chair (with the DFO's approval) or upon request of the Director, **[insert IC ACRONYM]**, not less than **[Insert number for**

**statutory committees or approximately (number) for discretionary committees]** times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Council's functions, dates and places of meetings, and a summary of the Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

### **DURATION**

Continuing.

### **TERMINATION**

Unless renewed by appropriate action, prior to its expiration, the Charter for the **[insert full Council name]** will expire two years from the date the charter is filed.

### **MEMBERSHIP AND DESIGNATION**

The Council will consist of not more than 18 members appointed by the Secretary and at least 5 nonvoting ex officio members. The nonvoting ex officio members will include the Secretary; the Director, NIH; the Director, **[insert IC ACRONYM]**; the Under Secretary for Health of the Department of Veterans Affairs **or** the Chief Dental Director of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Appointed members must be eligible to serve as Special Government Employees (SGEs) and will serve as SGEs. Two-thirds of the appointed members will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the **[insert IC ACRONYM]**. One-third of the appointed members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

Appointed members will be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term. The Secretary shall make appointments in such a manner as to ensure that the terms of the appointed members do not all expire in the same year. An appointed member may serve 180 days after the expiration of that member's term if a successor has not taken office. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office.

The Chair of the Council will be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, [IC ACRONYM], to be the Chair. The term of office of the Chair will be two years.

The Office of General Counsel (OGC) has determined that Councils established under 406 states that none of the appointed members may be federal employees. The PHS Act, states that all federal members serve as ex officio. Follow the OGC Federal Member Guidance on specific ex officio members for each Council. For new establishments, OFACP staff will obtain advice from OGC on the appointment of Federal members.

## **SUBCOMMITTEES**

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee/working group may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee will be three members. Ad hoc consultants are not members, do not count towards the quorum, and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

## **RECORDKEEPING**

Meetings of the Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Council and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

## **ESTABLISHMENT FILING DATE or FILING DATE**

Establishment Date is used when filing a charter for the first time. Filing Date is used when renewing a charter. OFACP Program Analyst will enter date for an establishment. The IC CMO will insert renewal date and keep date if submitting an amendment.

## **AMENDED FILING DATE**

Only include this section if amending an advisory committee. OFACP Program Analyst will enter date for an amendment.

**APPROVED:**

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Date

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[Title of Official Approving Charter]

Signature lines are dependent on authority used to establish or renew and advisory committee.  
Consult with assigned OFACP Program Analyst or other OFACP staff member for guidance.