NIH Policy Manual

1710 - Publishing and Maintaining Policies in the NIH Policy Manual

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Transmittal Notice

1. **Explanation of Material Transmitted:** This chapter describes the National Institutes of Health (NIH) Policy Manual, comprised of individual chapters, commonly referred to as Manual Chapters. The NIH Policy Manual is a central location for staff to easily find NIH-wide policy. This chapter establishes the requirements for preparing, reviewing, approving, and publishing policies within the NIH Policy Manual. This issuance clarifies requirements, roles and responsibilities for publishing and maintaining NIH-wide policy in the NIH Policy Manual.
2. **Filing Instructions:**

   Remove: NIH Policy Manual, Chapter 1710, dated 11/06/2009
   Insert: NIH Policy Manual, Chapter 1710, dated 07/01/2016

PLEASE NOTE:

- Contact the Issuing Office, listed above, for questions regarding this chapter.
- For information regarding the NIH Policy Manual, go to https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

This chapter describes and establishes the requirements for preparing, reviewing, approving, and publishing policies within the National Institutes of Health (NIH) Policy Manual.

B. Scope

The policy in this chapter applies to all NIH Institute or Center (IC) or Office of the Director (OD) Offices and any personnel involved in the development, issuance, use, and maintenance of NIH-wide policies in the NIH Policy Manual.

C. Background

The NIH Policy Manual provides NIH staff with a central location to easily find NIH-wide policy. It is an official mechanism for issuing NIH-wide policy and is comprised of individual chapters, commonly referred to as Manual Chapters.

Manual Chapters are accessible online and are available in both searchable web and Portable Document Format (PDF) versions. Specific chapters related to Information Technology, Privacy and Grants are limited to viewing only by NIH staff. Policies published in the NIH Policy Manual communicate essential requirements or mandatory procedures. It is appropriate to write a Manual Chapter when an NIH component plans to issue a policy that affects: 1) a significant number of people at NIH; or 2) more than one IC or OD component. Many Manual Chapters are initiated from higher level government authority such as legislation, regulation, and Department policies. In addition, a formal and structured development and review process ensures that all stakeholders are involved and that the result is a policy that is sound, has broad organizational acceptance and is consistent with other policies and the overall mission of the agency.

Issuing Offices (IOs) are responsible for writing new, and revising or rescinding existing chapters that fall within their functional area of responsibility.

Note: IOs may develop chapters to communicate what policies are issued in the NIH Policy Manual and what policies can be found in another identified source. See Appendix 3 for more information.

D. Policy

1. **Principles** - NIH-wide policy published in the NIH Policy Manual is defined by the following principles:

   NIH-wide Policies DO:

   - Communicate essential requirements or mandatory procedures; and
     - Affect a significant number of people at NIH; or
     - Affect more than one NIH IC or OD component.

   NIH-wide Policies DO NOT:

   - Communicate optional guidance or preferred procedures (e.g., handbooks, non-required SOPs);
   - Communicate information issued primarily for use by external audiences (e.g., grantees, the public); and
   - Conflict with or be less stringent than higher level policy.

2. **Categories** - NIH-wide policy is organized into two categories:

   Standing Policy: A governing principle in support of the NIH mission that standardizes and directs actions that change infrequently and set a course for the foreseeable future. IOs must ensure Standing policies:

   - Communicate essential requirements and functional responsibilities (e.g., what to do and who does it); or
   - Specify mandatory procedures to implement and comply with the requirements (e.g., how to do it); and
   - Are reviewed no less than every five years.

   Emergency or Temporary Policy: On rare occasions, a need may arise for policy issuance to be completed within a short time period. For example, new legislation or an executive order may alter existing programs or administrative practices and affect current policies and procedures at NIH. In these cases, the IO may need to establish policy quickly, with streamlined review and clearance as outlined in this Chapter. These policies communicate emergency or temporary requirements.

   - Emergency policies are effective up to one year after the initial issuance date. It is expected that needed changes to existing policy or drafting of a related Standing policy will be completed within the one-year period.
   - Temporary policies must have a predetermined expiration date, not to exceed two years, after the issuance date. The policy will either no longer be needed or policy elements will be incorporated into an appropriate Standing policy prior to expiration.
   - In the event of conflicts with existing policy, affected portions of existing policy will be rescinded until the short-term policy either expires or is converted to Standing policy.

E. Responsibilities

Responsibility for NIH-wide policy issued in the NIH Policy Manual is shared among several entities within NIH. Primary roles and responsibilities of various organizations within NIH are described below:

1. **Executive Officers (EOs) and OD Office Directors**

   a. Designate a Manual Chapter Coordinator (MCC), to serve as a liaison between the IC/OD Office and the Office of Management Assessment (OMA), if their office issues policy in the NIH Policy Manual or needs to receive notification of policy updates. EOs or OD Office Directors may designate multiple MCCs.
   b. Send MCC designations in an email to policymanual@nih.gov, specifying the MCC's name, organization, mailing address, telephone number(s), and email address.

2. **Issuing Offices (IOs)**

a. Monitor the policy subject area to determine the need to revise or rescind an existing policy, or publish a new policy.
b. Work with the designated MCC when executing the procedures described in Section F, Procedures.
Note: If MCC has not been designated, work with IO leadership to identify a MCC and notify OMA.
c. Contact OMA to discuss the development of a new NIH Manual Chapter and publishing requirements.
d. Maintain all NIH Manual Chapters within their area of functional responsibility and ensure accuracy and relevance of all policy content.
e. Review their chapters whenever there are substantive policy changes, or within 5 years of the last release (whichever comes first), and revise or rescind accordingly.
f. Ensure that policy meets all publishing requirements outlined in this chapter and is grammatically correct, free of typographical errors, and uses plain language.
g. Ensure NIH Manual Chapters are accurate and up-to-date by providing the appropriate stakeholders or Subject Matter Experts (SME), referred to as Reviewing Offices in this chapter, an opportunity to review new or revised NIH Manual Chapters. The review must be properly documented to support decision-making and approval. IOs can use Section A of NIH Form 414-6 *NIH Manual Chapter Review Record*. The IO must :

    1. Provide the organization or identified individuals with assigned responsibilities (Reviewing Offices) in the policy with the opportunity to review all or selected parts of the chapter;
    2. Ensure that the NIH Office of Human Resources (OHR), Workforce Relations Division (WRD) is consulted and reviews the chapter at early stages for potential Collective Bargaining issues; and
    3. Obtain concurrence from the NIH Head of the Contracting Activity (HCA) for contract or acquisition policies.

h. Maintain all substantive comments received from the Reviewing Offices and the responses from the IO.
i. Email draft chapters to OMA, policymanual@nih.gov, for OMA review and concurrence, and Office of the General Counsel (OGC) review and clearance.
j. Incorporate OMA and OGC review comments as appropriate and/or necessary into the chapter, or provide an explanation why a comment cannot be incorporated.
k. Prepare the chapter in final form and ensure it meets the accessibility requirements in Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended.
l. Submit the chapter to the appropriate official for approval (see Section E.8. below).
m. Send the approved chapter to OMA (see Section F.1.h. for details).

n. Review the final chapter after it is posted on the test website and notify OMA of any corrections, or provide final approval to publish.

Note: In cases where there is more than one IO for a chapter, a primary IO must be designated to coordinate future revisions or rescissions.

3. **Manual Chapter Coordinators (MCC)**

   a. Monitor the policy renewal timeframes and subject areas to determine the need to revise or rescind an existing policy, or publish a new policy.
   b. Contact OMA to initiate the process when the need for a policy action has been identified.
   c. Subscribe to the NIH-MANUAL-CHAPTERS email Listserv and alert appropriate personnel of issuances.
   d. Maintain knowledge of this policy, and all policies issued in the NIH Policy Manual by the MCC's organization.
   e. Coordinate with IOs to ensure requirements of this policy are met, including compliance with Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended.
   f. Sign Section C of NIH Form 414-7 before a chapter is submitted for approval and posting.

4. **Office of Management Assessment (OMA)**

   a. Supports the IOs and MCCs with revising or rescinding an existing policy, or writing a new policy.

      Note: OMA is not responsible for ensuring the accuracy of policy content unless serving as the IO.

   b. Ensures appropriate review of draft chapters by OMA functional area staff, and the HHS OGC.
   c. Refers the IO to the NIH Forms Officer when new or revised NIH forms are prescribed by the chapter.
   d. Publishes final policies in the NIH Policy Manual website that are compliant with Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended.
   e. Announce new, revised, or rescinded NIH Manual Chapters through the NIH-MANUAL-CHAPTERS email Listserv to alert subscribers.
   f. Maintain the permanent official record of each chapter issuance.

5. **Office of the General Counsel (OGC), Department of Health and Human Services (HHS)**

   a. Reviews all Manual Chapters for legal supportability and consistency and/or avoidance of conflict with applicable government ethics statutes and regulations, and implementing policies established by the NIH, the HHS, the Office of Government Ethics or other relevant authority. OGC will attempt to complete its

review within 30 working days of receipt, however more time may be needed depending on the length and/or complexity of a particular Manual Chapter. OGC will notify OMA if additional time is needed to discuss legal or ethical concerns that require a more extensive review.

b. Through its Public Health Division (OGC/PHD), Ethics Division (OGC/ED), and as necessary, General Law Division (OGC/GLD), indicates clearance and/or identifies comments. Where OGC clearance is contingent on making one or more changes to the draft Manual Chapter, OGC will note the contingency, as appropriate, in an accompanying comment.

6. **NIH Personnel**

a. Comply with the policies and required procedures identified in the NIH Manual Chapters.
b. Report inconsistencies, conflicts with other policy, or errors to the IO, MCC and OMA.

7. **Reviewing Offices**

a. Review the chapter and provide comments to the IO within five working days of receipt; notify the IO if additional time is needed for review.
b. Use the format identified by the IO to indicate concurrence with the chapter or to document any comments, questions, or suggested changes.

8. **Approving Officials**

Approvals are required to enact a NIH Manual Chapter and are documented by obtaining signatures on the approval line in Section C of NIH Form 414-7 *NIH Manual Chapter Concurrence and Approval Record*. Listed below is a summary of policy areas and the corresponding approvals required for each area:

Policy Area	Final Approval
General administrative issues (e.g., ethics, property, acquisition)	NIH Deputy Director for Management (DDM)
Finance, travel issues (e.g., gifts, lodging)	Director, Office of Financial Management (OFM), NIH Deputy Chief Financial Officer (CFO)
Human resource issues (e.g., compensation, personnel, training)	Director, Office of Human Resources (OHR)
Information Technology (IT) and security issues (e.g., email, networks)	NIH Chief Information Officer (CIO)
Intramural issues (e.g., animals, laboratories)	NIH Deputy Director for Intramural Research (DDIR)
Extramural issues (e.g., grants)	NIH Deputy Director for Extramural Research (DDER)

Note: Some policies may cover more than one area as noted above. In these cases, the IO should discuss necessary clearances and final approval with OMA.

F. Procedures

1. **Standing Policy** - To establish, update or rescind Standing policy, the IO or MCC must complete the following:

    a. Contact OMA to discuss publishing requirements, rationale for policy action, and to obtain a chapter number, templates, or latest versions for editing. OMA will assist the IO or MCC with revising or rescinding an existing policy, or writing a new policy.
    b. The IO or MCC will draft the chapter in Microsoft Word using the elements and format discussed in Section G;
    c. The IO or MCC will send the draft chapter concurrently to appropriate Reviewing Offices (for examples of required concurrences, see Section E.2.g.) for their review and comment;
    d. Incorporate appropriate Reviewing Office comments into the draft or provide a response to justify any rejection of comments, obtain a subsequent clearance from the Reviewing Office that originally provided the comment (if needed), and retain the official record of comments;
    e. The IO or MCC will submit the final draft to OMA at policymanual@nih.gov;
    f. OMA will ensure appropriate review of final drafts by OMA functional area staff, and the HHS Office of the General Counsel (OGC) – Public Health Division (OGC/PHD), Ethics Division (OGC/ED) and, as necessary, General Law Division (OGC/GLD);
    g. The IO or MCC will incorporate appropriate comments from OMA, OGC/PHD, OGC/ED and, as necessary, OGC/GLD, into the policy or provide an explanation of why a comment cannot be incorporated in order to obtain final OMA and OGC clearance;
    h. The IO or MCC will prepare and route the chapter and NIH Form 414-7, following the routing process of the IO, for final approval in accordance with Section E.8.;
    i. The IO or MCC will send the final, approved package to OMA via email at policymanual@nih.gov;

        1. The final package for new or revised chapters will include a Word version of the transmittal sheet, complete chapter and appendices, and a signed NIH Form 414-7.
        2. The final package for rescinded chapters will only include the transmittal sheet and signed NIH Form 414-7.

    j. OMA will post the final policy on the test website for the IO/MCC review and approval;

k. The IO or MCC will review the final chapter after it is posted on the NIH Policy Manual test website and notify OMA of any necessary changes; and
l. OMA will publish final policies on the NIH Policy Manual website and send out notification to the NIH-MANUAL-CHAPTERS Listserv.

2. **Emergency or Temporary Policy** - To establish Emergency or Temporary policy the IO must complete the following:

    a. Contact OMA to discuss publishing requirements, need for emergency or temporary policy action, and to obtain a chapter number in the appropriate series;
    b. The IO or MCC will prepare and route the chapter and NIH Form 414-7, following the routing process of the IO, for emergency or temporary approval in accordance with Section E.8.;
    c. Send the final, approved package to OMA via email at policymanual@nih.gov;
    d. Work with OMA to identify all existing policies that may need revision as a result of the new Emergency or Temporary policy; and
    e. If emergency or temporary, draft the Standing policy that will undergo the formal review and approval process identified above to replace the Emergency policy.

G. Required Elements and Format

Prepare the manual chapter in Microsoft Word using the outline format specified in this policy. Templates are available from the NIH Policy Manual website.

1. **Transmittal Sheet:** The cover page must include an explanation for writing, revising, or rescinding the chapter, as well as the removal/release dates and appropriate IO contact information. Rescissions must explain the rationale for rescinding the chapter and indicate, if appropriate, other guidance that is available for use.
2. **Chapter Text:** The body of the chapter that communicates the requirements, responsibilities, and mandatory procedures (if applicable) related to the subject. It is comprised of appropriate sections, beginning with capital letter designations (A, B, C, etc.) similar to those used in this chapter. The following sections are required for all chapters:

    a. **Purpose:** Describes why the policy is needed and summarizes what the policy will communicate to the reader.
    b. **Audience/Scope:** Identifies the target audience and who the policy applies or does not apply to.
    c. **Policy:** Communicates essential requirements, rules and guidelines.
    d. **Roles and Responsibilities:** Assign duties and required steps to the appropriate officials, organizations, or groups who have a stake in carrying out the policy.

    Note: Additional sections may be included if the IO determines that it is appropriate in order to communicate requirements (e.g., Background, Authority, Procedures, References, and Definitions).

3. **Hyperlinks (optional):** Automatic links to other websites.

    a. Each hyperlink must include the complete web address uniform resource locator (URL) after the information.
    b. URLs should appear without delimiters (angle brackets or parentheses).
    c. Hyperlink(s) will only be included within the References section; although the subject or information to be hyperlinked may appear throughout.

4. **Appendix Information (optional):** Supplemental information, optional guidance, or additional procedures that provide more detail for implementing chapter requirements should be included as appendix information. This could include a hyperlink to an internal IO website or other location, or information that is referenced in the chapter (e.g., a list of references, definitions that are too lengthy to include in the chapter text, or other explanatory information that relates to the chapter). Appendices will be numbered and titled (e.g., Appendix 1: [Title]), and comply with Section 508 of the Rehabilitation Act (29 U.S.C. 794d).

H. References and Forms

1. NIH Manual Chapter 1743 *Keeping and Destroying Records*
2. NIH Manual Chapter 1730 *Forms Management*
3. NIH Form 414-6 *NIH Manual Chapter Review Record*: https://oma.od.nih.gov/Lists/DMSFormsList/Attachments/112/NH414_6.pdf
4. NIH Form 414-7 *NIH Manual Chapter Concurrence and Approval Record*: https://oma.od.nih.gov/Lists/DMSFormsList/Attachments/113/NH414_7.pdf
5. NIH Form 414-8 *Example Transmittal Sheet and Chapter Template:* https://oma.od.nih.gov/Lists/DMSFormsList/Attachments/649/Example_MC-template_Transmittal.docx
6. HHS Section 508 information at: http://www.hhs.gov/web/508/
7. Plain Language information at: http://www.plainlanguage.gov; and, Plain Language Initiative at NIH at: http://www.nih.gov/clearcommunication/plainlanguage/index.htm

Appendix 1: Definitions

1. **NIH Policy Manual:** An official policy issuing mechanism for NIH-wide policy, comprised of individual chapters.
2. **NIH-wide Policy:** A governing principle that communicates essential requirements or mandatory procedures that affect 1) a significant number of people at NIH; or 2) more than one NIH IC or OD component.
3. **Manual Chapter:** A common term used when referring to an individual chapter of the NIH Policy Manual.
4. **NIH Personnel:** For the purposes of this chapter, this includes individuals who are NIH federal or contract employees, special volunteers, guest workers, and fellows/interns/residents.

5. **Issuing Office (IO):** An official NIH organization that authors and provides the main subject matter expertise for a specific manual chapter; responsible for writing, developing, and maintaining its manual chapters.
6. **Manual Chapter Coordinator (MCC):** Individual designated by the IC Executive Officer or OD Office Director to support the review and coordination of the Issuing Office's manual chapters. Each IO must have an MCC who will follow the requirements identified in this chapter.
7. **Reviewing Office:** An NIH office having subject matter expertise or stakeholders with assigned responsibilities in the policy (See E.2.g.).
8. **Standing Policy:** A governing principle in support of the NIH mission that standardizes and directs actions that change infrequently and set a course for the foreseeable future.
9. **Emergency or Temporary Policy:** A governing principle in support of the NIH mission that standardizes and directs actions that are used to issue one-time or short-term information.
10. **Functional Series:** An overall topic area used for grouping manual chapters into related subject matter areas.

Appendix 2: Points of Contact

NIH Policy Manual Program:

Office of Management Assessment (OMA)
Division of Management Support (DMS)
301-496-4606
policymanual@nih.gov

NIH Policy Manual Communications:

OMA announces each new, revised, or rescinded policy by email to the NIH-MANUAL-CHAPTERS Listserv to alert NIH. The listserv is located at list.nih.gov.

Manual Chapter Coordinators:

IC and OD Offices that issue policy in the NIH Policy Manual must have a designated MCC. The IOs assign MCCs through the EO or OD Office Director. A complete listing of MCCs can be found at: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters-Manual-System-Contacts.aspx

Office of the General Counsel:

- HHS Office of the General Counsel (OGC), Public Health Division (PHD): Building 31, Room 2B-50, 301-496-6043
- HHS Office of the General Counsel (OGC), Ethics Division (ED): Building 31, Room 2B-47, 301-402-2577
- HHS Office of the General Counsel (OGC), General Law Division (GLD): 330 Independence Ave., S.W., Room 4760, Washington, D.C. 20201, 202-619-0150

NIH Forms Management Program:

Office of Management Assessment (OMA)
Division of Management Support (DMS)
301-496-4606
https://oma.od.nih.gov/DMS/Pages/Forms-Management.aspx

Final Approving Officials:

Contact information for the following Final Approving Officials can be found at: https://execsec.od.nih.gov/contacts/od-staff.asp

- Deputy Director for Management (DDM)
- Director, Office of Financial Management (OFM), NIH Deputy Chief Financial Officer (CFO)
- Director, Office of Human Resources (OHR)
- NIH Chief Information Officer (CIO)
- Deputy Director for Intramural Research (DDIR)
- Deputy Director for Extramural Research (DDER)

Appendix 3: Additional Guidance and Options for Policy Issuing Offices and Manual Chapter Coordinators

1. **Contact:** IOs and MCCs may contact OMA at 301-496-4606 to write a chapter (new, revised, or rescinded) and to discuss procedures, options and next steps. This enables OMA to be aware of upcoming changes and help the IO and MCC throughout the entire process.
2. **Develop High-Level Functional Area Policy:** The IO may publish a chapter or chapters outlining its requirements for policy development within a functional area or subject matter or the requirements for policy issued by the entity. This also communicates the criteria or process to be considered when determining whether the IO will publish policy in the NIH Policy Manual or through a different mechanism.
    - Writing a high-level policy helps to:
        - Reinforce the areas of IO subject matter expertise;
        - Provide a foundation for policy development;
        - Clarify roles and responsibilities;
        - Ensure continuity through staffing changes;
        - Allow flexibilities for issuing targeted policies and guidance; and
        - Identify additional guidance locations for the NIH community.
    - For an example of a high-level policy, see NIH Manual Chapter 2800 *NIH Policy on Information Security Policy Development*
    - For additional guidance or options please contact OMA.

3. **Style and Formatting Tips:**

   - **Identifying Titles:** When identifying names or titles of references, other chapters, forms, etc., simply use *italics* instead of quotations.
   - **Adding Emphasis:** Use **bolding** or *italics* for emphasis, underlined words can imply that there is a hyperlink.
   - **Acronyms:** Fully identify an acronym when it is first introduced and then use just the acronym throughout the remainder of the document. Listing them in an appendix may be an additional option.
   - **Providing Contact Information:** Avoid identifying a person as a point of contact; list an office or position title instead.

Appendix 4: NIH Manual Chapters Functional Series and Numbering

The NIH Office of Management Assessment (OMA), Division of Management Support (DMS) will assign a number for a chapter based on the following functional series, after receiving a request from an IO.

- Emergency or Temporary [any subject area] (0000)
- Management (1000)
- Equal Opportunity (2200)
- Human Resources (2300)
- Ethics (2400)
- Property and Logistics (2600)
- Information Technology (2800)
- Intramural (3000)
- Grants (4000 and 5000)
- Acquisition (6000 – includes Simplified Acquisition and Contract policy)
- Combined Grants and Contracts (7000)