NIH POLICY MANUAL

1184 - Scientific, Technical, and Other Professional Information Presented by NIH Employees: Review, Approval, and Distribution

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1. Explanation of Material Transmitted: The purpose of this chapter is to provide information on the NIH policy and procedures for the review, approval, and distribution of scientific, technical, and other professional information by individual employees (including intramural, extramural, and OD staff). This chapter provides guidelines for written, electronic, or oral presentations, and reiterates the many quality control measures embedded in the scientific process, and at NIH, to ensure that the information disseminated by NIH employees is of the highest quality. Scientific and professional information presented by NIH employees must be considered differently from information presented in other professional settings (such as when scientists from universities or industry labs present information in public forums.) A clear distinction must be made between the presentation of scientific data and the presentation of opinion that may be construed as the position of the agency. It is important to follow the review, approval, and distribution guidelines with your supervisors in order to ensure compliance. This issuance covers only official distribution of scientific, technical and professional information presentation clearance, and other products such as letters to the editor. Employees writing, presenting or otherwise distributing materials in their personal capacities are instructed to consult their ethics officials for applicable rules and restrictions, including those requiring prior approval and limiting the use of title or NIH affiliation.

2. Filing Instructions:

Remove: NIH Manual Chapter 1184, dated 2/27/02
Insert: NIH Manual Chapter 1184 dated 3/10/2008

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Office of Management Assessment, OM, on 301-496-4606.
- Online information, enter this URL: http://www1.od.nih.gov/oma/manualchapters/

A. Purpose: The purpose of this chapter is to provide information on the policy and procedures for the review, approval, and distribution of scientific, technical, and other professional information by NIH employees. The policy covers

intramural, extramural, and OD staff. This chapter provides guidelines for written, electronic, or oral presentation of scientific and professional information by individual employees. Information is required to be consistent with the framework of applicable guidance which may include the OMB and HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, and the NIH Guidelines for Ensuring the Quality of Information Disseminated to the Public, hereinafter referred to as Information Quality Guidelines. See http://ospp.od.nih.gov/infoquality/ for further guidance.

B. Applicability: This chapter applies to the review, approval, and release of any scientific, technical, or other professional information related to the official duties of NIH employees to the public regardless of the medium used for dissemination, e.g., Web, print, audio or video broadcast, etc. These materials include:

- written or electronic reports, lectures, books, chapters, editorials, reviews, proceedings, or abstracts;
- broadcast scripts, audio or video tapes;
- prepared (i.e., not extemporaneous) formal speeches, oral presentations, interviews or commentaries for publication or broadcast;
- official letters-to-the-editor, and
- official correspondence submitted for publication.

Materials are related to the employee's official duties if they:

- Report on or describe work performed as an official duty;
- Draw conclusions, advocate or oppose professional practices or stances on subjects related to NIH activities or mission;
- Evaluate, summarize, or review work by others in an area related to a position or official duty at NIH; or
- State or comment on Federal or agency policies or practices or might be construed as reflecting an official position of the Federal government.

C. Policy: NIH encourages public dissemination of scientific research and other information on public health matters by its employees. Scholarly writing, lecturing, editing, and publishing are an essential part of research. These activities are in the public interest and bring credit and distinction to both the NIH and to the employees themselves. In assisting employees to share information about their official and professional activities, NIH seeks to advance scientific knowledge and contribute to professional education. Ordinarily first report of any scientific research results or other professional findings is made by:

- publication in a scientific or professional journal; or

- presentation at a meeting of a professional organization.

The choice of the journal or meeting to which reports are offered is generally the prerogative of the author(s).

Sometimes the NIH provides "breaking news" to the public on research findings prior to publication in scientific journals and prior to peer review by journals. This is usually the result of an important public health finding, such as publication of the results of a clinical trial result that has immediate health implications. In such cases, there are applicable internal review processes devised to ensure that information disseminated to the public summarizes the facts as NIH currently knows them, and that appropriate disclaimers are attached, if necessary.

There are many quality control measures embedded in the scientific process to ensure that the information disseminated by NIH employees is of the highest quality. NIH expects publications or presentations by NIH employees to meet high standards of quality, make a substantial contribution to the field, and contain sufficient information for the informed audience to assess its validity.

Any non-extemporaneous presentation (written or electronic) by an NIH employee on a subject related to the employee's NIH duties must be reviewed and approved through an internal NIH process. This review process must precede the author submitting material for publication consideration. Formal oral presentations on health policy or practice must also be cleared in advance. (See Section E for review and approval procedures and Section F [“Clearance Not Required”] for exemptions.) All of these procedures are designed to ensure the highest quality of information is made public.

Individual Institutes and Centers (IC), because they vary in structure, size, and mission, have the flexibility to implement the quality and accountability requirements of Federal and NIH guidelines in the most sensible manner for their organization, as long as they ensure appropriate review.

D. Preparation: In preparing a document or presentation for publication, an employee should give particular attention to the following:

> **1. Propriety, Accuracy, and Quality**. Each publication or presentation must be of high quality (including objectivity, utility, and integrity) and accurate both in specific details and in general impressions. It should demonstrate the highest professional and ethical standards, as well as generally accepted standards of good taste. General principles governing the conduct of good science, including data management, publication practices, and authorship can be found in "Guidelines for the Conduct of Research in the Intramural Research Programs at

NIH," (http://www.nih.gov/news/irnews/guidelines.htm).

2. Sufficient Detail for Reproducibility . Where appropriate, supporting data should have full, accurate, transparent documentation. The NIH supports and encourages the timely release and public sharing of final data from NIH-supported studies for use by other researchers and others whenever feasible. Investigators should retain research data long enough to allow others to repeat and analyze the studies. At a minimum data must be retained consistent with applicable record retention requirements. Refer to NIH Manual Chapter 1743 "Keeping and Destroying Records," Appendix 1 for specific guidance. Publication of the data and methods in peer-reviewed journals, or making data available through data archives, are two accepted mechanisms for making results available.

3. Disclaimers. Normally, the need for a disclaimer in relation to official materials, presentations, or publications is eliminated through the clearance process. However, a disclaimer may still be needed even after official clearance to make clear that the presentation should not be construed as necessarily representing the NIH view. Investigators may also need to use disclaimers to distinguish the status of information, e.g., preliminary data or incomplete data. Where appropriate, potential error sources affecting the quality of the data should be identified and disclosed.

4. Use of Name, Logo or Marks Associated with DHHS, NIH or the IC. Any use of DHHS, NIH or IC or other subdivisions names, logos, marks, etc., must be consistent with the provisions of NIH Manual 1186, “Use of the NIH Names and Logos” (pending release, contact 301-496-5787 for information), which provides NIH policy and procedures for the review and approval of ANY materials that bear the logos and/or names of NIH or any of its entities or programs.

E. Review and Approval Procedures: In general, any writing by an NIH employee on a work-related subject, whether intended for electronic or print publication, or for oral delivery, must be prepared according to accepted NIH standards, reviewed for substantive content, and administratively approved. This process both protects the public and the employee.

IC Directors (or their delegates) are responsible for establishing and maintaining controls to ensure competent and timely clearance of materials covered by this chapter by developing procedures appropriate to each type of information. Individual IC's may determine how best to meet these

requirements. IC Directors should ensure that senior staff are knowledgeable about their IC's internal clearance procedures and are also responsible for maintaining files of requests for approval and actions taken. IC Directors should ensure that senior staff are knowledgeable about their IC's internal clearance procedures and are also responsible for maintaining files (See the NIH Manual Chapter 1743, "Keeping and Destroying Records"; http://www1.od.nih.gov/oma/manualchapters/management/1743/) of requests for approval and actions taken.

Intramural Scientists: Materials produced by intramural scientists are generally reviewed and approved by Lab/Branch Chiefs and sometimes Scientific Directors. The intramural approval process helps to assure that applicable animal, human subjects, and/or technology transfer issues have been considered, that major press and policy implications are noted, and that at least one supervisory scientist finds the work to be of merit. (See the Intramural Research Sourcebook.) In the case of materials having press implications, the lab chief or scientific director will inform the communication director of the Institute or Center, and in the case of policy implications, the director of the IC's policy office.

Fellows: Each NIH Fellow must follow publication review rules set by the NIH and his/her IC. Fellows may not personally profit from any publication associated with his or her official duties at NIH. Ordinarily publications related to work done at the NIH and with NIH resources are in the public domain, It is highly recommended that both the Fellow and the Fellow's assigned Institute/Office refer to the HHS/NIH publication rules/guidelines of this Chapter.

All Others: Written presentations by extramural scientists or office of the director staff will be reviewed and approved according to the policy established by the applicable IC and any applicable policies issued by the Office of Extramural Research.

> **1. Policy Material.** Information prepared for dissemination by an employee that includes any discussion of Federal policy, has policy implications, or makes public health practice recommendations must be approved in the Office of the Director, NIH.
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> **2. Official NIH Publications and Audiovisuals.** All official publications and audiovisuals by organizational components of NIH must comply with the provisions of NIH Manual Chapter 1183 even though some or all of the contents may have been approved under the provisions of this Chapter.

3. Non-policy Material.

a. OD/NIH Staff. Non-policy material or professional statements/correspondence prepared by staff within the Office of the Director, NIH, shall be cleared by the director of the employee's division or office for content and appropriate disclaimers. Materials or statements prepared by the director of a division or office in the Office of the Director, NIH, should be cleared by an NIH Associate Director or Deputy Director.

b. IC Associate Director Level and Above. Professional statements/correspondence or materials on a subject related to the official duties of an employee at or above the Associate Director level requires approval by that IC's Director (or designee). Employees should follow specific instructions for publication and speech clearance developed by their IC. If there is any question about whether the material has policy implications, it should also be reviewed by the Office of the Director, NIH. See section 4.a. below for guidance on OD/NIH clearance procedures.

c. All Other Staff. Professional statements/correspondence or material on a subject related to the official duties of an employee below the Associate Director level must be approved by the IC Director or designee (e.g., Scientific Director, Laboratory or Branch Chief). In the case of joint authorship, each author must receive approval from his or her respective IC Director or designee, unless IC internal policies direct otherwise.

4. Clearance Procedures: Requests for clearance must be resubmitted if information has changed substantially.

a. OD/NIH Approval. Professional statements/correspondence or materials requiring clearance from the Office of the Director, NIH, must be approved by a designated officer within the originating IC, and by the author's supervisor, prior to submission to the Office of the Director,

NIH. No such preliminary review is required for writing or presentation by an IC Director, however. For each manuscript, speech text, or other material requiring approval in the Office of the Director, NIH, the originator must submit to the Editorial Operations Branch, PIO/OCPL/OD, Bldg 31, Room 5B52 one copy of a completed Request for Publication and Speech Clearance (NIH Form 1616-1) signed by both the Director and Communications Director of the employee's IC. NIH Form 1616-1 is available at http://forms.nih.gov/adobe/procurement/NH1616_1.pdf).

b. Institute/Center (IC) Approval. Professional statements/correspondence or materials requiring clearance at the IC level must be approved by the Director (or designee) of the employee's IC. Employees should follow specific instructions for publication and speech clearance developed by their IC. IC's may use a variation of NIH Form 1616-1 (Request for Publication and Speech Clearance) or the clearance form described in the Intramural Sourcebook: http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear.htm.

5. Appeals. An employee whose presentation or material has been disapproved may ask for review of the decision. The Deputy Director for Extramural Research, NIH, reviews requests by extramural staff. The Deputy Director for Intramural Research, NIH, reviews requests by intramural staff. The Director, NIH, has responsibility for reviewing all other requests for materials disapproved for publication or presentation.

F. Clearance Not Required:

1. Routine Oral Presentations. Oral scientific presentations that do not discuss Federal policies and do not have policy implications (e.g., usual intramural scientific oral presentations), and routine presentations on existing NIH or IC procedures for information purposes (e.g., to describe NIH grant application or management procedures or to publicize priority areas for the purpose of soliciting grant applications), do not typically require official clearance. Individual IC's may implement their own procedures for requiring IC clearance of these materials prior to

presentation.

2. Answers to Inquiries and Informal Presentations. Except when disallowed by Institute, Center, or Department policy, an NIH employee may respond orally to questions and requests for information from any source, including the news media. Similarly, an employee may appear as a member of a discussion panel or seminar and on radio and television broadcasts without prior approval if the appearance does not require a manuscript or written text or statement and is in keeping with NIH policies for responsible presentation of information as described above. Speakers should limit their statements and responses to subjects within their field of expertise and should present only official DHHS and NIH positions in discussion of policy matters. For news media interviews, responses or appearances, employees are encouraged to seek advice from the relevant IC communications office or, for OD employees--from the NIH Office of Communications and Public Liaison.

3. Unofficial Activities. Employees writing, presenting or otherwise distributing materials, as defined in section 2.B. of this manual chapter, in their personal capacities are instructed to consult their ethics officials for applicable rules and restrictions, including those requiring prior approval and limiting the use of title or NIH affiliation.

G. Employee Responsibility and Identification: NIH employees are responsible for the statements they make, regardless of whether they have been cleared. Employees who present material that requires clearance but material that has not been cleared prior to presentation, must inform the audience that the material represents the individual's views. An example of an appropriate disclaimer follows:

"This material is presented from my own perspective, and should not be taken as representing the viewpoint of the Department, NIH, or [IC]."

H. NIH Staff (Co-)Authorship of Publications from NIH Extramural Awards: Responsibilities of program officials and project officers include providing suggestions and critiques to awardee investigators and other staff -- for example, developing or negotiating acceptable project direction or budget; monitoring extramural awards; or commenting on research design or conduct, draft manuscripts and other awardee presentations. To merit approval for (co-)authorships on publications from extramural awards (including grants, contracts, and other award mechanisms), NIH staff must have played a **substantial** role, such as contributing intellectually to the concept, design,

conduct and/or analysis of the results of the research.

The conditions allowing NIH staff to be (co-)authors of publications under NIH extramural awards ordinarily arise only from contracts and cooperative agreements, where, by definition, there is substantial programmatic, i.e., scientific-technical, staff involvement. Deviations from these provisions must be approved by IC directors, and only when justified under special circumstances. NIH staff should work with supervisors when seeking approval of activities as official duties. Review and clearance according to applicable IC procedures is required.

I. Copyrights and Electronic Access: Papers authored by government employees as part of official duties are not subject to copyright in the United States. This applies to the version submitted to the publication and not always what appears in the publication as the publication may claim copyright for its formatting or other enhancements. The citation to the publication may be listed on an IC Website. The version submitted to a journal or publication may be scanned and posted on the IC Website. To the extent possible, the scanned document should be compliant with Section 508 standards (http://www.section508.gov) that ensure accessibility to people with disabilities.

J. Records Retention and Disposal: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section 1100 - General Administration, Item 1100-B-1, "Policy Files" and all other sections that apply.

NIH e-mail messages: NIH e-mail messages (messages, including attachments, that are created on the NIH computer systems or transmitted over the NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, the NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to the Congressional Oversight Committees, if requested, and are subject to the Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original

messages.

K. Management Controls: The purpose of this Manual issuance is to ensure that information disseminated to the public by the NIH is of maximum quality, objectivity, utility, and integrity. This is achieved through review and approved through an internal NIH process outlined in this chapter. The use of appropriate disclaimers is addressed in Section D3.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter: The NIH Office of Communications and Public Liaison (OCPL) is accountable for the method used to ensure that management controls are implemented and working.

2. Frequency of Reviews: Ongoing

3. Method of Review: On an ongoing basis, OCPL evaluates input concerning this policy from users based on e-mail, telephone calls, meetings and memoranda, and makes appropriate changes as needed. Formal review of this policy is conducted annually by the Associate Director for Communications and Public Liaison and the Deputy Associate Director for Communications and Public Liaison. Comments concerning this policy, including agency controls, compliance, and reporting requirements, may be addressed to John T. Burklow, Associate Director for Communications and Public Liaison, NIH, and Marin P. Allen, Ph.D., Deputy Associate Director for Communications and Public Liaison, NIH, both at 1 Center Drive, Room 344, Bethesda, Maryland 20892, 301-496-5787, fax 301-496-0017.

4. Review of Reports: are sent to DDM, DDER, and DDIR upon request. Reports should indicate that controls are in place and working well or indicate any internal management control issues that should be brought to the attention of the report recipient(s).

L. References:

1. OMB and HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies and NIH Guidelines for Ensuring the Quality of Information Disseminated to the Public. See http://ospp.od.nih.gov/infoquality.

2. NIH Manual Chapter 1130 Delegation of Authority, Program: General No. 3, Publish Articles and Results of Scientific Research, and Program: General No. 4, Availability of Records

for Examination or Copying, both dated January 11, 1985. See http://www1.od.nih.gov/oma/manualchapters.

3. NIH Manual Chapter 1183, NIH Publications and Audiovisuals: Preparation, Review, Approval, and Distribution, http://www1.od.nih.gov/oma/manualchapters/management/1183/ .

4. NIH Manual Chapter 1185 (in development), Complaints about NIH Information Quality.

5. "Guidelines for the Conduct of Research in the Intramural Research Programs at NIH," http://www.nih.gov/science/irnews.htm .

6. The Intramural Research Sourcebook: http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear.htm.

7. NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule: http://www1.od.nih.gov/oma/manualchapters/management/1743/ .