United States Department of Health Human Services

Guidelines for Ensuring the Quality of Information Disseminated to the Public

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These guidelines were developed to implement the Office of Management and Budget (OMB) Guidelines and the Department of Health and Human Services (HHS) guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, hereafter referred to as the OMB Information Quality Guidelines and the HHS Part I: Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public. This report provides the information quality guidelines for the National Institutes of Health (NIH), and explains how these guidelines will ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by NIH to the public. This report also details our administrative mechanisms for allowing affected persons to seek and obtain appropriate correction of information maintained and disseminated by the NIH.

The OMB Information Quality Guidelines can be found in the Federal Register, September 28, 2001 The guidelines apply primarily to the dissemination of substantive information (e.g., scientific reports, articles, studies, summaries, speeches, official expert opinions, brochures, statistical information, or compendiums) rather than information pertaining to basic agency operations. Such information can be in any media -- printed, electronic, audiovisual, and the like -- and must be authored or issued by the agency or its contractors, and represent our view.

NIH will ensure that disseminated information meets the standards set forth in the OMB, HHS, and NIH guidelines. It is NIH's policy to ensure and maximize the quality, objectivity, utility, and integrity of the information it disseminates to the public. We strive to provide information that is accurate, reliable, clear, complete, unbiased, and useful. The quality assurance process begins at the inception of the information development process. NIH is committed to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination. Each federal agency is already required to demonstrate the "practical utility" of a proposed collection of information in its Paperwork Reduction Act (PRA) submission, i.e., for draft information collections designed to gather information that the agency plans to disseminate. NIH will demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with OMB, HHS, and NIH information quality guidelines. NIH intends to make use of the PRA clearance process to help improve the quality of information that we collect and disseminate, and to ensure that it complies with all applicable guidelines. The standards to which NIH shall adhere include the following: .

- Information should be objective in substance and presentation. Objectivity means ensuring that information is accurate, reliable, and unbiased and that information is presented in an accurate, clear, complete, and unbiased manner. If analytic results have been subject to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is refutable based on a persuasive showing by the petitioner in a particular instance. As described in more detail in Section V, NIH works to maintain objectivity through existing review and clearance procedures, and the peer review of disseminated information.

- Information should be responsive to its intended users, including the public. NIH strives to stay informed of user needs, through user feedback, consultation with advisory committees and peer review groups, and conference participation. Appropriate public access to government information and data play a useful role in improving the overall quality of information disseminated by federal agencies.

- The integrity of information should be protected. As described in more detail in Section V.3, NIH ensures the integrity of its data and information products through the enforcement of rigorous controls that protect against unauthorized access, revision, or corruption. Some of the controls used at NIH include access control, user authentication, encryption, access monitoring, provision of unalterable electronic content, and audit trails.

I. Agency Mission

Founded in 1887, today NIH is one of the world's foremost medical research centers, and the Federal focal point for medical research in the U.S. NIH, comprised of 27 separate Institutes and Centers, is 1 of 8 health agencies of the Public Health Service, which, in turn, is part of the U.S. Department of Health and Human Services (HHS).

Simply described, the goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the most rare genetic disorder to the common cold. The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by: Conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; assisting in the training of research investigators; and promoting communication of medical and health sciences information.

In FY 2002, NIH received $23.5 billion in support of its mission. Of that amount, nearly 84 percent supports non-Federal researchers working in universities, medical centers, hospitals, and research institutions throughout the country and abroad (collectively referred to as extramural research), and about 10 percent is allocated to in-house research laboratories located on the NIH campus and several off-campus sites (referred to as intramural research). NIH has over 17,000 employees, approximately 3,000 of which have doctoral or medical degrees.

It is NIH policy to make available to the public the results and accomplishments derived from the activities that it funds. Therefore, NIH-funded intramural and extramural investigators are expected to make the results and accomplishments of their activities available to the research community and to the public at large, and to effect their timely transfer to industry for commercialization.

1. NIH Policy Issuances

NIH is organized into Institutes and Centers (ICs), each with its own mission and functions, separate appropriations, and statutory authorities. Although these ICs may have different administrative procedures in place, they operate under the same general NIH policies and requirements. The NIH Policy Manual System is the formal mechanism for issuing NIH policy. The system is comprised of a series of NIH Manual Chapters. It provides an organized, central repository of information that is accessible to all NIH employees. Individual IC's have the flexibility to incorporate the quality and accountability requirements of Federal and NIH guidelines into their own information resource management and administrative practices in the most applicable manner.

2. Responsible Official

At NIH, the Associate Director for Communications, who is also the Director of the Office of Communications and Public Liaison (OCPL) in the Office of the Director, will have overall responsibility for implementing NIH Information Quality Guidelines, and will work collaboratively with the ICs. OCPL is the central office for communications at NIH. As such, OCPL takes the lead across the NIH for setting communications policy, and for communicating information about NIH programs, issues, and accomplishments to the public and public interest groups and, to a lesser extent, to the scientific community and the medical professions. The office is the communications link between the ICs and the Office of the Assistant Secretary for Public Affairs in the HHS, and serves as the coordinating office or central source for NIH IC matters related to publications, including printing, HHS/PHS/NIH clearance and review procedures, Joint Committee on Printing, U.S. Congress, and Government Printing Office printing and binding regulations, and copyright rules. Among its many activities, the office produces and distributes a number of publications that highlight NIH research results and scientific advances; provides print, radio, and TV coverage of NIH news and activities; produces the NIH Record; and publishes consumer health information, primarily in a newsletter for the press and public entitled *The NIH Word on Health*. OCPL also supports and coordinates the principal NIH Web site (www.nih.gov) with direct responsibility for several major areas of the NIH home page that address the special needs of healthcare professionals, patients, members of the press, the public, and employees. It manages the NIH Web Coordinating Committee that provides leadership for the design and content of the NIH Web site, including reviewing new Web sites before they are integrated into the structure of the NIH home page; works with other relevant offices and committees in establishing operational standards and guidelines for Web sites at NIH; and manages the responses to electronic mail sent to the NIH home page.

It is likely that any formal complaint regarding information quality will go first to the IC or Office responsible for originating the information. It is therefore essential that the relevant components of NIH work cooperatively with OCPL to ensure a timely and appropriate response to any complaints.

As the lead office for NIH Information Quality, OCPL responsibilities include:

a. Developing policies and procedures to effectively meet the requirements of the OMB Information Quality Guidelines;
b. Providing information and/or training to NIH staff on their responsibilities in meeting Federal requirements and NIH policies on ensuring the quality of information disseminated to the public;
c. Assisting in the review of information quality complaints;
d. Reviewing the proposed IC response for appropriateness, and assisting in finalizing a response;
e. Establishing a tracking database for complaints, with information on the type of complaint and its disposition and any resolution or corrective action taken;
f. Submitting an annual report on behalf of NIH to HHS with the number and types of complaints, and the actions taken, in time for the HHS to report to OMB by January 1 (beginning in 2004);
g. Posting on the OCPL Web site any further clarifications, guidelines, and Frequently Asked Questions (FAQs) about handling NIH information

complaints;

h. Making available examples of typical complaints and appropriate responses collected from IC reports.

II. Scope of Applicability of Guidelines for Agency

The OMB Information Quality Guidelines require NIH to evaluate and identify the types of NIH information that will be subject to the Guidelines. This section identifies the types of information covered by the Guidelines, and also lists the types of information that are exempt. The NIH Office of the General Counsel originally reviewed this information on November 27, 2001 and considered NIH's interpretation to be consistent with the intent of the law.

The pre-dissemination review described in the guidelines only applies to official information (with the NIH imprimatur) that is released on or after October 1, 2002. The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information. They apply to information in all media — printed, electronic, audiovisual, verbal, and other. The Guidelines focus primarily on the dissemination of substantive information (i.e., reports, studies, summaries) rather than information pertaining to basic agency operations. Information that is disseminated at the request of NIH or with specific NIH approval through a contract or a grant is subject to these Guidelines. Examples are provided below of the kinds of information that the NIH considers to be covered and not covered by the OMB Information Quality Guidelines. Although information that is not covered by the OMB Guidelines are not subject to the new administrative complaint procedures, the information is still subject to the usual NIH internal review procedures for accuracy and quality.

1. NIH Information Covered by the OMB Guidelines

Scientific research papers, books, journal articles, and similar authoritative materials, unless they have disclaimers alerting the audience that they do not represent official views of the NIH

Other official reports, brochures, documents, newsletters, electronic documents, and audiovisual productions (i.e., a unified presentation, developed according to a plan or script, containing visual imagery, sound, or both, and used to convey information)

Editorials, commentaries, letters-to-the-editor, only if NIH staff representing official NIH viewpoints provides them

Oral information, including speeches, interviews, expert opinions, only if representing NIH's views, official positions, or policies

Statistical information -- statistical analyses, aggregated information by program, IC, or for NIH, including funding information and histories (by disease, funding mechanism, dollars, and other criteria) -- prepared for public dissemination

Consensus panel reports and open meetings' proceedings and minutes

2. NIH Information Not Covered by the OMB Guidelines

National Library of Medicine (NLM) databases or other archival records, CRISP, and similar databases

Documents not authored by the agency and not representing the agency's views, including information authored and distributed by NIH grantees[1]

Information that is limited in dissemination to Government employees or agency contractors or grantees

Information pertaining to basic agency operations, e.g., information about agency authorities, activities, programs, along with contact information for the public, organizational charts, NIH or IC Directors' Status Reports, solicitations [program announcements (PAs)/requests for applications (RFAs)], receipt and review materials (e.g., summary statements, information for advisory councils or advisory committee members)

Information intended solely for intra- or interagency use or sharing of Government information

Responses to requests for agency records under the Freedom of Information Act (FOIA), the Privacy Act, the Federal Advisory Committee Act, or other similar laws

Information relating solely to correspondence with individuals or persons

Press releases that support the announcement or give public notice of information that NIH has disseminated elsewhere

Information intended for public filings, subpoenas, or adjudicative processes involving specific parties (There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal.)

Opinions where the agency's presentation makes it clear that what is being offered is personal opinion rather than fact or the agency's views

III. Types of Information Disseminated by NIH to the Public

Each year, NIH components produce 400 or more publications of various types, and about 140,000 static Web pages. All publications that carry the NIH imprimatur, i.e. are considered official NIH publications or releases, must follow NIH policy and procedures for preparation, review, approval, and distribution (see Section V). The types of information disseminated by NIH to the public include the following, however, the OMB guidelines are not directly applicable to all of the information in these categories (See Section II):

1. Program Reviews, Analyses, and Evaluations.

This category includes research project descriptions [e.g., abstracts of funded grant proposals available through the NIH Computer Retrieval of Information on Scientific Projects (CRISP) database[2]], bibliographies, collection of abstracts, reviews, and

recurring reports. Summaries of research findings are routinely shared with interested parties (e.g., the public, other researchers, the press, Congress). These findings can be released in the form provided by the investigator, or the investigator-supplied information can be used as the basis of a narrative describing research progress in a particular program area. Syntheses of research findings are used for many purposes, including in meeting annual reporting requirements, such as the Government Performance and Results Act (GPRA). Highlights of research findings are posted on the NIH Web site, and can be found in testimonies and speeches by NIH staff in many venues, including annual Appropriations Hearings, presentations on NIH funding opportunities, and literature reviews.

2. Grants and Funding Opportunities.

The *NIH Guide* is the official document for announcing the availability of NIH funds for biomedical and behavioral research and research training, and disseminating policy and administrative information. Current and past issues of the NIH Guide are available on the NIH Web site, along with other information on grants policy, peer review, award data, research contracts, application forms, and CRISP database, and links to each of the 27 ICs.

3. Scientific Reports.

Can be in the form of a book, chapter of a book or textbook, monograph, journal article, proceedings, or the like. These are generally authored or co-authored by NIH staff scientists as part of their official duties, or may be authored by working groups convened by the NIH. 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.[3]

4. Statistical Compendiums.

Examples of statistical compendiums include annual appropriations by IC, employment data (e.g., numbers of staff and staffing by professional degree), and data books produced by statistical agencies (e.g., Census Bureau, NCHS) under contract to NIH (e.g., *Aging World, 65+ in America*). Also prominent is the annual table showing research dollars allocated by disease entitled Funding for Research Areas of Interest released by the NIH Budget Office. The estimated spending amounts are self-reported by individual ICs. Although ICs are requested to use consistent methods across years, estimation methods and assumptions across ICs may not be consistent.

5. Guidelines or Authoritative Health Information.

This type of information is issued after careful review and deliberation of available scientific evidence, usually with the assistance of a panel of outside experts, and is generally associated with a formal meeting or consensus panel specifically convened for the purpose. Prime examples are NIH Consensus Statements and State of the

Science Statements issued as part of the NIH Consensus Development Conference program managed by the NIH Office of Medical Applications of Research (see Section V.2.c), and the Report on Carcinogens prepared by the National Toxicology Program at the National Institute of Environmental Health Sciences, NIH (see Section V.2.d).

6. **Editorials, Commentaries, Letters-to-the-Editor.**

   Only if they are provided by NIH staff representing official NIH viewpoints.

7. **Consumer Information.**

   NIH provides a number of resources for the general consumer to learn about health conditions, participate in research studies, look up drug information, contact the NIH, find health literature references, and read about special programs. A considerable amount of this information is developed and distributed through IC-established clearinghouses, some of which are required by law. Other sources of consumer information include MedLine Plus, a health database maintained by the NIH's National Library of Medicine; the NIH Word on Health, a newsletter of articles on health maintenance and prevention; A-Z topic index with primary Institute contact; PubMed, a comprehensive database of article titles and abstracts; Clinical Trials database on medical studies around the country; a MEDLINEplus guide to over 9,000 medications; and much more. Other information provided to the public includes Information about NIH, Visitor Information, Job Opportunities, Employee Directory, and FOIA provisions.

8. **Science Education Materials and Training Modules.**

   NIH provides science education materials as well as training modules for clinical investigators and extramural scientists. The NIH Curriculum Supplement Series are interactive teaching units that combine cutting-edge scientific research discoveries with state-of-the-art instructional materials for grades K-12. Examples of training aids available to extramural researchers include Human Subjects Assurance Training, and various self-instructional guidebooks and videotapes.

9. **Press Releases.**

   NIH press releases are archived 2 weeks after their release date and made available on the NIH Web site. Interested persons can subscribe to receive these press releases via email.

IV. Types of Dissemination Methods

NIH information is disseminated in many mediums, with the following four being most common:

1. **Print --**
   publications, books, newsletters, brochures, booklets, pamphlets, and reports.

2. **Oral --**
   formal speeches, oral presentations, interviews, or commentaries for publication or broadcast; letters-to-the-editor or correspondence likely to result in similar publications.

3. **Audio-Visual --**
   broadcast scripts, audio or videotapes, and videocasting. The Center for Information Technology (CIT) makes special NIH events, seminars, and lectures available to viewers on the NIH network and the Internet from the VideoCast Web site.

4. **Electronic --**
   The NIH Web site is the most popular Government Web site after the Internal Revenue Service, and has about 3 million unique visitors per month. The NIH Web site is recognized as one of the most respected and trusted sources for authoritative health information (*Consumer Reports*, January 2002; *Forbes.com* review, September 10, 2001; *Business Wire*, January 29, 2001). The NIH Web site is not just one site, but also a large collection of sites residing on over 150 servers with over 140,000 static pages that are crawled and indexed on public servers. Some areas are updated daily, while others may not be updated for weeks or months.

V. Agency Quality Assurance Policies, Standards, and Processes for Ensuring the Quality of Information Disseminated to the Public

1. Overview

All NIH documents and audiovisuals must be prepared in accordance with professional and ethical standards, as well as generally accepted standards of good taste. They must be appropriate for dissemination by this Federal agency, and must undergo appropriate review and approval prior to release. NIH must adhere to the laws and regulations applying to publications and audiovisuals, including OMB Information Quality Guidelines, the HHS Printing Handbook, and relevant NIH Manual chapters. NIH efforts to ensure and maximize information quality begin at the preparation stage, and continue through the review and approval stages. Existing NIH policies developed in concert with Federal computer security laws provide appropriate security safeguards to ensure integrity of NIH documents, i.e., ensure that the information is protected from unauthorized access, revision, corruption, or falsification.

The NIH has many quality control measures embedded in the scientific process to ensure that the information disseminated is of the highest quality. NIH grant applications undergo rigorous scientific review. Scientific journals do not publish articles until they have gone through a similar peer review process. There is a tension inherent in biomedical research between releasing information in a timely fashion and waiting for the peer review process to result in a published article. Sometimes the NIH provides "late breaking news" to the public on research findings prior to publication in scientific journals and prior to peer review by the journals. However, when it does so, there is an internal review process that routinely draws

upon external expertise and monitoring/advisory review boards to ensure that information disseminated to the public summarizes the facts as they are currently known, and that appropriate disclaimers are attached.

The policies and procedures to be followed in the preparation, review, approval, and distribution of NIH information materials, including scientific and professional materials, can be found in NIH Manual Chapter 1183: NIH Publications and Audiovisuals: Preparation, Review, Approval, and Distribution and NIH Manual Chapter 1184: Scientific and Professional Information Presented By NIH Employees: Review, Approval, and Distribution. The procedures currently in place were developed to be sensible, workable, flexible, and timely, and were updated in February 2002 to better articulate OMB, HHS, and NIH information quality guidelines. In the scientific and research context, technical information that has been subjected to formal, independent, external peer review is generally presumed to be of reasonable quality.

The general principles concerning the responsibilities of the NIH research staff in the collection and recording of data, publication practices, authorship determination, peer review, confidentiality of information, collaborations, human subjects research, and financial conflicts of interest are exemplified in the "Guidelines for the Conduct of Research in the Intramural Research Programs at NIH." These guidelines can be found on the Web (www.nih.gov/news/irnews/guidelines.htm). NIH recognizes the scientific need for replication of findings, and encourages data sharing as appropriate. After publication, the research data, any unique reagents, and any supporting data that form the basis of the communication in question should be made available promptly and completely to all responsible scientists seeking further information. Exceptions may be necessary to maintain the confidentiality of clinical data or if unique materials were obtained under agreements that preclude their dissemination. Investigators should retain research data long enough to allow replication of study results -- in general, 5 to 7 years.

2. NIH Information Review and Approval Policies and Procedures by Type of Information

The review, approval, and dissemination of substantive scientific information by NIH and/or its ICs require adherence to appropriate clearance procedures set forth in NIH Manual Chapters, internal Web sites, or memos, and are consistent with HHS and OMB guidelines. The originating office is responsible for obtaining the necessary clearances for reproduction and distribution of printed materials and should ensure that written material distributed is appropriate and consistent with HHS policy.[4]

A document that has obtained publication clearance for paper printing is often posted on the sponsoring IC's Web page for greater accessibility. NIH/IC Web documents derived from IC-approved printed publications should not need additional approvals. NIH/IC Web documents with no print counterpart require content clearance by the appropriate IC office or contact person to ensure that the information observes all applicable requirements governing information for release to the public. These include the requirements provided in NIH Manual Chapter 1183. When IC Web pages are related to more than one IC (e.g., trans-IC publications, special interest groups), the appropriate IC office or contact person for the

primary IC responsible for creating the Web page should be notified regarding clearance requirements.

This section describes NIH procedures and practices in place for review and approval of substantive scientific information that is meant for dissemination primarily to the public, and that NIH considers being subject to the OMB Information Quality Guidelines (see Section II above).

a. *Scientific research papers, books, journal articles, brochures, documents, statistical compendiums, newsletters, electronic documents, audiovisual productions, authoritative health information, and similar materials*

NIH encourages professional dissemination of scientific research and other information on behalf of public health by its employees. Professional and scholarly writing, lecturing, editing, and publishing are an essential part of research, are in the public interest, and bring credit and distinction to 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 the prerogative of the author (s).

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. Publications or presentations by NIH employees are expected 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.

To ensure and maximize the quality of information disseminated by NIH employees, any non-extemporaneous presentation (written or electronic) by an NIH employee on a subject related to his/her NIH duties must be reviewed and approved through an internal NIH process prior to submitting for publication consideration. With few exceptions, non-extemporaneous oral presentations on health policy or practice, or presentations with policy implications, must also be cleared in advance. Manuscripts intended for publication are customarily subjected to an external peer review process directed by the interested publisher, volume editor, or journal editor.

Publication or oral presentation of scientific and professional information by individual employees must conform to applicable laws and regulations, including OMB Information Quality Guidelines, and the HHS Standards of Conduct Regulations. Customary professional practices impose certain constraints on the degree to which NIH employees may be identified with the results of research and development work, including that obtained in collaboration with extramural grantees.[5]

All Institutes have either formal or informal internal operating procedures for

identifying printing requirements and tracking publications. These procedures come in a variety of forms such as policy issuances, internal Web sites, memos, or annual requests for printing requirements. In addition, the concept clearance process for new publications is often the vehicle that Institutes use to track the development of a new publication and to identify its attendant printing requirements. The requirements for clearance of prospective publications are contained in NIH Manual Chapter 1183. These requirements state that each prospective publication must be cleared through the Communications Office within the originating NIH component and then be approved by the Office of Communications and Public Liaison, OD/NIH and the Office of the Assistant Secretary for Public Affairs (OASPA), HHS.

In brief, the NIH Manual Chapter 1183 requires that any official publication (including book, bibliography, chapter of a book or textbook, booklet, brochure, collection of abstracts, fact sheet, house organ, index, leaflet, manual, monograph, newsletter, pamphlet, review, periodical, proceeding, recurring report, statistical compendium, Internet document, audiovisual, or the like), prepared by any NIH component directly or through a contract must be sent for HHS clearance through the Editorial Operations Branch, using form HHS-615, Publication Planning and Clearance Request. This clearance requirement does not apply to publication of articles in journals. The authority to permit the initial publication of articles written by NIH employees in privately published journals, encyclopedias, and textbooks can be delegated according to NIH Manual Chapter 1130 (Delegation of Authority).

All NIH Audio/Visual projects and exhibits must be cleared through OASPA, whether produced in-house or under contract. To obtain clearance for all NIH audiovisual products, including exhibits, Form HHS 524A must be completed. It can be obtained on the Web (http://www.nih.gov/icd/od/ocpl/resources/audiovisual.htm) and must be filed with the Office of the Assistant Secretary for Public Affairs and approved before actual production may begin. If the cost exceeds $50,000, a written evaluation plan is required. If more than $100,000 is involved, a written evaluation and formal message testing are required. No subsequent change in terms, dollar amounts, conditions, or additions can be made to the product without written approval of OASPA.

Statistical compendiums, including statistical analyses, aggregated information by program, IC, or for NIH, including funding information and histories (by disease, funding mechanism, dollars, or other criteria), do not require approval by the Office of the Director, NIH. However, the Director of the originating IC is required to determine that the data conform to the accepted quality standards, and if applicable, that the reported statistics be substantially reproducible (see NIH Manual Chapter 1183).

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 of quality, reviewed for substantive content, and administratively approved. The purpose of the NIH clearance process is to improve the quality of information, and to ensure the accuracy, objectivity, utility, and validity of information. NIH Manual Chapter 1184, states the policy and procedures to be followed in the review, publication, and distribution of scientific, technical, and other professional manuscripts and speeches by NIH employees. IC Directors (or their delegates) are responsible for establishing and maintaining

controls to ensure competent and timely clearance of professional writing and presentations by developing procedures appropriate to the type of information. They are also responsible for maintaining files of requests for approval and actions taken. Individual ICs may determine how best to meet these requirements.

Written presentations by intramural scientists are reviewed and approved by Laboratory/Branch Chiefs and sometimes by Scientific Directors. The intramural approval process also ascertains that all animal, human subjects, and technology transfer requirements are met, 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 at www1.od.nih.gov/oir/sourcebook/oversight/pub-clear.htm).

Materials requiring review in the Office of the Director, NIH, should be approved by a designated review officer within the originating IC, or by a person in a supervisory relationship to the author, prior to submission to the Office of the Director, NIH. No such preliminary review is required for writing by an IC Director. Any statement, commentary, or discussion of Federal policies or practices related to the employee's position or duties that might be construed as reflecting an official position by NIH, HHS, or the Federal Government must be approved in the Office of the Director, NIH.

For scientific and technical documents, the scientific community recognizes peer review as the primary means of quality control. According to OMB Information Quality Guidelines, material subjected to formal, independent, external peer review may generally be considered to be of acceptable objectivity. However, this presumption of objectivity is refutable based on a persuasive showing to the contrary by a complainant in the particular instance. The single most important determinant of a scientific review group's competence and credibility is its members. Reviewers must have scientific excellence (as demonstrated by their grant and publication records, and academic degrees and honors), and must merit respect in the scientific community. They must possess a wide breadth of expertise, be fair and objective, and should not be influenced by inappropriate personal interests (competition, scientific bias, personal antagonisms, and other irrelevant factors.). Reviewers should review materials for propriety, accuracy, completeness and quality (including objectivity, utility, and integrity).

Consistent with HHS Standards of Conduct (73.735-705 Writing and Editing), employees are encouraged to engage in outside writing and editing when such activity is not otherwise prohibited. If the writing or editing activity is related to the employee's official duties or other responsibilities and programs of the Federal Government, the employee must (i) make no mention of his or her official title or affiliation with the Department, or (ii) use his or her official title or affiliation with the Department and a disclaimer, or (iii) submit the material for clearance within the operating component, under procedures established by the component. When clearance is denied at any lower level, the employee shall have recourse for review up to the head of the principal operating component. This clearance will show there are no official objections to the activity and the employee may then use his or her official title or affiliation usually without a disclaimer. Except where the requirement for disclaimer is waived as a result of official clearance, disclaimers shall be used in all writing and editing related to the employee's official duties or other responsibilities and programs of the Federal Government: (i) in which the

employee identifies himself or herself by official title or affiliation with the Department, or (ii) when the prominence of the employee or the employee's position might lead the public to associate him or her with the Department, even without identification other than name. Disclaimers shall read as follows unless a different wording is approved by the Assistant General Counsel, Business and Administrative Law Division, Office of the General Counsel: "This (article, book, etc.) was (written, edited) by (employee's name) in (his or her) private capacity. No official support or endorsement by (name of operating component or of Department) is intended or should be inferred."

Normally, the need for a disclaimer is eliminated through the clearance process. However, a disclaimer may still be needed even after official clearance to clarify that the presentation should not be construed as necessarily representing NIH views, and/or to distinguish the status of information (e.g., preliminary, based on partial data set). The Department's regulations (Standards of Conduct) to which the NIH subscribes, require that disclaimers be used in all unofficial writing and editing related to the employee's official duties and/or affiliation with programs of the Federal Government in which the employee's identification with NIH is to be shown, can be inferred, or is well-known.

b. Oral information, including speeches, interviews, expert opinions, only if representing NIH views, official positions, or policies

Any statements, comments, or discussion of Federal policies or practices that are relevant to the employee's position or duties, draw conclusions, advocate or oppose professional practices or positions on subjects related to NIH duties, or might otherwise be construed as reflecting an official position by NIH, HHS, or the Federal Government, are covered by the OMB Guidelines, and must be approved in the Office of the Director, NIH.

An NIH employee may respond orally to questions and requests for information from any source, including the news media, without prior review and approval but must adhere to internal IC guidelines for informing the IC Information Officer, Congressional Liaison Officer, or other appropriate official about the nature of the information to be discussed. An employee may appear as a member of a discussion panel or seminar and on radio, television, and Web broadcasts without prior approval if the appearance does not require a manuscript or written text or statement, and if there is no conflict with NIH Policy as provided in Manual Chapter 1184. An employee should limit his/her statements and responses to subjects about which he/she has official knowledge and should present only official HHS and NIH positions in discussion of policy matters.

No review or approval is required for nonofficial and private writing, speaking, and publishing by an employee unless his/her NIH employment is likely to be regarded as influencing the content.

NIH employees are responsible for the statements they make, regardless of whether they have been cleared. If one presents material that requires clearance but that has not been cleared prior to presentation, then the employee must inform the audience of the personal or unofficial nature of his or her 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]."

NIH employees shall not identify themselves as NIH employees in unofficial materials prepared for dissemination to nonprofessional audiences, such as a letter-to-the-editor. These materials must be reviewed prior to presentation in the Office of the Director, NIH, if an employee's identification with NIH is to be shown, can be inferred, or is well known.

c. *NIH Consensus Development Program*

The NIH Office of Medical Applications of Research (OMAR) manages the NIH Consensus Development Conference (CDC) Program, the focal point for evidence-based assessments of medical practice and state of the science on behalf of the medical community and the public. Under this program, OMAR organizes major conferences that produce Consensus Statements and State of the Science Statements on controversial issues in medicine important to healthcare providers, patients, and the general public. NIH Consensus Statements and State of the Science Statements are disseminated widely, and more than 120 NIH Consensus Statements and State of the Science Statements have been issued since the program's inception in 1977. Organizationally, OMAR is under the Associate Director for Disease Prevention in the Office of the Director, NIH, and works closely with NIH Institutes, Centers, and Offices to assess, translate, and disseminate the results of biomedical research that can be used in the delivery of important health services to the public.

An *NIH Consensus Statement* is a report evaluating scientific information on a given biomedical or public health intervention with the purpose of resolving a particular controversial issue in clinical practice. Each NIH Consensus Statement answers a series of four to six questions concerning efficacy, risk, and clinical applications, and recommends directions for future research, and is the product of an NIH Consensus Development Conference. NIH Consensus Statements synthesize *new* information, largely from recent or ongoing medical research, that has implications for reevaluation of routine medical practices. They do not give specific algorithms or guidelines for practice.

NIH Consensus Statements are written by broad-based, independent panels of non-Federal, non-advocate individuals knowledgeable in the field of medical or public health science under consideration. The makeup of each panel represents various sectors of professional and community life and typically includes research investigators, healthcare providers, methodologists, and a public representative.

Following circulation of the draft statement to the conference audience for comment, the panel resolves any conflicting recommendations and releases a revised statement at the end of the conference. The Web site for the Consensus Development program can be found at: consensus.nih.gov.

If a suggested topic does not have an adequately defined and available base of