

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

POLICIES AND PRINCIPLES FOR ASSURING SCIENTIFIC INTEGRITY

Overview

Purpose. This document describes Department of Health and Human Services (“Departmental” or “HHS”) policies and principles designed to assure the integrity of scientific and scholarly activities that the Department conducts and supports, and the science it uses to inform management and public policy decisions. The development of authoritative scientific information is a primary focus of the missions of several HHS agencies, and HHS uses scientific information to support and inform policy and program decision making. Accordingly, scientific and scholarly information developed by the Department or considered in Departmental decision making must be of the highest quality and the result of rigorous scientific and scholarly processes. Most importantly, it must be trustworthy. Accordingly, maintaining the integrity of our scientific and technical activities is essential.

The Department and its various Operating and Staff Divisions already have numerous well established policies addressing the principles central to the preservation and promotion of scientific integrity. Developed in response to the President’s and the Office of Science and Technology Policy (OSTP) Director’s memoranda on scientific integrity, this document describes the overall principles which guide those policies. Operating Divisions have program-specific statutes, regulations, guidelines, policies and principles on scientific integrity appropriate to their missions and programs. Our goals are to protect and strengthen scientific integrity in the conduct of science, assure the public of the credibility of our scientific findings and results, and provide a transparent platform to demonstrate our commitment to a culture of scientific integrity.

Background. The Presidential Memorandum on Scientific Integrity dated March 9, 2009, and the December 17, 2010 OSTP guidance memorandum on scientific integrity, call for ensuring the highest level of integrity in all aspects of the Executive Branch’s involvement with scientific and technological processes. The HHS Information Quality Guidelines provide additional guidance for ensuring the quality of scientific and technological information that HHS disseminates.

Scope. The guiding principles in this document represent an identification and synthesis of policies and activities that support scientific integrity in four key areas. They are meant to complement and highlight the numerous policies and activities at HHS that address and support scientific integrity and serve as an overarching framework under which existing policies and more detailed program guidance and activities will continue. Due to the integrated nature of the guiding principles outlined in this document, and the breadth of some policies, certain policies and activities may be cited in more than one section.

HHS encompasses a broad and diverse range of health and human services programs which, while unified in their pursuit of broad goals, are themselves very diverse, encompassing the nation’s largest health insurance plan, the nation’s preeminent biomedical research agency, as well as most of the nation’s Federal capacity for public health protection and preparedness and income assistance to needy families. Accordingly, the HHS approach to implementing the

President's directives allows HHS Operating and Staff Divisions to use existing agency scientific integrity mechanisms, and apply the principles in a flexible manner that recognizes the individual mission of each Operating and Staff Division and the wide range of scientific, scholarly, and technological processes in which they engage.

Principles are outlined below in the four major areas of scientific integrity described in the OSTP Director's Memorandum:

- I. Foundations of Scientific Integrity
- II. Public Communications
- III. Use of Federal Advisory Committees
- IV. Professional Development of Government Scientists and Engineers

I. Foundations of Scientific Integrity

HHS recognizes that the development and use of scientific and technical information is essential to the success of the HHS mission. To effectively address the many public health and human services challenges our programs target- from providing access to quality health care for all Americans, to reducing the burden of illness and disease and extending healthy life, to protecting our population from known and unknown public health threats, to maximizing the impact of the social service safety net and many others, HHS employs innovative, knowledge-based approaches. To do so, HHS must expand its scientific understanding of how to best advance health care, public health, human services, biomedical research, and the availability of safe medical and food products. Chief among these efforts are the identification, implementation, and rigorous evaluation of new approaches in science, health care, public health, and human services that reward efficiency, effectiveness, and sustainability.

HHS focuses on promising strategies with the potential to yield positive results from public investments. These strategies include using technology to improve collaboration, modernizing the regulatory approval process, and expanding biomedical and behavioral research. In addition, HHS works to promote service integration and delivery, community-based approaches, and collaboration with the private sector to advance scientific knowledge.

HHS uses scientific data from appropriate sources to determine how best to increase the pace of science and its ultimate use in practice. For example, a previous evaluation of FDA's capacity to support current and future regulatory needs led HHS to set priorities for investments in the regulatory sciences as a new objective. An evaluation of AHRQ's prevention portfolio identified crucial gaps in knowledge about the safety and effectiveness of clinical preventive services. Information from studies supported by NIH will guide the transformation of clinical and translational science programs to speed the delivery of new drugs, diagnostics, and medical devices resulting from laboratory studies to patients. Evaluation of the best available scientific evidence and data is used by CDC to develop strategies, guidelines and recommendations used by partners in practice to promote and ensure a healthy population, to determine the best course of action in response to events, and to determine effectiveness of programs. HHS also uses findings from evaluations to advance patient care, for example, by determining the effectiveness of health information sites geared toward particular populations of interest and the providers who serve them.

Because scientific, technologic, and scholarly information are significant contributors to the development of sound policies at HHS, it is important that policymakers involve science and technology experts where appropriate and that the scientific and technological information and processes relied upon in policymaking reflect the highest integrity. Successful and appropriate application of science in public policy depends on the integrity of the scientific process both to ensure the validity of the information itself and to engender public trust in Government. Toward that end:

- HHS shall sustain a culture of scientific integrity. Scientific progress depends upon honest investigation, open discussion reflecting a balance of diverse scientific views, refined understanding, and a firm commitment to evidence. Science, and public trust in science, thrives in an environment that shields scientific data and analyses from inappropriate political influence. Political officials should not suppress or alter, nor appear to suppress or alter, scientific or technological findings.
- HHS shall ensure that the credibility of Government research is strong. HHS agencies shall ensure that selection of candidates for scientific positions is based primarily on their scientific and technological knowledge, credentials, experience, and integrity. HHS agencies shall ensure that the scientific information used to inform and support policy decisions represents the best science available, is performed with strict adherence to relevant safety and security procedures, and undergoes peer review by qualified experts, where feasible and appropriate, and consistent with law. HHS agencies shall abide by existing whistleblower protections that apply to employees by law or regulation.
- HHS shall facilitate the free flow of scientific information consistent with applicable laws, regulations, and policies. In support of the HHS Open Government Plan, agencies shall expand and promote access to appropriate scientific information and data by making it available online and in open formats, to the extent permitted by applicable law.
- HHS shall convey scientific and technological information to the public such that the presentation is accurate, transparent, and informative. To do so, HHS shall communicate scientific and technological findings by including a clear explication of underlying assumptions and, where appropriate, an accurate contextualization of uncertainties and a description of the probabilities associated with both optimistic and pessimistic projections.

Depending on their specific statutes and missions and the nature of their scientific, technological, and scholarly activities, HHS agencies currently use a variety of methods and procedures designed to maximize the quality, accuracy, objectivity and utility of the scientific and substantive information they disseminate. These methods include convening and participating in conferences, working with advisory committees and stakeholders, sponsoring outreach activities, and, where appropriate, testing publications with targeted audiences to ensure relevance, clarity, and comprehensiveness.

II. Public Communication

HHS provides the public with scientific information through written publications, the media, and a variety of other means. HHS is committed to a culture of openness with the media and the

public. HHS values the free exchange of ideas, data, and information as advancing the Department's mission. Examples of communication vehicles include, but are not limited to: media interviews, press releases, media advisories, audio, and social media.

- As practical and appropriate, HHS shall widely disseminate information concerning its scientific activities, research and programs. Media requests for public information concerning HHS science-related activities shall be addressed promptly, factually and as completely as feasible, in accordance with applicable Federal laws and regulations.
- To ensure timely responses to requests for information, HHS shall ensure cooperation and coordination among the agency's scientific, policy, and public affairs personnel. In response to media interview requests about the scientific and technological dimensions of their work, HHS agencies will offer, to the extent feasible, articulate and knowledgeable spokespersons who can, in an objective fashion, describe and explain their work to the media and the American people.
- HHS scientists may speak to the media and the public about scientific and technological matters based on their official work, with appropriate coordination with their immediate supervisor and the appropriate public affairs office. In no circumstances may public affairs officers ask or direct HHS scientists to alter their scientific findings.
- Within HHS, mechanisms are in place to resolve disputes that arise from decisions to proceed or not to proceed with proposed interviews or other public information-related activities. HHS employees are generally not required to respond to the media.

Research and scientific study findings disseminated by HHS are subject to an external, objective peer review at both the inception stage and the pre-dissemination stage as part of the publication process in peer reviewed journals. Substantive reports from HHS statistical activities undergo a quality review process within their organizations before they are released, including expert review by supervisors, internal peer review by qualified scientists and statisticians, and, in some cases, external peer review as well as expert review by other offices prior to dissemination. Results of evaluation activities are released to the public only after agency management has taken steps to evaluate the quality, accuracy and completeness of the report.

From time to time, HHS agencies disseminate influential scientific information. In such instances, care is taken to ensure that the information is substantially reproducible and replicable. This goal is accomplished by using reliable data sources and sound analytical techniques, and by employing a high degree of transparency about the data, sources, methods, measures, assumptions and limitations used to develop the information in order to facilitate reproducibility by qualified third parties. In the case of original or supporting data, most major epidemiological and statistical activities sponsored by HHS agencies have well-developed public use data dissemination programs that make much of the data available to the public in standardized, de-identified micro-data files.

Because of confidentiality, ethical and feasibility constraints and legal obligations to third parties supplying the information, there may be instances where original or supporting data may not be available to the public, but HHS agencies typically will work with owners of the data to facilitate understanding of the underlying data and resultant analysis, and transparency in data sources and methods will be emphasized in reports or reference documents. In the case of analytical studies,

HHS agencies strive to make provisions for sufficient transparency about data and methods to facilitate independent analysis by qualified members of the public.

III. Use of Federal Advisory Committees

HHS's advisory committee program is governed by a number of federal laws, including the Federal Advisory Committee Act, the Ethics in Government Act, the Government in the Sunshine Act, the Public Health Service Act, the Privacy Act, the Freedom of Information Act, and the Negotiated Rulemaking Act, as well as respective implementing regulations. HHS agencies coordinate with the General Services Administration in matters relating to the Federal Advisory Committee Act.

- HHS shall conduct its recruitment process for new Federal Advisory Committee (FAC) members in an open and transparent manner. When practicable and appropriate, FAC member vacancies shall be announced widely, including notification in the Federal Register with an invitation for the public to recommend individuals for consideration and for self-nominations. When appropriate, HHS agencies shall seek nominations for scientific members – as well as consumer, industry, and patient representatives – from professional societies, industry, consumer and patient advocacy groups, individuals, or other interested parties.
- HHS provides information on each committee on an applicable Web page, such as Advisory Committee meeting announcements, meeting materials, committee charter, and a membership roster. Subject to Privacy Act, Ethics in Government Act, and other statutory/regulatory considerations, professional biographical and other information related to individual qualifications (including current and past professional affiliations) for service as appointed committee members shall be made widely available to the public. Although nonpublic information derived from an OGE 450 Confidential Financial Disclosure Form must be redacted, conflict of interest waivers issued under 18 U.S.C. § 208(b)(3) to members of Federal advisory committees by law are available to the public upon request pursuant to 18 U.S.C. § 208(d)(1). Requestors may seek such covered records through section 105 of the Ethics in Government Act, specifically through use of the Office of Government Ethics Form 201 submitted to the Operating or Staff Division Freedom of Information Office.
- In accordance with law and regulation, members of policy advisory committees are selected based on diverse interests, education, training, and experience. Members of scientific and technical advisory committees should be selected based on expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee members collectively have the appropriate knowledge and experience to address the scientific issues that may arise.
- Consistent with the requirements of the Federal Advisory Committee Act, agency advisory committees should be fairly balanced in terms of the points of view represented with respect to the functions to be performed by the advisory committee.
- Except when explicitly stated in a prior agreement between HHS or one of its agencies and a FAC, all reports, recommendations, and products produced by FACs

should be treated as solely the findings of such committees rather than of the U.S. Government, and thus are not subject to intra- or inter-agency revision.

IV. Professional Development of Government Scientists and Engineers

The foundation of HHS's long-standing record of excellence and accomplishments in science is embodied in our personnel. Accordingly HHS has a significant interest in promoting and facilitating the professional development of its scientists and engineers. Subject to Operating and Staff Division authorities, Federal ethics rules, individual job responsibilities, and existing agency policies, HHS permits and encourages:

- The publication of research findings in peer reviewed, professional or scholarly journals;
- The presentation of research findings at professional meetings; and
- Government scientists and engineers to become editorial board members, to participate in professional and scholarly societies, and on the committees, task forces, and other specialized bodies of these entities, and to receive honors and awards.

V. Implementation

The principles described above are intended to apply only to HHS personnel and internal operations. This document is not intended to impair or otherwise affect authority granted by law to HHS, nor is it intended to create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its Departments, agencies, or entities, its officers, employees or agents, or any other person. Individual HHS agencies may develop agency-specific scientific integrity principles, policies, and procedures of their own suitable for and consistent with their own specific laws, regulations and program needs.