NIH Policy Manual

1111 - Laws and Regulations

Issuing Office: OD/OM/OMA/DCM **Phone:** (301) 496-4606

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Transmittal Notice

1. **Explanation of Material Transmitted:** This chapter is being revised by the Office of Management Assessment (OMA) to reflect changes in the sources of information on laws that affect NIH operations.
2. **Filing Instructions:**

   Remove: NIH Manual 1111 dated 1/31/2002.
   Insert: NIH Manual 1111 dated 10/7/09.

PLEASE NOTE: For information on:

- Content of this chapter, contact OMA at 301-496-4607.
- NIH Manual System, contact OMA at 301-496-4606 or visit http://oma.od.nih.gov/manualchapters

A. Purpose

This chapter presents the sources of information on laws and regulations that affect National Institutes of Health (NIH) programs and operations.

B. Background

Generally, state and local laws do not apply to federal departments and agencies, and therefore, are not considered in this chapter. However, many federal laws, regulations and other policies implemented by the Executive Branch and its departments and agencies apply to NIH.

Questions regarding the applicability of general laws, regulations or policies to NIH programs and operations may be referred to the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) http://www.hhs.gov/ogc. Information on obtaining formal and informal decisions and advice from OGC is contained in NIH Manual Chapter 1170, “Relationships with the Office of the General Counsel”.

Most of the provisions of law that establish the programs of the NIH are found in the Public Health Service (PHS) Act, as amended (42 U.S.C.201 et seq.), particularly in Titles III, IV, and XXIII.

C. Sources of Laws

A public law is a law passed by the Congress and signed by the President or enacted by the Congress over the President's veto. A public law has general applicability, as opposed to a private law that applies only to those persons or entities specifically designated. Public Laws are numbered in sequence throughout the 2-year life of each Congress. Public and private laws are prepared and published by the Office of the Federal Register (OFR), National Archives and Records Administration (NARA). The Government Printing Office (GPO) Access web site contains the text of enacted public and private laws from the 104th Congress to the present at https://www.govinfo.gov/.

Beginning with the 104th Congress, the public and private laws on GPO Access have been digitally signed and certified to assure users that the online documents are official and authentic.

One of the primary sources of information at NIH on existing laws and regulations and their applicability is the NIH Branch of the Public Health Division of the Office of the General Counsel (OGC). The Deputy Associate General Counsel for Public Health, NIH, is located on the NIH campus in Building 31, Room 2B-50, telephone 301-496-6043. The Deputy Associate General Counsel for Public Health, NIH, is the head of the NIH Branch and is known internally at NIH as the NIH Legal Advisor.

Another primary source of information at NIH on existing laws as well as pending legislation, recently enacted public laws, legislative implementation action plans, and legislative proposals, and existing laws is the Office of Legislative Policy and Analysis (OLPA) at https://www.nih.gov/institutes-nih/nih-office-director/olpa. The OLPA is located on the NIH campus in Building 1, Room 244, telephone 301-496-3471. The OLPA offers bill tracking information, legislative update information, information on public laws relevant to NIH, information on Congressional hearings, and information concerning committees of interest to NIH. The OLPA prepares and distributes comprehensive "OLPA Weekly Reports" with timely legislative information.

The OLPA also periodically obtains and distributes to select NIH offices copies of the *Compilation of Selected Acts within the Jurisdiction of the Committee on Energy and Commerce – Health Law* to select offices, including OMA and IC Directors. The *Compilation* also includes the PHS Act, as amended. The Committee usually publishes the *Compilation* periodically. Copies of the*Compilation* are available for inspection at OLPA.

The OLPA also maintains a copy of the United States Code Annotated (United States Code, U.S. Code or U.S.C.). The U.S. Code is available at

https://www.govinfo.gov/app/collection/uscode. The U.S. Code is the codification by subject matter of the general and permanent laws of the United States based on what is printed in the Statutes at Large at https://www.govinfo.gov/app/collection/statute. It is divided by broad subjects into 50 titles and published by the Office of the Law Revision Counsel of the U.S. House of Representatives at http://uscode.house.gov/. The U.S. Code has been published every 6 years since 1926.

Other U.S. Code products exist in addition to those that are available from the Federal Government. For example, the U.S.C.A. (U.S. Code Annotated) and the U.S.C.S. (U.S. Code Service). They contain everything that is printed in the U.S. Code, but also include annotations to case law relevant to the particular statute. While these publications may be more current, they are not the official version of the U.S. Code that is published by the Office of the Law Revision Council.

The Library of Congress also makes comprehensive federal legislative information available online via THOMAS at https://www.loc.gov/item/lcwaN0003262/. THOMAS was launched in 1995 at the request of the leadership of the 104th Congress.

Information on the development of plans, i.e., legislative implementation action plans (LIAPs) that NIH develops to implement specific public laws, as discussed in NIH Manual Chapter 1792, "Legislative Implementation".

D. Sources of Regulations

In accordance with the Administrative Procedure Act (APA) (5 U.S.C. 551), at http://www.archives.gov/federal-register/laws/administrative-procedure/, a rule or regulation is the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy, or describing the organization, procedure, or practice requirements of an agency. Executive Order 12866, "Regulatory Planning and Review", at https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf, also discusses federal regulations and defines a regulation or rule as an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret or prescribe law or policy or to describe the procedure or practice requirements of an agency. However, it does not include administrative actions under 5 U.S.C. 556 and 557, military or foreign affairs, functions of the U.S., or regulations related to agency organization, management, or personnel matters.

The issuance of federal regulations is authorized by the APA. Specifically, 5 U.S.C. 553 is the APA's rulemaking section, as codified in the U.S.C. It describes notice-and-comment requirements that apply to most rulemaking. Violation of federal regulations can be as serious a matter as violation of statutes.

Regulations and proposed regulations are printed in the Federal Register, the daily Federal Government publication that provides a uniform system for publishing Presidential documents, regulations and proposed regulations, notices of meetings, and other official

documents issued by Federal departments and agencies. The Federal Register is available at https://www.govinfo.gov/app/collection/fr.

Regulations.gov at http://www.regulations.gov is the primary online source for all regulations (or rules) issued by U.S. government departments and agencies. The content includes: (1) all regulations that are open to public comment issued by U.S. government departments and agencies including NIH; (2) many federal agency notices published in the Federal Register; and (3) additional supporting materials, public comments, and Federal agency guidance and adjudications. Comments may be submitted through the web site on those documents that are open to the public for comment.

In general, HHS regulations which apply to NIH and the NIH biomedical research community are set forth in Titles 41, 42, and 45 of the Code of Federal Regulations (CFR), an annual codification of the general and permanent regulations published in the Federal Register by Departments and agencies of the Federal Government, available at https://www.ecfr.gov/cgi-bin/ECFR?page=browse.

The regulations of other agencies that apply to NIH operations, such as the regulations of the U.S. Office of Personnel Management (OPM) and the General Services Administration (GSA), are also set forth in the Code of Federal Regulations (CFR). Questions about NIH regulations under development should be directed to the NIH Regulations Officer, OMA, DMS, 301-496-4607.

The Office for Human Research Protections (OHRP) within the Office of Public Health and Science (OPHS), Office of the Secretary (OS), HHS, interprets and oversees implementation of the regulations concerning the Protection of Human Subjects which are codified at 45 CFR Part 46. Information about the regulations is available at http://www.hhs.gov/ohrp/.

The Office of Human Subjects Research (OHSR) within the Office of Intramural Research (OIR) is responsible for ensuring that NIH investigators understand and comply with ethical principles and regulatory requirements involved in human subjects research at NIH. Information about the ethical principles and regulatory requirements is available at https://humansubjects.nih.gov/ethical-guidelines-regulations. Information about OSHR's other activities is available at http://ohsr.od.nih.gov/.

The Office of Laboratory Animal Welfare (OLAW) within the Office of Extramural Research (OER) interprets and oversees implementation of the policies and guidelines concerning the protection of animals involved in biomedical or behavioral research conducted or supported by the Public Health Service, as required by the Health Research Extension Act of 1985, Public Law 99-158, and "Animals in Research." The OLAW has responsibility for the general administration and coordination of the Public Health Service Policy on Humane Care and Use of Laboratory animals on behalf of the Public Health Service. Information about the OLAW is available at http://grants.nih.gov/grants/olaw/olaw.htm.

E. Sources of Guidelines and Policy Statements

There are many policies and guidelines that govern the internal operations of NIH. The NIH Manual, at https://policymanual.nih.gov, is the official agency repository. The NIH Manual System is the formal mechanism for issuing NIH policy. The System is comprised of a series of NIH Manual Chapters issued in the areas of Management (1000 series), Delegations of Authority (1130 series), Equal Opportunity (2200 series), Human Resources (2300 series), Ethics (2400 series), Property and Logistics (2600 series), Information Technology (2800 series), Intramural (3000 series), Grants (4000 and 5000 series), and Combined Grants and Contracts (7000 series).In addition to information provided in the NIH Manual System, supplemental guidance and information about implementing procedures is available from the programs and offices that develop the NIH Manual chapters. For example:

- *Animal Research* – The Office of Animal Care and Use (OACU) within OIR has responsibility for the oversight of adherence to federal regulations and other matters concerning humane care and use of animals within the IRP. The OACU serves as the issuing office for key IRP policy manuals that relate to the animal research program. The Animal Research Advisory Committee Guidelines also govern IRP animal research and can be found on the OACU web site. Information about OACU and its activities, relevant policies, guidelines, standards and procedures is available at http://oacu.od.nih.gov.
- *Contracts* – The Office of Acquisition Management and Policy (OAMP), OALM, has responsibility for the development and implementation of NIH-wide contracting and simplified acquisition policies and procedures that adhere to the Federal Acquisition Regulation and all supplemental departmental and NIH policies and procedures. Information about OAMP and its activities, relevant policies, guidelines, and procedures applicable to contracts may be obtained from OAMP at http://oamp.od.nih.gov/ and from the Offices of Acquisition of each IC at https://oamp.od.nih.gov/division-of-acquisition-policy-and-evaluation.
- *Delegations of Authority* – The OMA, DMS, is the source for information on NIH delegations of authority. Information on the latest delegations of authority is available at http://www.delegations.nih.gov/ and from the NIH Delegations Officer, 301-402-6201 and IC Points of Contact.
- *Federal Register* – The OMA, DMS, is the originating office for NIH guidance on publishing documents in the Federal Register. Information about current Federal Register procedures is available at https://oma.od.nih.gov/DMS/Pages/Federal-Register.aspx and from the NIH Federal Register Liaison Officer, 301-496-4607.
- *Grants* – The Office of Extramural Research (OER) has responsibility to provide guidance to the research institutes on the development and management of extramural (grant, cooperative agreement, and contract) research and training programs. Information about HHS Grants Policy Directives, the HHS Grants Policy Statement and the NIH Grants Policy Manual, applicable to the provision of federal financial assistance through grants and cooperative agreements, and grants procedures is available from OER at https://grants.nih.gov/grants/oer.htm and from the grants

management offices of each Institute/Center (IC) at https://extramural-intranet.nih.gov/.

- *Human Resource Management – (Title 5 Human Resource Management Law and Regulations)* – The Office of Human Resources (OHR), Office of Management, Office of the Director, is the source for information on Title 5 of the U.S. Code, HHS human resource policy and regulations. OHR is the originating office for NIH human resource policies. Information about OHR and OHR guidance and procedures is available at http://hr.od.nih.gov/ and from OHR, 301-496-3592, and IC HR contacts.
- *Information Security* – The NIH Office of the Chief Information Officer (OCIO) is the originating office for NIH security policies, procedures, standards, and guidelines based on federal and HHS requirements under the direction of the NIH Chief Information Officer (CIO). The NIH CIO has delegated authority to the NIH Chief Information Security Officer (CISO) to oversee the NIH Information Security Program to ensure that NIH complies with the Federal Information Security Management Act of 2002 (FISMA), National Institutes of Standards and Technology (NIST) guidance, and HHS policy. Information about the OCIO is available at http://ocio.nih.gov, from the NIH CIO, 301-496-5703, and from the Information System Security Officers (ISSOs) at https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/scroster.aspx.
- *NIH Manual Chapter System* – The OMA, DMS, is the source for the NIH Manual Chapter System, the official NIH policy-issuing mechanism and the official agency repository. Information about the NIH Manual Chapter System and respective chapters is available at http://oma.od.nih.gov/manualchapters/ and from the OMA/DMS, 301-496-4606, and Manual System Contacts.
- *NIH Guidelines for Research Involving Recombinant DNA* – The Office of Biotechnology Activities (OBA), within the Office of Science Policy, (OSP), is the source for information on the latest NIH Guidelines for Research Involving Recombinant DNA. The Guidelines are published in the Federal Register and are incorporated by reference in the HHS regulations that apply to all financial assistance. Information about OBA and the Guidelines is available at https://osp.od.nih.gov/ and from the Director, OBA, 301-496-9838.
- *Organization Change* – The OMA, DMS, is the originating office for NIH policies on organization change. Information on the latest organization change procedures is available at https://oma.od.nih.gov/DMS/Pages/Organizational-Changes.aspx from the NIH Organization Officer, 301-496-8155, and Organizational Change Coordinators.
- *Records Management* – The OMA, DMS, is the originating office for NIH records management policies. Information about the latest records management procedures is available at https://oma.od.nih.gov/DMS/Pages/Records-Management.aspx and from the NIH Records Officer, 301-496-2463, and IC Records Liaisons.
- *Risk Management* – The Risk Management Program establishes and outlines procedures for managing risks and for evaluating controls that improve programs and operations within the agency's extramural, intramural, and administrative components. Information about the NIH Risk Management Program is available from the Director, Division of Risk Management & Audit Liaison, 301-496-1873, and at https://oma.od.nih.gov/RMAL/Pages/Home.aspx.

- *Safety* – The Office of Resource Services (ORS) is the originating office for policies relating to safety. Information about ORS and guidance and procedures relating to safety is available at http://www.ors.od.nih.gov and from the ORS Information Line at orsinfo@mail.nih.gov, and by calling 301-594-6677.
- *Science Policy* – The Office of Science Policy (OSP) is the originating office for science policy on issues of significance to the NIH and the medical research community. Information about science policy is available at https://osp.od.nih.gov/ and from the Director, OSPA, and by calling 301-496-9838.
- *Technology Transfer* – The Office of Technology Transfer (OTT) is the originating office for technology transfer policies. Information about OTT and technology transfer guidance and procedures is available at https://www.ott.nih.gov/, and by calling 301-496-7057 or contacting Technology Development Coordinators at http://www.ott.nih.gov/technology-development-coordinators.

F. 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 NIH Manual 1743, "Keeping and Destroying Records, Appendix I, NIH Records Control Schedule," Item 1100-A-4, Regulations Files Created for the Purpose of Publishing NIH Rules in the Federal Register.

NIH E-mail messages. NIH E-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over 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 guidance. 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 requestor. Employees' supervisors, 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 Chairs of Committees if requested. Requests from individual Members of Congress who are not chairs and are treated as Freedom of Information Act (FOIA) requests. Since most E-mail systems have back-up files that are sometimes 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.

G. Internal Controls

This chapter outlines the sources of information on laws and regulations that affect National Institutes of Health (NIH) programs and operations.

1. **The Office Responsible for Reviewing Laws and Regulations Relative to this Chapter:** The Office of Management Assessment, OM, has the lead responsibility for updating the information outlined in this chapter.

2. **Frequency of Review:** Bi-annually.
3. **Method of Review:** Working with the NIH intramural, extramural, and administrative communities, the OMA develops updated information for the chapter.
4. **Review Reports:** Updated versions of this chapter are sent to the Deputy Director for Management, NIH.