

NIH POLICY MANUAL

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1. **Explanation of Material Transmitted:** This chapter is being revised to reflect changes in the sources of information on laws that effect NIH operations.

2. **Filing Instructions:**

Remove: NIH Manual 1111 dated 12/04/92 in entirety

Insert: NIH Manual 1111 dated 1/31/2002

PLEASE NOTE: For information on:

- o **content of this chapter,** contact the Office of Management Assessment on 301-496-4606.
- o **NIH Manual System,** contact the Office of Management Assessment on 301-496-2832 or visit website < <http://www1.od.nih.gov/oma/manualchapters> >.

NIH MANUAL 1111

PAGE i

DATE: 01/31/2002

REPLACES: 12/04/92

ISSUING OFFICE: OA/OMA/DMS 301-496-4606

TABLE OF CONTENTS

LAWS AND REGULATIONS

Table of Contents

- A. What is the purpose of this chapter?
- B. What background information is relevant to this chapter?
- C. Where can I obtain information about laws?
- D. Where can I obtain information about regulations?
- E. Where can I obtain information about guidelines and policy statements?
- F. What records retention and disposal responsibilities apply to this chapter?
- G. What management controls apply to this chapter?

NIH MANUAL 1111
PAGE 1
DATE: 01/31/2002
REPLACES: 12/04/92
ISSUING OFFICE: OA/OMA/DMS 301-496-4606

LAWS AND REGULATIONS

A. WHAT IS THE PURPOSE OF THIS CHAPTER?

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

B. WHAT BACKGROUND INFORMATION IS RELEVANT TO THIS CHAPTER?

Federal laws are passed by the Congress and enacted by signature of the President (unless Congress overrides a Presidential veto) as described in the Constitution of the United States. Federal laws are implemented and enforced by the Executive Branch and interpreted by the Judiciary (the courts). Federal laws are supplemented by the Executive Branch through the issuance of Executive Orders, regulations and other rulings by the President, Executive Branch agencies, and the Attorney General or administrative law judges, respectively. Generally, state and local laws do not apply to federal agencies and are not, therefore, considered in this chapter.

The applicability of federal laws to NIH operations is determined by the DHHS Office of the General Counsel (OGC). Information on obtaining formal and informal decisions and advice from OGC is contained in NIH Manual 1170, "Relationships with the Office of the General Counsel," available on-line at <http://www1.od.nih.gov/oma/manualchapters/management/1170> >.

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, XXVII, and XXXIII.

C. WHERE CAN I OBTAIN INFORMATION ABOUT 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. Public Laws are numbered in sequence throughout the 2-year life of each Congress. The primary source for obtaining the text of a Public Law is the Government Printing Office, searchable electronically at www.access.gpo.gov/nara/nara005.html. Another option is the Thomas Web site at the Library of Congress < <http://thomas.loc.gov> >. Also, Public Laws are renumbered and incorporated into the United States Code, searchable electronically at www.gpo.gov/congress/cong013.html. The NIH Branch, OGC, DHHS, located in

NIH MANUAL 1111

PAGE 2

DATE: 01/31/2002

REPLACES: 12/04/92

ISSUING OFFICE: OA/OMA/DMS 301-496-4606

LAWS AND REGULATIONS

Building 31, Room 2B50, telephone 301-496-6043, maintains a law library that contains several hard copy sources of laws, including the *United States Code Annotated* and a compilation of laws applicable to NIH called the *Compilation of Selected Acts Within the Jurisdiction of the Committee on Energy and Commerce*. The Office of Legislative Policy and Analysis (OLPA), Office of the Director (OD), located in Building 1, Room 244, telephone 301-496-3471, also maintains a copy of the *United States Code Annotated* and is a primary source for information on new legislative proposals and recently enacted Public Laws. The Office of Management Assessment (OMA) and some IC Directors also have copies of the *Compilation of Selected Acts Within the Jurisdiction of the Committee on Energy and Commerce*.

Information on plans that NIH has developed to implement specific laws, as discussed in NIH Manual 1792, "Legislative Implementation," is available on-line at < <http://www1.od.nih.gov/oma/manualchapters/management/1792> >.

Delegations of authority to operate programs created by laws that apply to NIH are found in NIH Manual 1130, "Delegations of Authority," available on-line at < <http://www1.od.nih.gov/oma/manualchapters> >.

D. WHERE CAN I OBTAIN INFORMATION ABOUT REGULATIONS?

Executive Order 12866, <http://www.faa.gov/avr/arm/EO12866.html> defines a regulation (also called a "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. The issuance of regulations is authorized by the Administrative Procedures Act (5 USC § 551) and violation of regulations is as serious a matter as violation of statutes.

In general, the HHS regulations that apply to NIH and NIH clientele are found in Titles 41, 42, and 45 of the *Code of Federal Regulations* (also referred to as "C.F.R."), an annual codification of the general and permanent regulations promulgated by departments and agencies of the Federal government, available electronically at < <http://www.access.gpo.gov/nara/cfr> >. The regulations of other agencies, such as the Office of Personnel Management (OPM) or the General Services Administration (GSA), that apply to NIH operations are also found in the C.F.R.. Notice of proposed and final

NIH MANUAL 1111

PAGE 3

DATE: 01/31/2002

REPLACES: 12/04/92

ISSUING OFFICE: OA/OMA/DMS 301-496-4606

LAWS AND REGULATIONS

regulations are published in the *Federal Register*, a daily Federal government publication that provides a uniform system for publishing Presidential documents, all regulations and proposed regulations, notices of meetings, and other official documents issued by Federal departments and agencies, available electronically at < <http://www.nara.gov/fedreg> >. Additional information about the *Federal Register* can be found in the *Federal Register Document Drafting Handbook*. (October 1998 Revision), available electronically at < <http://www.nara.gov/fedreg/ddhread.html> > .

The Division of Management Support (DMS), OMA, located at 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20892, maintains a set of the *Code of Federal Regulations* and the *Federal Register* (copies issued in the last 3 months). The NIH Branch of the Office of the General Counsel, DHHS, located in Building 31, Room 2B-50, telephone 301-496-6043, also has these documents (including *Federal Registers* issued in the last 2 years). The NIH Library, located in Building 10, Room 1L25, telephone 301-496-2447, maintains a microfiche set of *Federal Registers* issued in the last 10 years. Microfilm copies are available for periods back to 1960.

Questions about regulations under development should be directed to the NIH Regulations Officer, DMS, OMA, telephone 301-496-4607.

The Office for Human Research Protections (OHRP) within the Office of Public Health and Science (OPHS), Office of the Secretary (OS), DHHS, interprets and oversees implementation of the regulations regarding the Protection of Human Subjects codified at Title 45, Part 46, of the Code of Federal Regulations issued by DHHS. Information about the regulations is available on-line at < <http://ohrp.osophs.dhhs.gov/polasur.htm> >. The OHRP is located in the Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone 301-496-7005.

The Office of Human Subjects Research (OHSR) within the Office of Intramural Research (OIR) helps NIH investigators understand and comply with ethical principles and regulatory requirements involved in human subjects research within the Intramural Research Program (IRP). Information about OHSR activities is available on on-line at < http://ohsr.od.nih.gov/info/ainfo_1.php3 >. The OHSR is located in Building 10, Room 1C116, telephone 301-402-3444. (Note: OHSR's activities are limited to the IRP, while the OHRP has oversight and educational responsibilities wherever DHHS funds are used to conduct or support research involving human subjects.)

NIH MANUAL 1111

PAGE 4

DATE: 01/31/2002

REPLACES: 12/04/92

ISSUING OFFICE: OA/OMA/DMS 301-496-4606

LAWS AND REGULATIONS

The Office of Laboratory Animal Welfare (OLAW) within the Office of Extramural Research (OER) handles regulations and other matters concerning the protection of animals involved 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 and the Policy is available on-line at < <http://grants.nih.gov/grants/olaw/olaw.htm> >. The OLAW is located in Rockledge 1, Suite 1050, MSC 7982, 6705 Rockledge Drive, Bethesda, MD 20892-7982, telephone 301-594-2382.

The Office of Animal Care and Use (OACU) within the Office of Intramural Research (OIR) handles regulations and other matters concerning humane care and use of animals within the IRP. Information about the OACU and its activities relevant regulations and standards is available on-line at < <http://oacu.od.nih.gov> >. The OACU is located in Building 31, Room B1-C37, telephone 301-496-5424. (Note: The OACU's activities are limited to the IRP, while the OLAW has oversight and educational responsibilities wherever DHHS funds are used to conduct or support research involving animals in the Public Health Service.)

E. WHERE CAN I OBTAIN INFORMATION ABOUT GUIDELINES AND POLICY STATEMENTS?

There are many policies that govern the internal operations of NIH. The NIH Manual < <http://www1.od.nih.gov/oma/manualchapters> >, is the most comprehensive source of these policies. The HHS Grants Administration Manual, PHS Grants Administration Manual, and PHS Grants Policy Statement set forth policies that are applicable to the provision of Federal financial assistance through grants and cooperative agreements. Copies of the documents are available from the Office of Extramural Research (OER) on-line at < <http://www.nih.gov/grants/oer.htm> > and at the grants management offices of each IC.

NIH MANUAL 1111

PAGE 5

DATE: 01/31/2002

REPLACES: 12/04/92

ISSUING OFFICE: OA/OMA/DMS 301-496-4606

LAWS AND REGULATIONS

Policies applicable to contracts may be obtained from the Office of Acquisition Management and Policy (OAMP), Office of Administration, telephone 301-496-4422, and from the contracts management offices of each IC.

Other specialized policies may be obtained from the office that is responsible for that facet of NIH operations. For example, the Office of Human Resource Management (OHRM), Office of the Director, telephone 301-496-3592, is the source of Title V law and regulations, DHHS and NIH personnel policies and regulations. Policies relating to safety may be obtained from the Division of Safety (DS), Office of Research Services, telephone 301-496-1357. Technology Transfer policies and procedures may be obtained from the NIH Office of Technology Transfer, (301) 496-7057, < <http://ott.od.nih.gov> >. NIH's *Guidelines for Research Involving Recombinant DNA Molecules* are published in the *Federal Register* and are incorporated by reference in the HHS regulations that apply to all financial assistance. Information on the latest *NIH Guidelines* is available from the Office of Biotechnology Activities (OBA) within the Office of Science Policy (OSP). Information about OBA and the *Guidelines* is available on the Internet at web site < <http://www4.od.nih.gov/oba/> >. The OBA is located at 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985, telephone 301-496-9838.

F. WHAT RECORDS RETENTION AND DISPOSAL RESPONSIBILITIES APPLY TO THIS CHAPTER?

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 1, NIH Records Control Schedule," Item 1100-A-4, Regulations Files Created for the Purpose of Publishing NIH Rules in the Federal Register, available on-line at < <Http://www1.od.nih.gov/oma/manualchapters/management/1743> >.

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 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 requestor. Employees'

NIH MANUAL 1111

PAGE 6

DATE: 01/31/2002

REPLACES: 12/04/92

ISSUING OFFICE: OA/OMA/DMS 301-496-4606

LAWS AND REGULATIONS

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. WHAT MANAGEMENT CONTROLS APPLY TO THIS CHAPTER?

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, OA, 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 the chapter are sent to the Deputy Director for Management.