NIH Policy Manual

1189 - Policy for the Management of and Access to Scientific Collections

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Transmittal Notice

1. **Explanation of Material Transmitted:** This chapter establishes the National Institutes of Health (NIH) policy for the management of and access to a specific subset of scientific collections under NIH stewardship, as set out in the memorandum released by the White House's Office of Science and Technology Policy (OSTP) in March 2014.
2. **Filing Instructions:**
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A. Purpose

This chapter establishes the National Institutes of Health (NIH) policy for the management of and access to a specific subset of scientific collections under NIH stewardship, as set out in the memorandum released by the White House's Office of Science and Technology Policy (OSTP) in March 2014 (see References J.1.).

B. Background

In March 2014, OSTP released a memorandum entitled, "Improving the Management of and Access to Scientific Collections" (see References J.2). The "2014 Memo" directs federal agencies that own, maintain, or otherwise financially support permanent scientific collections to develop a scientific collections management and access policy. In response, this chapter describes the NIH policy and procedures to comply with this directive.
Within the Department of Health and Human Services (HHS), the NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. In addition to funding biomedical and behavioral research into the causes, diagnosis, prevention, and cure of

human diseases and the training of basic and clinical researchers capable of carrying out such research, NIH is also responsible for:

- Developing and maintaining scientific resources that will ensure the Nation's capability to prevent disease; and
- Expanding the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research.

The goals of the 2014 Memo align with NIH's mission; NIH's scientific collections are agency assets that serve as important, primary resources for scientific reference, research, and discovery. The proper management and stewardship of the agency's scientific collections is critical to maintaining their value. Public access to these scientific collections is critical to NIH's mission and the agency's biomedical research efforts. The availability of agency scientific collections advances biomedical research by sparking scientific discovery and prompting the scientific community to address critical challenges in human health. Commensurate with the Administration's goal, as set forth in the 2014 Memo, NIH is committed to the ethical and responsible management of NIH scientific collections to preserve and protect the specimens and the substantial investment these resources represent. Furthermore, NIH supports the objectives of transparency and maximizing public access to NIH scientific collections where feasible and appropriate.

C. Definitions

Scientific collections are sets of physical specimens,[1] living or inanimate, and their supporting records and documentation. For the purposes of this policy, NIH scientific collections are classified as either institutional scientific collections or project collections.

1. Institutional Scientific Collection

   Physical specimens, living or inanimate, owned, managed[2], or funded by NIH and assembled for long-term or permanent preservation due to their importance for biomedical research, and will not be depleted. Institutional scientific collections are preserved, cataloged, and managed or supported by NIH for research, training, and other uses.

2. Project Collection

   Physical specimens, living or inanimate, owned, managed, or funded by NIH and assembled for short-term research use and not intended to be held for long-term or permanent preservation. Project collections are maintained as resources for discrete projects and ancillary studies. These collections are research resources that may at some point in time be depleted.
   Additional guidance on identifying an institutional scientific collection is available in the *Companion Guide* (see References J.3). See Appendix 1 for a Glossary of other terms used in this policy.

D. Scope and Applicability

This policy applies to all current and future institutional scientific collections that are owned or managed by NIH, including those owned by the agency but managed by non-federal entities through a contract. Institutional scientific collections that are owned and managed by non-federal entities but financially supported wholly or in part by NIH grants, including cooperative agreements, may be encouraged to adhere to this policy and its procedures and, in some cases, NIH may require them to comply as a term and condition of individual awards. This policy does not apply to project collections, and does not require the creation of institutional scientific collections or the conversion of project collections into institutional scientific collections. However, NIH Institutes and Centers (ICs) and the NIH Office of the Director (OD) (collectively termed "ICOs"), should periodically review existing project collections under their stewardship to determine whether any should be accessioned (i.e., designated as an institutional scientific collection).
The policy described herein only applies if NIH owns or manages an institutional scientific collection.

E. Policy

The long-term preservation, maintenance, and accessibility of NIH institutional scientific collections are in keeping with the NIH mission. NIH follows many statutes, regulations, and policies (listed in Appendix 2) to ensure the sound management of its institutional scientific collections.
Outlined below are additional requirements established by this policy, specifically relating to the management of and access to institutional scientific collections. This Policy will take effect on October 1, 2017 to allow NIH ICOs to establish the procedures necessary to comply with this Policy.
For more information on implementation of this policy, see the Responsibilities and Procedures sections. Additional guidance is available in the *Companion Guide* (see References J.3.).

1. **Management of Institutional Scientific Collections**

    a. **Institutional Scientific Collection Coordinator**

    An institutional scientific collection coordinator ("Collection Coordinator") must be identified for each IC within three months of the effective date of this policy. For NIH OD, one Collection Coordinator will be assigned to cover all OD program offices. The Collection Coordinator will be responsible for implementing the policy within his/her ICO (see Responsibilities F.2.).

    b. **Institutional Scientific Collection Plan**

    For each institutional scientific collection that is subject to this policy, an Institutional Scientific Collection Plan ("Collection Plan") must be established,

implemented, reviewed annually, and updated as needed. The Collection Plan describes procedures for the long-term preservation, maintenance, and accessibility of that collection (see Procedures G.1.a.), consistent with applicable federal statutes, regulations, and policies (see Appendix 2). For intramural collections, procedures must also be consistent with the *NIH Intramural Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program* (see References J.4.).
For existing institutional scientific collections subject to this policy, a Collection Plan must be developed and implemented within 12 months of the effective date of this policy. For Collections accessioned after the effective date of this policy, a Collection Plan must be developed and implemented within 12 months of the collection being accessioned. The annual review must be completed by October 1 of each year.

c. **Acquisition and Accessioning of an Institutional Scientific Collection**

NIH acquires specimens by a variety of methods, including purchase, donation, transfer, and research project collecting. NIH recommends responsible, disciplined acquisition of specimen collections, and the accessioning to an institutional scientific collection (see Procedures G.1.b.), according to the following principles:

- The acquisition and accessioning of an institutional scientific collection must be relevant to the NIH mission;
- There must be compliance with all applicable laws and regulations relating to collections acquisition and maintenance (see Appendix 2); and
- Collection specimens should be acquired and accessioned to an institutional scientific collection only when there is a good faith intention to retain them as an NIH institutional scientific collection for the long-term—either permanently, or for the natural lifetime of a collection (see information on natural-end-dates in Procedures G.1.d.).

In the initial instance for collections that will become subject to this policy, when accessioning to institutional scientific collection status, a notification of proposed accession must be submitted through the management chain of command and approved before accessioning of that collection (see Procedures G.1.b.).

d. **Deaccessioning and Disposal of an Institutional Scientific Collection**

Each Collection Plan should include procedures and guidance for deaccession and disposal (see Procedures G.1.c.). Once deaccessioned, a specimen is no longer part of an institutional scientific collection and may be disposed of. Deaccessioning and disposal occur for a variety of reasons, such as duplication or redundancy of institutional scientific collection material; deterioration of items beyond their usefulness; selection for research in which samples will be consumed (depleted); or insufficient relationship of collection items to the mission and goals of NIH such that they are judged to be better placed elsewhere.

Prudent management includes considering appropriate deaccessioning and disposal as part of the periodic review and evaluation of existing institutional scientific collections.
A notification of proposed deaccession and disposal of either an entire or portion of an institutional scientific collection subject to this policy must be submitted through and approved by the ICO management chain of command before any samples can be disposed (see Procedures G.1.c.(2)).

e. **Funding of Institutional Scientific Collections**

NIH institutional scientific collections are owned, managed, or funded by the NIH ICOs using available and applicable appropriations through the IC or OD administration budget or programs, as appropriate. Each year, the development, management, and preservation of institutional scientific collections should be addressed in the proposed budget for the program under which they reside (see Procedures G.1.d.).
A realistic cost projection of operational costs for the intended life of a collection should be developed and used to inform the decision to create or maintain an institutional scientific collection (see Procedures G.1.d.).

f. **Third Party Management**

Whenever practicable and appropriate, NIH may make formal arrangements with qualified public or private outside entities to manage an institutional scientific collection that NIH owns or is otherwise responsible for managing. The third party will manage and provide access to the institutional scientific collection in compliance with NIH policies (see Procedures G.1.e.).

2. **Public Access to Institutional Scientific Collection Information and Contents**

a. **Access**

NIH is committed to providing qualified researchers, academics, educators, and others access to its institutional scientific collections where feasible, appropriate, and consistent with the agency's mission and pursuant to applicable statutes, regulations, and policies.
To optimize the accessibility of institutional scientific collections, information about the contents of the collections and associated metadata (including records and documentation) must be made available in digital form, when feasible (See Procedures G.2.a.).
A website, including information, databases or other relevant online resources, if available, should be developed for each institutional scientific collection within 12 months of the effective date of this policy for established institutional scientific collections subject to this policy, and within 12 months of accession of the first specimen for new institutional scientific collections (see Procedures G.2.a.).

b. **Access Limitations**

Physical and digital access to NIH institutional scientific collections must be balanced with preservation, privacy, proprietary, budgetary, human resources, and security concerns. Those seeking physical and electronic access to an institutional scientific collection must adhere to the procedures outlined in the Collection Plan and relevant associated laws, regulations, and policies (see Appendix 2).
All restrictions on physical or digital access shall be limited to the minimum subset of specific specimens, records, and metadata as possible, with all other collection content made public. Where possible, redaction of specific metadata should be favored over limiting digital access to the full metadata associated with an institutional scientific collection (see Procedures G.2.b.).

c. **Federal Clearinghouse and Annual Inventory**

The Registry of U.S. Federal Scientific Collections (herein referred to as the "Federal Clearinghouse", see References J.5.) is an online digital registry of federal scientific collections. It provides information on institutional scientific collections under federal stewardship, with links to the collection databases or websites, in order to provide centralized information about accessing the contents of these collections. The Federal Clearinghouse will serve as a centralized gateway for information on NIH's institutional scientific collections subject to this policy.
Information about existing institutional scientific collections must be submitted to the Federal Clearinghouse within 12 months of the effective date of this policy (see Procedures G.2.c.). Information about new NIH institutional scientific collections must be submitted to the Federal Clearinghouse within 12 months of accession of the first specimen in the institutional scientific collection.
NIH should update entries as needed to maintain current information about NIH institutional scientific collections on the Federal Clearinghouse. In addition, NIH will conduct an annual inventory of existing entries on the Federal Clearinghouse to verify that all entries are up-to-date. This must be completed by October 1 of each year.

F. Responsibilities

1. **IC Directors and the DPCPSI Director**

Each IC Director, or their responsible delegate, is required to implement this policy within the portfolio of his/her IC. For the OD, the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) Director, or their responsible delegate, is required to implement this policy within the portfolio of DPCPSI and other applicable OD program offices. Each Director is responsible for:

- Appointing a Collection Coordinator (see Responsibilities F.2.);
- Ensuring that all collections subject to this policy are identified. This includes determining whether new collections should be accessioned as institutional collections, as well as periodically reviewing existing collections to identify those that should be accessioned (i.e., designated as an institutional scientific collection) (see Scope and Applicability D.);
- Approving any notifications of proposed accession for institutional scientific collections that will be subject to this policy (see Procedures G.1.b.);
- Approving any notifications of proposed deaccession and disposal for institutional scientific collections subject to this policy (see Procedures G.1.c.); and
- Reviewing and approving the annual budget for the program under which each institutional scientific collection subject to this policy falls (see Procedures G.1.d.).

2. **Institutional Scientific Collection Coordinators (Collection Coordinators)**

The Collection Coordinator is the main point person for the institutional scientific collection under the purview of their ICO. They liaise between the Collection Custodians, program offices, and NIH Office of Science Policy (OSP). The Collection Coordinator is responsible for:

- Managing the process for approval of any notification of proposed accession for an institutional scientific collection that will be subject to the policy (see Procedures G.1.b.);
- Informing OSP when the accession of an institutional scientific collection is approved;
- Managing the process for approval of any notification of proposed deaccession for an entire or subset of an institutional scientific collection that is subject to the policy (see Procedures G.1.c.);
- Informing OSP when the deaccessioning of an entire collection (but not of individual specimens) is approved;
- Supporting the development, implementation, and update (as needed) of the Collection Plan by the Collection Custodian for each institutional scientific collection (see Procedures G.1.a.), including final review and approval of the Collection Plan;
- Conducting the annual review of the Collection Plan, to be completed by October 1 each year, and informing OSP that each review has been conducted (See Procedures G.1.a.);
- Sharing each approved and annually reviewed Collection Plan with OSP;
- Making each Collection Plan available to relevant personnel at all times;
- Providing guidance to the Collection Custodian, as needed, to ensure that specimens and associated metadata are collected, processed, stored, accessed and used properly and according to the Collection Plan as well as applicable laws,

regulations, and policies;
- Providing guidance to the Collection Custodian on the development of a realistic cost projection for collection, maintenance, and operation for the intended life of the institutional scientific collection, when necessary (see Procedures G.1.d.);
- Sharing any information and updates to OSP on institutional scientific collections under their purview that are subject to this policy for inclusion in the Federal Clearinghouse (see Procedures G.2.c.). Information about current/new institutional scientific collections must be submitted to OSP within nine months of the effective date of the policy/accession of the first specimen for inclusion on the Federal Clearinghouse; and
- Ensuring that a publically accessible website is developed and maintained for each institutional scientific collection under their purview.

3. **Collection Custodian**

The Collection Custodian is the individual caretaker responsible for ensuring that collection specimens are collected, processed, stored, and used appropriately. The Collection Custodian may be affiliated with NIH or a third party, depending on who has responsibility for managing the collection. In cases where there is not a single Custodian, the term Collection Custodian refers to the point-person for the collection as specified by the ICO. The Collection Custodian is responsible for:

- Preparing the notice of proposed accession for any institutional scientific collection that will be subject to this policy (see Procedures G.1.b.);
- Preparing the notice of proposed deaccession for any institutional scientific collection, subject to this policy (see Procedures G.1.c.);
- Developing, implementing, and updating, as needed, the Collection Plan (see Procedures G.1.a.);
- Annually addressing the proposed budget for the development, management, and preservation of the institutional scientific collection (see Procedures G.1.d.);
- Developing a realistic cost projection to maintain and operate the institutional scientific collection for the duration of its intended life (see Procedures G.1.d.);
- Ensuring that specimens are collected, processed, and stored properly, and in accordance with applicable laws, regulations, and policies;
- Developing and maintaining a publically accessible website for the institutional scientific collection;
- Employing high digitization and formatting standards for institutional scientific collection metadata (see Procedures G.2.a.);
- Making accessible digital metadata associated with institutional scientific collections subject to this policy (where not limited by law, regulation, or policy) online, or via request (see Procedures G.2.a.); and
- Ensuring that specimens and metadata are accessed and used according to the Collection Plan, and in accordance to applicable laws, regulations, and policies.

4. **NIH Office of Science Policy (OSP)**

OSP advises the NIH Director on science policy issues affecting the biomedical research community and participates in the development of new policy and program initiatives. Along with the ICO Directors, OSP will oversee NIH compliance with this policy, and will serve as the main OD point of contact for the Collection Coordinators (see Responsibilities F.2.). OSP is responsible for:

- Verifying that all NIH Collection Plans are reviewed annually;
- Submitting information about NIH institutional scientific collections provided by Collection Coordinators to the Federal Clearinghouse within 12 months of the effective date of this policy for current collections, and 12 months of accession of the first specimen for new collections (see Procedures G.2.c.); and
- Conducting an annual inventory of collection entries on the Federal Clearinghouse (see Procedures G.2.c.), to be completed by October 1 of each year.

G. Procedures

1. **Management of Institutional Scientific Collections**

   a. **Institutional Scientific Collection Plan**

   The Collection Custodian for each institutional scientific collection, assisted as needed, by the ICO Collection Coordinator, will develop, implement, and update an appropriate Collection Plan (see Appendix 3). The Collection Coordinators will perform the final review and approval of their ICO's Collection Plans, conduct the annual review of each Collection Plan under their purview, and send the approved plans to OSP by October 1 of each year.

   b. **Acquisition and Accessioning of an Institutional Scientific Collection**

   Notifications of proposed accession must be submitted through the management chain of command. The ICO Director must approve the initial accessioning of a collection that will be subject to this policy, but not when additional samples are accessioned into an existing collection. The Collection Custodian will prepare the notification, and the Collection Coordinator will manage the approval process. The Collection Coordinator will inform OSP of approvals when a collection is first accessioned, but not when individual specimens are accessioned to that institutional scientific collection thereafter.

   To ensure compliance before accessioning specimens into an institutional scientific collection, the Collection Coordinator should ensure that a Collection Plan has been developed and maintained.

   c. **Deaccessioning and Disposal of an Institutional Scientific Collection**

1. **Standards for Deaccession and Disposal of Scientific Collections**

   The decision to deaccession and dispose of a specimen should be made after careful review of the research and educational values of a collection, as well as the available resources. Subject matter experts who have used the collection as well as those interested in its value for research, resource management, and educational purposes, should be consulted, as appropriate.
   Once deaccessioned, NIH may dispose of specimens via transfer, destruction, and/or consumption as part of a project collection. If transfer to a qualified entity is sought, the Collection Coordinator will perform the effective transfer of specimens and associated metadata, including records and documentation, as appropriate and permitted by law. When transferring an institutional scientific collection, preference should be given to other NIH ICOs, followed by other federal agencies or institutions that will continue to make the collection and associated metadata accessible for research and educational purposes. Moreover, NIH should prefer transferring the complete collection in lieu of dispersing to multiple entities.
   Institutional scientific collections, or specimens within, may only be deaccessioned and disposed of following approval of the appropriate ICO Director and when consistent with any applicable law and other restrictions.

2. **Notification, Review, and Approval**

   Notifications of proposed deaccession must be submitted through the management chain of command, with final approval given by the appropriate ICO Director. The Collection Custodian will prepare the notification, and the Collection Coordinator will manage the approval process. The Collection Coordinator will inform OSP of approvals when they relate to entire collections, but not individual specimens. A notice of proposed deaccession and disposal should contain the following information:

   - Name and contact information of the Collection Coordinator;
   - Signature of each approving official and date approved;
   - Itemized list of specimens to be deaccessioned and disposed;
   - Reason for proposed deaccessioning and disposal;
   - Proposed disposition method (e.g., transfer/destruction/consumptive research);
   - Proposed transfer recipient, if applicable; and
   - Proposed deaccession and disposal date(s).

d. **Funding of Institutional Scientific Collections**

The Collection Custodian should annually address the development, management, and preservation of institutional scientific collections under their purview in the proposed budget for the program. This will be reviewed and approved by the ICO Director, as appropriate.
The Collection Custodian, in consultation with the Collection Coordinator, should develop a realistic cost projection for maintenance and operation of each institutional scientific collection for the duration of its intended life (see Appendix 4 for guidance). A realistic cost projection should reflect the estimated natural-end-date of the collection—the date by which a specimen may no longer be viably stored based on available storage methodologies and the inherent limitations—as determined by the Collection Custodian.

e. **Third Party Management**

Each ICO should develop procedures for the management by a third party of NIH institutional scientific collections subject to this policy.
If managed by a third-party federal agency, then its scientific collections policy will be reviewed for conformance with the provisions of this policy and apply to the institutional scientific collection. An interagency agreement must be executed to document the transfer of the institutional scientific collection and included with the Collection Plan.
If managed by a non-federal entity, then this NIH policy will guide the management of the institutional scientific collection. For all NIH solicitations and contracts that direct an outside, non-federal entity to obtain or create an institutional scientific collection, the Statement of Work must include the requirement that the contractor comply with the policy.
For institutional scientific collections supported fully or in part by an NIH grant, NIH may encourage grantees to comply with this policy and may, in specific cases, be required to comply as a term and condition of award.

2. **Public Access to Institutional Scientific Collection Information and Contents**

a. **Digitization and Formatting Standards**

Specimen metadata is information that describes or characterizes a specimen that is part of an institutional scientific collection and may have its own research or educational value. Metadata includes, but is not limited to, photographs, videos, and associated records and documentation.
When constructing and formatting the institutional scientific collection metadata, the Collection Custodian and associated staff should employmachine-readable and open formats, data standards, and extensible metadata for all new information creation and collection. This will facilitate search and discoverability and provide clear public guidance for accessing collections materials, consistent with the Office of Management and Budget Open Data

Policy (see References J.6.). For institutional scientific collections existing prior to the issuance of this policy, every reasonable effort will be made to comply with these digitization and formatting standards.
When available and not limited by law, regulation, or policy, the Collection Custodian will make accessible to the public all digital metadata associated with institutional scientific collections subject to this policy. This digital metadata must be of the highest available fidelity and resolution, and should be made available to the public by request or online through a database or website. The online institutional scientific collection database or website will be linked to the Federal Clearinghouse (see Procedures G.2.c.).

b. **Access Limitations**

Collection Coordinators, in consultation with their IC management and OSP may limit access to NIH institutional scientific collections and related catalogs, databases, records, and metadata for purposes of:

- Safeguarding individual privacy, confidentiality, trade secrets, copyright, and intellectual property rights;
- Adhering to laws, regulations, treaties, and international or tribal agreements;
- Addressing general security concerns and protecting national security; and
- Responsibly acting on to resource limitations, specimen availability, and preservation constraints.

Any limits on public access to an institutional scientific collection must be justified in the Collection Plan (see Appendix 4). These include any:

- Restrictions on physical access to specimens in the institutional scientific collection; and
- Redactions of the digital access to data about the institutional scientific collection.

Custodians of NIH institutional scientific collections subject to this policy must ensure that the investigators using the collections comply with all statutory and regulatory requirements for safeguarding individual privacy, confidentiality, intellectual property rights, and national security.

1. **Practices for Safeguarding Privacy of Individuals and Confidentiality of Their Data**

   Protecting the privacy of individuals and the confidentiality of human data is essential for the ethical conduct of research. Many laws, regulations, and policies govern privacy and confidentiality of human specimens and data. Among the statutory and regulatory requirements that may apply are:

- The Privacy Act of 1974, as amended, and HHS implementing regulations (see References J.7.);
- The HHS Regulations for Substance Abuse and Mental Health Records (see References J.8.);
- The HHS Human Subjects Protections Regulations (see References J.9.); and
- NIH Genomic Data Sharing (GDS) Policy (see References J.10.).

More information on how these federal statutes, regulations, and policies might apply to institutional scientific collections is included in Appendix 5. Additional privacy protections may be appropriate for data maintained in institutional scientific collections. For example, data in NIH institutional scientific collections may be protected by Certificates of Confidentiality, which are used to prevent compelled release of information (see References J.11. and J.12.).

2. **Practices for Safeguarding Intellectual Property**

   As appropriate, NIH encourages patenting of technology suitable for subsequent private investment that may lead to the development of products that address public health needs without impeding research, in accordance with the Stevenson-Wydler Act of 1980 (see References J.13.). Collection Coordinators must ensure that proprietary information in the institutional scientific collections under their stewardship is handled appropriately.

3. **Practices for Safeguarding National Security**

   Institutional scientific collections may contain living or inanimate specimens that are potentially harmful to human health or the environment. In some cases, access to these collections (including both the physical specimens and information associated with the specimens) may be governed by additional laws or regulations. These include regulations governing the possession, use, and transfer of select agents and toxins (the Select Agent Regulations (see References J.14.)), and/or regulations governing access by foreign nationals (the Export Administration Regulations (see References J.15.) and the International Traffic in Arms Regulations (see References J.16.)).

c. **Federal Clearinghouse and Annual Inventory**

Each Collection Coordinator will provide the following information, updating as required, to OSP about each NIH institutional scientific collection under their stewardship for inclusion in the Federal Clearinghouse:

- Collection name;
- Brief (no more than 1 paragraph) description of institutional scientific collection contents;
- Contact information to request access to the institutional scientific collection, as appropriate;
- Link(s) to the existing entry in the Federal Clearinghouse (see References J.5.) and any relevant collection websites and databases; and
- Plans or approved decisions, if any, to deaccession and dispose of the collection and rationale for doing so (see Procedures G.1.c.).

OSP will update the Federal Clearinghouse (see References J.4.) to reflect information provided by Collection Coordinators on new and current institutional scientific collections. In addition, OSP will conduct an annual inventory via data call to the Collection Coordinators, to verify that NIH entries in the Federal Clearinghouse are current and accurate, and collect any updates that had not been made throughout the year.

H. Records Retention and Disposal

All records 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 Schedules" (as amended) (see References J.17.). These records must be maintained in accordance with current NIH Records Management and federal guidelines. Contact your ICO Records Liaison or the NIH Records Officer for additional information.

I. Internal Controls

The purpose of this manual issuance is to describe the management of and access to institutional scientific collections under NIH stewardship.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:**
    - NIH Office of the Director, Office of Science Policy.
2. **Frequency of Review**
    - Annual inventory of listings on Federal Clearinghouse.
    - Annual review of the Collection Plans.
3. **Method of Review**
    - OSP will conduct an annual inventory (data call) of collection entries on the Federal Clearinghouse to ensure compliance with the policy. The ICO Collection Coordinators will be asked to report any institutional scientific collections under

their purview, as well as notify of any changes or other relevant information as appropriate.
    - OSP, informed by the Collection Coordinators, will verify that all Collection Plans are reviewed annually.

4. **Review Reports are sent to the NIH Deputy Director for Science, Outreach, and Policy.**

J. References

1. National Science and Technology Council, Committee on Science, Interagency Working Group on Scientific Collections. *Scientific Collections: Mission-Critical Infrastructure of Federal Science Agencies*. Office of Science and Technology Policy, Washington, DC. 2009. Available at: http://www.whitehouse.gov/sites/default/files/sci-collections-report-2009-rev2.pdf.
2. Holdren, J.P. Memo, *Improving the Management of and Access to Scientific Collections*. Office of Science and Technology Policy, Washington, D.C. March 20, 2014. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_memo_scientific_collections_march_2014.pdf.
3. *Companion Guide: Guidance for Implementing the National Institutes of Health Policy for the Management of and Access to Scientific Collections*. Available at: https://osp.od.nih.gov/wp-content/uploads/2016/08/Companion%20Guide.pdf.
4. *NIH Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program* (2013). Available at:https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-biospecimen.pdf.
5. *Registry of U.S. Federal Scientific Collections*. Available at: http://usfsc.grscicoll.org/.
6. Burwell, S.M., VanRoekel, S., Park, T., Mancini, D.J. Memo, *Open Data Policy—Managing Information as an Asset*. Office of Management and Budget. (May 9, 2013). Available at: https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2013/m-13-13.pdf.
7. *Privacy Act of 1974* (U.S.C. § 552a), as amended, and HHS Implementing Regulations (45 C.F.R. Part 5b). Available at: http://www.justice.gov/opcl/privacy-act-1974 and https://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1-part5b.
8. *HHS Regulations for Substance Abuse and Mental Health Records* (42 C.F.R. Part 2). Available at: http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2.
9. *HHS Regulations for the Protection of Human Subjects* (45 C.F.R. Part 46). Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
10. *NIH Genomic Data Sharing (GDS) Policy*. Available at https://gds.nih.gov/03policy2.html.
11. *NIH Certificates of Confidentiality Kiosk*. Available at: https://grants.nih.gov/grants/policy/coc/index.htm.

12. *HHS Regulations for Substance Abuse and Mental Health Records* (42 C.F.R. Part 2a). Available at: http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2.
13. *Stevenson-Wydler Technology Innovation Act of 1980* (P.L. 96-480). Available at: http://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg2311.pdf.
14. *Select Agent Regulations* (42 C.F.R. Part 73). Available at: http://www.selectagents.gov/regulations.html.
15. *Export Administration Regulations* (15 C.F.R. Part 730-774). Available at: https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear.
16. *International Traffic in Arms Regulations* (22 C.F.R. Part 120-130). Available at: https://www.pmddtc.state.gov/regulations_laws/itar.html.
17. NIH Manual 1743. *Keeping and Destroying Records*. Appendix 1, NIH Records Control Schedules. 2015.

Appendix 1 – Glossary

- **Accession:** The formal process used to acquire and record a collection specimen, or group of specimens as part of an NIH institutional scientific collection.
- **Acquisition:** Acquiring a specimen, or group of specimens, into an NIH collection.
- **Biospecimen:** Tissue, blood, urine, or other human-derived material. See *Specimen*.
- **Collection Coordinator:** See *institutional scientific collection coordinator*.
- **Collection Custodian:** The Collection Custodian is the individual caretaker responsible for ensuring that collection specimens are collected, processed, stored, and used appropriately. The Collection Custodian may be affiliated with NIH or a third party, depending on who has responsibility for managing the collection. In cases where there is not a single Custodian, the term Collection Custodian refers to the point-person for the collection as specified by the ICO.
- **Collection Plan:** See *Institutional Scientific Collection Plan*.
- **Deaccession:** The formal process used to approve and record the removal of a specimen, or group of specimens from within an NIH institutional scientific collection.
- **Disposal:** Physically removing a specimen, or group of specimens, from an NIH scientific collection.
- **Federal Clearinghouse:** See *Registry of US Federal Scientific Collections.*
- **Institutional scientific collection:** Physical specimens, living or inanimate, which are owned, managed, or funded by NIH and assembled for long-term or permanent preservation due to their importance for biomedical research, and will not be depleted. Institutional scientific collections are preserved, cataloged, and managed or supported by NIH for research, training, and other uses.
- **Institutional scientific collection coordinator (Collection Coordinator)**: IC or DPCPSI staff person that liaises with the OSP and works with each of the Collection Custodians within their ICO to develop, implement, and report on the procedures required for each institutional scientific collection.
- **Institutional Scientific Collection Plan (Collection Plan):** Documentation on the procedure for managing and operating an institutional scientific collection.

- **Intellectual property:** An intangible product of the human intellect such as a copyright, a protectable trademark, an invention, or a trade secret.
- **Managed:** Stored and/or administered by.
- **Metadata:** Information that describes a specimen that is part of an institutional scientific collection, making it uniquely identifiable and more easily searchable. The information about the specimen may have its own research or educational value (e.g., digital images of macroscopic specimens or cultures of microscopic specimens).
- **Natural-end-date:** The date by which a specimen may no longer be viably stored based on available storage methodologies and the inherent limitations.
- **Project collection:** Physical specimens, living or inanimate, owned, managed, or funded by NIH and assembled for short-term research use and not intended to be held by NIH for long-term or permanent preservation. Project collections are maintained as resources for discrete projects and ancillary studies. These collections are research resources that may at some point in time be depleted.
- **Registry of US Federal Scientific Collections (registry of USFSC):** An online, public, digital repository that identifies information about a Federal Agency's institutional scientific collections, and as appropriate, the institutional scientific collections database associated with that collection. Located at: http://usfsc.grscicoll.org/.
- **Repository:** An organization, place, room, or container (a physical entity) where specimen samples are stored.
- **Sample:** A portion or aliquot of a specimen.
- **Scientific collection:** Sets of physical specimens, living or inanimate, and their supporting records and documentation.
- **Specimen:** Material (either a whole object or part of an object) held within a collection derived from a living (e.g., animal, plant, fungi, bacteria) or inanimate (e.g., rock, mineral) source.Note, a single biopsy may generate several biological specimens, including multiple paraffin blocks or frozen specimens. A biological specimen can comprise genetic material, subcellular structures, cells, tissue (e.g., bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta).

Appendix 2 – Relevant Statutes, Regulations, and Policies

Many federal statutes, regulations, and policies provide the authority and establish the framework for the management of and access to NIH institutional scientific collections. These include, but are not limited to the following (note, a full citation is provided only for items not previously cited in the main body of the Chapter, and therefore listed in the Reference Section):

- *America COMPETES Reauthorization Act of 2010* (P. L. 111-358 Section 104). Available at: https://www.gpo.gov/fdsys/pkg/PLAW-111publ358/pdf/PLAW-111publ358.pdf.[3]

- Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH (2015). Available at: http://ohsr.od.nih.gov/ohsr/public/SOP_21_v4_10-20-15_AppD4-16-16.pdf
- *Bayh-Dole Act Bayh-Dole University and Small Business Patent Procedures Act of 1980* (P.L. 96-517). Available at: https://history.nih.gov/research/downloads/PL96-517.pdf
- *Copyright Act* (17 U.S.C. § 101, et seq). Available at: http://www.copyright.gov/title17/92chap13.html
- *Dept. of Labor Regulations for Occupational Exposure to Bloodborne Pathogens* (29 C.F.R. 1910.1030). Available at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- *Executive Order on Making Open and Machine Readable the New Default for Government Information* (May 9, 2013). Available at: https://www.whitehouse.gov/the-press-office/2013/05/09/executive-order-making-open-and-machine-readable-new-default-government-
- Burwell, S.M., VanRoekel, S., Park, T., Mancini, D.J. Memo, *Open Data Policy—Managing Information as an Asset.* Office of Management and Budget (May 9, 2013). Available at:https://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-13.pdf
- *Export Administration Regulations* (15 C.F.R. Part 730-774). Available at: https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear
- *Federal Acquisition Regulations System, Solicitation Provisions and Contract Clauses* (48 C.F.R. Part 52) Available at: https://www.gpo.gov/fdsys/pkg/CFR-2011-title48-vol2/pdf/CFR-2011-title48-vol2-chap1.pdf
- *Federal Information Security Management Act of 2002* (44 U.S.C. § 3541, et seq). Available at: http://csrc.nist.gov/drivers/documents/FISMA-final.pdf
- *Freedom of Information Act* (5 U.S.C. § 552), and *HHS Freedom of Information Act Regulations* (45 C.F.R. 5). Available at: http://www.foia.gov/index.html, andhttp://www.hhs.gov/foia/statutes-and-resources/45cfr5/index.html
- *HHS Regulations for the Protection of Human Subjects* (45 C.F.R. Part 46). Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- *Regulations for Clinical Research Subject to FDA Oversight* (e.g., 21 C.F.R. 50, 56, 312 and 812). Available at:http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118903.htm
- *International Traffic in Arms Regulations* (22 C.F.R. Part 120-130). Available at: https://www.pmddtc.state.gov/regulations_laws/itar.html.
- *NIH Genomic Data Sharing (GDS) Policy.* Available at https://gds.nih.gov/03policy2.html.
- *Guidelines for the Conduct of Research in the Intramural Research Program at NIH* (2007). Available at:https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research-6_11_07.pdf

- *NIH Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program* (2013). Available at:https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-biospecimen.pdf
- *Standards for Clinical Research Within the NIH Intramural Research Program* (2009). Available at: http://www.cc.nih.gov/ccc/patientcare/pdf/cc_research_standards.pdf
- *Paperwork Reduction Act* (44 U.S.C. § 3501–3521) and applicable regulations (5 C.F.R. 1320). Available at: https://www.gpo.gov/fdsys/pkg/USCODE-2011-title44/pdf/USCODE-2011-title44-chap35-subchapI.pdf
- *Privacy Act of 1974* (5 U.S.C. § 552a), and *HHS Privacy Act Regulations* (45 C.F.R. 5b). Available at: http://www.justice.gov/opcl/privacy-act-1974 , andhttps://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1-part5b.
- *Select Agent Regulations* (42 C.F.R. Part 73). Available at: http://www.selectagents.gov/regulations.html.
- *HHS Technology Transfer Policies*. Available at: https://www.ott.nih.gov/hhs-technology-transfer-policies
- *Small Business Innovation Research Reauthorization Act of 2011* (P.L. 112-81). Available at: https://www.congress.gov/bill/112th-congress/senate-bill/493
- *Stevenson-Wydler Technology Innovation Act of 1980* (P.L. 96-480). Available at: http://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg2311.pdf.
- *Trade Secrets Act* (18 U.S.C. § 1905). Available at: https://www.gpo.gov/fdsys/pkg/USCODE-2012-title18/pdf/USCODE-2012-title18-partI-chap93-sec1905.pdf

This NIH policy to improve the management of and access to NIH institutional scientific collections does not conflict with any existing Department of Health and Human Services policies.

Appendix 3 – Institutional Scientific Collection Plan

The Collection Plan should include, without limitation and as applicable:

- Institutional scientific collection information, including collection name, content descriptions, and identification of the Collection Custodian;
- Procedures for the development and maintenance of an online public institutional scientific collection website that is available to be linked to the Federal Clearinghouse (see Procedures G.2.c.);
- Specimen and data collection procedures and processing methods;
- Specimen identification and labeling procedures, including the use of unique identifiers;
- Specimen storage and retrieval procedures, ideally using a computer-based inventory system capable of generating reports on the location of and key information about tracking specimens;

- Plans for monitoring and maintaining collection equipment and facilities;
- Plans for ensuring staff proficiency and training for handling specimens;
- Other aspects of ensuring quality control and quality assurance;
- Provision of collection metadata;
- Procedures for shipping and receiving specimens;
- Procedures and guidance for the deaccession and disposal of specimens, including a procedure for the orderly transfer of specimens to a new manager, IC or outside entity;
- Biosafety procedures;
- Security procedures;
- Application of human subject protections and privacy; and
- Any limits on public access to the collection, including justification for these limitations.

Appendix 4 – Establishing a Cost Projection

A realistic cost projection may include the costs associated with the following activities:

- Acquisition of new specimens and growth of the collection;
- Documentation of specimens (accessioning, cataloging, database input) and periodic inventorying;
- Sharing and loaning of specimens and associated records and documentation;
- Ensuring specimen and information security, if and as required by law;
- Staffing (salary and benefits);
- Overhead expenses for infrastructure to include building, fixtures, cabinets, shelving, archival boxes, bags, labels, freezers, etc.;
- Space;
- Quality control and quality assurance;
- Emergency or contingency planning, including backup power; and
- Special infrastructure needs assessment and implementation, including:
    - Higher quality infrastructure than standard office, laboratory, or other standard space;
    - Additional physical security or other infrastructure or services that would be required by applicable statute, regulations, or policy (e.g., security and procedures necessary for management of controlled substances);
    - Additional specialized services (e.g., liquid nitrogen and other specialized gases) and backing up collections to protect against a catastrophic event;
    - Additional fire safety considerations associated with storage of flammable substances; and
    - Special IT infrastructure.

Appendix 5 – Safeguarding Individual Privacy and Confidentiality

Provided below is information on some of the federal statutes, regulations, and policies that may apply at NIH to protect individual privacy and confidentiality relating to human specimens and associated data:

- The *Privacy Act of 1974*,[4] protects records held by federal agencies that are included in systems designed to be retrieved by personal identifiers such as a name, social security number, or other identifying number or symbol. An individual is entitled to access to his or her records and to request correction of these records if applicable. The Privacy Act prohibits disclosure of these records without the written consent of the individuals to whom the records pertain unless one of the twelve disclosure exceptions enumerated in the Act, or a routine use described in the system notice applies. If an institutional scientific collection contains such records protected under the Privacy Act, then the Collections Coordinator will oversee the process to develop a notification in the Federal Register when any such system of records is established.
- The *HHS Regulations for the Protection of Human Subjects*[5] stipulate that, where applicable, unless exempted or waived, an individual must consent to collection, use or reuse of identifiable data and an Institutional Review Board must approve the provisions to protect the privacy of subjects and to maintain the confidentiality of data before research may be conducted using identifiable human biospecimens and any data associated with human biospecimens that may be linked to living individuals. Note that the *Regulations for Clinical Research Subject to FDA Oversight*[6] might also apply in some cases.
- Other NIH and program-specific policies may also apply. For example, the Collection Coordinator for, and any investigators using, NIH institutional scientific collections that include genomic data in addition to human specimens, even if stripped of identifiers, may be subject to the NIH GDS Policy.[7] The GDS Policy within the NIH requires that human genomic data be de-identified and access to that data be controlled, unless explicitly consented for unrestricted access, among other conditions.

Appendix 6 – Additional Resources

The resources listed below are not intended to be exhaustive but rather to provide useful examples and references for biospecimen resources and scientific collections.

- *National Cancer Institute's Best Practices for Biospecimen Resources,* (2016). Available at: http://biospecimens.cancer.gov/practices/.
- *International Society for Biological and Environmental Repositories Best Practices for Repositories, Collection, Storage, Retrieval and Distribution of Biological Materials for Research*, Third Edition (2011). Available at: http://biorepository.uic.edu/Contact_Us_files/ISBERBestPractices3rdedition.pdf

[1] See Appendix 1 for the definition of specimen, as it is referred to in this policy. Please note that the term specimen includes, but is not limited to, material derived from a human source (i.e., biospecimen).

[2] See Appendix 1 for the definition of managed, as it is referred to in this policy. Managed by NIH, specifically refers to collections stored at an NIH location and/or administered by NIH staff.

[3] This legislation requires the OSTP Director to "develop policies for the management and use of federal scientific collections to improve the quality, organization, access, including online access, and long-term preservation of such collections for the benefit of the scientific enterprise."

[4] Federal Privacy Act of 1974 (U.S.C. § 552a), as amended. Available at: http://www.justice.gov/opcl/privacy-act-1974.

[5] HHS Regulations for the Protection of Human Subjects (45 C.F.R. Part 46). Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html..

[6] Regulations for Clinical Research Subject to FDA Oversight (21 C.F.R. 50, 56, 312 and 812). Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118903.htm.

[7] NIH Genomic Data Sharing (GDS) Policy. Available at https://gds.nih.gov/03policy2.html.