Companion Guide:

Guidance for Implementation of the NIH Policy for the Management of and Access to Scientific Collections

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Introduction

This guidance is meant to assist NIH Institutes and Centers (ICs), and offices within the NIH Office of the Director (OD), to implement the NIH Policy for the Management of and Access to Scientific Collections (herein referred to as the "NIH Policy").

Background

The NIH Policy was developed in response to a memorandum issued by the White House Office of Science and Technology Policy (OSTP) on March 20, 2014 (herein referred to as the "2014 Memo").[1] The 2014 Memo mandated that Federal agencies develop individualized policies focused on improving the management of and access to certain scientific collections under agency stewardship, whose long-term preservation is important to the scientific endeavor.

Scientific collections are broadly defined in the 2014 Memo as ***"****a set of physical objects, living or inanimate, and their supporting records and documentation."*[2] The specific scientific collections that the 2014 Memo identifies as subject to the agency policies are those that *"serve as long-term research assets preserved, cataloged, and managed by or supported by Federal agencies for research, resource management, education, and other purposes."*[2] Examples of federal scientific collections for which the policy is directed include: moon rocks (NASA); the National Fungus Collection (Agricultural Research Service); insect collections (Natural History Museum); and, rock cores (USGS Core Research Survey).[3]

Collections subject to the NIH Policy

The NIH Policy only applies to scientific collections that are object-based (i.e., not solely data sets) and intended for long-term preservation. These scientific collections are referred to as "institutional scientific collections" in the NIH Policy.[4] NIH anticipates that most of its collections will not be

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[1] Available at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_memo_scientific_collections_march_2014.pdf

[2] Page 2-3 of the 2014 Memo.

[3] 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. See also the current listing on the *Registry of U.S. Federal Scientific Collections*. Available at: http://usfsc.grscicoll.org/.

[4] Section C.1 of the NIH Policy.

considered institutional scientific collections, as many are assembled for consumatory research in which they will be depleted and are not intended for long-term preservation.

Furthermore, only NIH-owned or managed institutional scientific collections are required to be subject to the NIH Policy.[5] Institutional scientific collections that are not owned by NIH—such as those funded through grants—are only subject to the NIH Policy if it is made a Term and Condition of an award.[6]

NIH ICs and OD offices (ICOs) will identify which collections under their stewardship are subject to the NIH Policy, based on the parameters outlined in the Scope and Applicability section of the Policy. This Companion Guide will assist ICs identify which scientific collections fall within the scope of the NIH Policy, as well as those which are excluded.

Key actions that the NIH Policy requires

The NIH Policy is not designed to change the way NIH manages its collections. Rather, for collections subject to the Policy, it is designed to formalize certain procedures to maximize management of and access to these collections.

In implementing the NIH Policy, each NIH IC Director and the Director of the NIH OD Division of Program Coordination, Planning, and Strategic Initiatives must appoint an "institutional scientific collection coordinator" (herein referred to as the "Collection Coordinator"). The Collection Coordinator will help collection custodians develop and implement an "institutional scientific collection plan" (herein referred to as the "Collection Plan") for each collection in their portfolio that is subject to the NIH Policy, performing an annual review of these plans, and updating as necessary. The plan will describe the procedures for the long-term preservation, maintenance, and accessibility of the collection. To make collections more accessible, a website must be developed for each collection subject to the NIH Policy, and information on the collection must be posted on a centralized government registry that is publically accessible online, known as the *Registry of US Federal Scientific Collections* (herein referred to as the "Clearinghouse").[7]

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[5] See Section D of the NIH Policy. Note that page 3 of the 2014 Memo indicates that these policies should apply to scientific collections that are owned, directly managed, or financially supported by Federal agencies. However, Section 3h (page 5) of the 2014 Memo indicates that for collections that are not owned by NIH (e.g., those funded through grants), the policy is not mandatory, but should instead be applied where appropriate.
[6] Section D of the NIH Policy.
[7] The *Registry of U.S. Federal Scientific Collections*. Available at: http://usfsc.grscicoll.org/.

Identifying Collections Subject to the NIH Policy

The following is a tool to help identify whether or not a scientific collection falls under the purview of the NIH Policy.

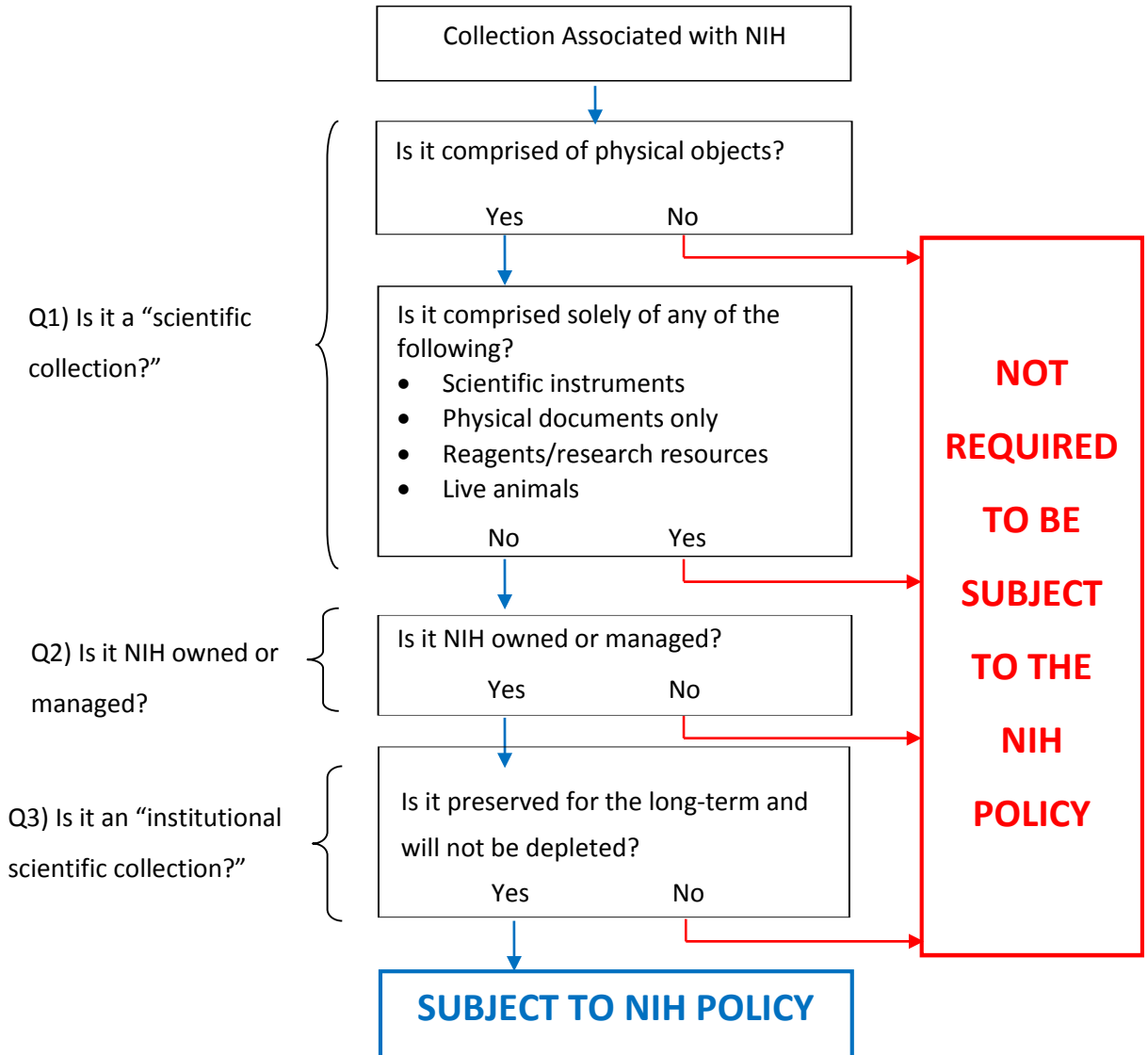
There are three overarching questions:

Question 1: Is the collection a "scientific collection?"

Question 2: Is the collection owned or managed by NIH?

Question 3: Is the collection an "institutional scientific collection?"

If the answer is YES to all these overarching questions, then the collection is subject to the NIH Policy. Following is a decision tree designed to help answer the three overarching questions. Please note, more information on each question is provided following the decision tree.



Question 1: Is the collection a scientific collection?

Scientific collections are defined in the NIH Policy as "*sets of physical specimens, living or inanimate, and their supporting records and documentation.*"[8]

Question 1a: Is the collection comprised of physical objects (specimens)?

For the purposes of the NIH Policy, scientific collections must be comprised of physical objects (specimens), with the caveat that certain object-based collections do not fall under the Policy (see Question 1b below). A scientific collection may include supporting records and documentation. However, it cannot consist entirely of digitized information or metadata that describe or have replaced physical objects.

- **If YES, then address Question 1b below.**
- **If NO (i.e., purely *in silico/*computer generated), then the collection is not subject to the NIH Policy.**

Question 1b: Does the collection comprise any of the following:

- **Scientific instruments**: Instruments considered to have historical, rather than scientific value.
- **Physical documents or archives:** Supporting documentation/data (e.g., lab notebooks) alone are excluded, but could be included as part of an object-based scientific collection as a whole.
- **Reagents and research resources:** Materials that may be feasibly or practically manufactured or readily reproduced (e.g., chemical synthesis repositories as well as commercially available cell lines, nucleic acids, antibodies, or viral stocks).
- **Live animals**: Living animals (e.g., transgenic mice). Note this exemption excludes organs, tissues, or other specimens collected from live animals, as well as gametes and embryos.

- **If NO, then the collection constitutes a scientific collection, and may be subject to the NIH Policy; address Question 2 below.**
- **If YES then the collection is not subject to the NIH Policy.**

[8] Definition originated from an OSTP Memorandum released on March 20, 2014. Available at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_memo_scientific_collections_march_2014.pdf.

Question 2: Is the scientific collection owned[9] or managed by NIH?

The NIH Policy applies to all institutional scientific collections that are owned or managed by NIH.[10] For reference, NIH is considered to own scientific collections that are funded (wholly or in part) through contracts and/or Intramural budget mechanisms. Furthermore, if NIH manages a collection fully supported by another federal agency, then that collection could be considered subject to the NIH Policy if it meets the criteria for an institutional scientific collection.

Scientific collections owned and managed by non-federal entities that receive support from NIH grants or cooperative agreements are not typically subject to the NIH Policy. However, they may be subject to the NIH Policy if this requirement is written into the Terms and Conditions of the award.

- **If YES, then the scientific collection may be subject to the NIH Policy; address Question 3 below.**
- **If NO, then the scientific collection is not subject to the NIH Policy.**

Question 3: Is the scientific collection (either in part or as a whole) an institutional scientific collection?

The NIH Policy applies only to NIH owned or managed institutional scientific collections assembled and preserved as long-term[11] or permanent research assets (i.e., not assembled for short-term use).[12]

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[9] The term "owned" refers only to the implications of the funding mechanism used to support the collection. NIH recognizes that from an ethical standpoint, it may be considered a custodian rather than the owner of human-derived specimens.

[10] Section D of the NIH Policy.

[11] Each ICO will define what "long-term" means for a specific collection. Factors that may influence an IC's definition include, but are not limited to, the realistic lifespan of that specific specimen due to storage methods, type of specimen, and its usefulness in serving the NIH mission.

[12] Sections C and D of the NIH Policy.

Samples of specimens within an institutional collection may be used, but not in such a way that they would be destroyed or damaged, leading to their depletion.

An entire collection does not have to be designated an institutional scientific collection. For example, reference samples, portions of collections past which samples may not be depleted, or sections of collections considered important for preservation, may be designated as institutional scientific collections. The remainder is considered a project collection, and not subject to the NIH Policy.

- **If YES, then the scientific collection (or part of it) is designated an institutional scientific collection and is subject to the NIH Policy.**
- **If NO, then the scientific collection is not subject to the NIH Policy.**

Additional questions when identifying an institutional scientific collection.

Are future collections subject to the NIH Policy?

Yes. The NIH Policy applies to all current and future institutional scientific collections that are owned or managed by NIH.

Is the size of the collection relevant to the NIH Policy?

No. Size does not affect whether a collection is designated as an institutional scientific collection.

Can part of a collection be designated as an institutional scientific collection?

Yes. Refer to Question 3 of the decision tree for more detail.

Is a collection's location relevant?

No. The location does not affect whether a collection is subject to the NIH Policy (i.e., it can be onsite at NIH or at another U.S. or international location). Institutional scientific collections subject to the NIH Policy may also span multiple sites.

Can an institutional scientific collection or project collection change status?

Yes. A scientific collection may transition between an institutional and project collection based on the current parameters of the collection (referred to in the NIH Policy as accessioning and deaccessioning of an institutional scientific collection). For example, in situations where specimens must be depleted (e.g., during a public health emergency where consummatory research is necessary), an institutional collection might be deaccessioned and re-designated as a project collection.

Are collections held within repositories[13] subject to the NIH Policy?

Maybe. Each ICO has the discretion to determine on a case-by-case basis whether a specimen collection held within a repository—in its entirety, or just a subset of specimens/samples of specimens—is subject to the NIH Policy. An ICO may consider the following when making the decision:

- Owned or managed by NIH: Repositories owned or managed by NIH are subject to the NIH Policy if they meet the other criteria outlined above. Repositories funded by grants or cooperative agreements may only be considered if indicated within the Terms and Conditions of award.
- Reproducibility of specimens: Repositories are not subject to the NIH Policy if they are solely comprised of reagents, samples, and/or materials that may be replenished by being reproduced (e.g., chemical synthesis repositories, as well as commercially available cell lines, nucleic acids, antibodies, or viral stocks).
- Purpose of the repository: Repositories may be excluded if their sole function is to provide reagents or samples (e.g., brain tissue, DNA, or microorganisms) on an on-going basis, as opposed to preserving them for the long-term. However, part of a repository may be subject to the NIH Policy if, for example, it stores reference samples or standards intended to preserve unusual and/or unique specimens.

[13] "Repository" is referred to here as an organization, place, room, or container (a physical entity) where specimen samples are stored.

Are collections located in NIH Intramural laboratories or facilities subject to the NIH Policy?

Maybe. Each ICO has the discretion to determine on a case-by-case basis whether an entire or sub-set of an intramural collection of specimens located in an NIH Intramural laboratory or facility is subject to the NIH Policy. An ICO may consider the following when making the decision:

- Owned or managed by NIH: NIH owns collections funded by the Intramural Research Program (IRP). Furthermore NIH is considered to manage collections owned by another entity, if located in an Intramural laboratory or facility. In these situations, the collection may be subject to the NIH Policy if it is established by the ICO that it meets the other criteria outlined above.
- Purpose of the collection: A collection located in an intramural laboratory or facility may be subject to the NIH Policy if it is intended for long-term preservation, will not be depleted, and is considered a valuable scientific asset for the wider community. Collections located in an NIH Intramural laboratory or facility may be excluded from the NIH Policy if they are either being actively used in research, or will feasibly be used in future research, in which the specimens are depleted (i.e., damaged or consumed during the research). Furthermore, collections located in an NIH Intramural laboratory are excluded if they are being held because of their usefulness or potential usefulness for a single scientific program/project (e.g., histology slides or other specimens being stored for potential future analyses relating to previous research conducted in that laboratory), rather than the wider community.
- Collections of data or physical documents: Collections comprised solely of data or physical documents are excluded from the NIH Policy.
- Collections of live animals: Living animals are excluded from the NIH Policy. However, tissue specimens collected from these animals as well as gametes and embryos may be subject to the NIH Policy.
- Reproducibility of specimens: Collections are excluded from the NIH Policy if they solely comprise reagents or samples that may be replenished by being reproduced (e.g., chemical reagents, as well as commercially available cell lines, nucleic acids, antibodies, or viral stocks).

Are institutional scientific collections subject to the NIH Policy even if there are access concerns such as those related to preservation, proprietary information, national security, and/or patient privacy?

Yes. All NIH owned or managed institutional scientific collections are subject to the NIH Policy; access concerns are not considered when deciding whether a collection is subject to the NIH Policy. In general,

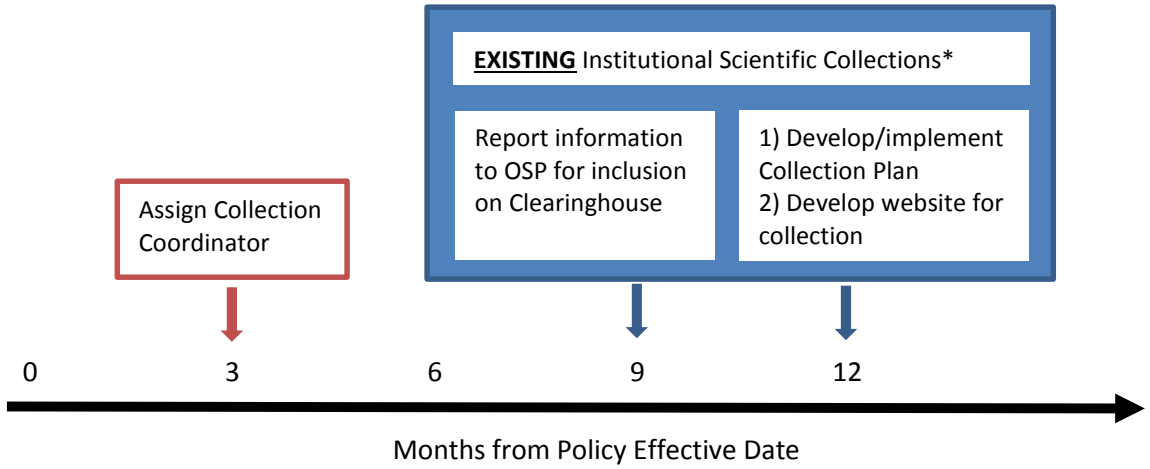
the NIH Policy promotes access to all institutional scientific collections and their supporting information. However, when implementing the NIH Policy, access may be limited as a means of preservation, honoring international or tribal agreements, maintaining patient privacy and confidentiality, guarding national security, and/or protecting proprietary information.[14] Each ICO will determine if access should be limited to a collection. If necessary, access shall only be limited to the smallest subset of specimens and information possible. Applicable laws/regulations that may impact access include:

- Patient Privacy: the 1974 Privacy Act, the Health Insurance Portability and Accountability Act, the HHS human subjects protections regulations (45 CFR part 46), and other NIH and program specific policies (e.g., NIH Genomic Data Sharing).
- Intellectual Property: Bayh-Dole Act of 1980, the Small Business Innovation Research Reauthorization Act of 2011, and the Copyright Act.
- National Security: Select Agent Regulations, and/or regulations governing access by foreign nationals (the Export Administration Regulations and the International Traffic in Arms Regulations).

[14] Section G.2.b of the NIH Policy.

Implementation Timeline

The following figure provides an overview of key dates in the implementation of the NIH Policy by ICOs. Note that there are other requirements stated in the NIH Policy, but these don't have a specified timeline.[15]



* For **NEW** institutional scientific collections that are accessioned after the effective date of the NIH Policy, the timeline for the requirements contained in the blue box above are 9 and 12 months from accessioning of the first specimen.

[15] See Section G of the NIH Policy for a description of all requirements outlined in the policy.

Implementing the Requirements of the Policy

The following two tables summarize key management and access responsibilities assigned to specific individuals in the NIH Policy.[16]

Management Responsibilities

	ICO Director	Collection Coordinator	Collection Custodian
Appoint Collection Coordinator	1. Responsible for appointing		
Collection Plans		1. Oversee all ICO custodians 2. Final approval 3. Annual review and inform OSP 4. Provide OSP with current Plan and make available to personnel	1. Develop and update as needed 2. Implement
Notifications of proposed accession[17]	1. Final approval	1. Manage approval process 2. Inform OSP of approval	1. Prepare notification
Notifications of proposed deaccession	1. Final approval	1. Manage approval process 2. Inform OSP of approval[18]	1. Prepare notification
Funding	1. Review and approve annual budget for all ICO collections	1. Provide guidance to custodian on cost projection	1. Annually address budget 2. Develop cost projection
Specimens and metadata[19]		1. Provide guidance to custodian	1. Responsible for managing (processing, storage etc.)

[16] See Section F of the NIH Policy for more details on responsibilities required of specific individuals, and Section G of the NIH Policy for more details on implementation of these responsibilities.
[17] This refers to initial accessioning of a collection to institutional scientific collection status, not subsequent additions (accessioning) of specimens to an accessioned collection.
[18] Required when deaccessioning an entire collection only, not when individual specimens are deaccessioned and the overarching institutional scientific collection remains.
[19] The NIH Policy indicates that that this must be done appropriately and in accordance to the Collection Plan, applicable laws, regulations, and policies.

Access Responsibilities

	ICO Director	Collection Coordinator	Collection Custodian
Specimens and metadata		1. Provide guidance to custodian	1. Ensure appropriate access 2. Employ high digitization & formatting standards for metadata
Clearinghouse		1. Share updates with OSP	
Publically accessible collection website		1. Ensure website is developed	1. Develop & maintain website

Contact Information

General Inquiries

For general inquiries regarding the NIH Policy, please contact:

Office of Science Policy, OD

Rockledge 1, Suite 750

6705 Rockledge Drive

Bethesda, MD 20817

Phone: (301) 496-9838

Fax: (301) 496-9839

Email: SciencePolicy@od.nih.gov

Collection Coordinators

A list of Collection Coordinators will be forthcoming as they are assigned by the ICO Directors.