NIH Policy Manual

1743-2 - NIH Litigation Hold Policy

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Transmittal Notice

1. **Explanation of Material Transmitted:** This policy applies to document preservation related to civil litigation, often referred to as "litigation holds". This policy does not address records retention under the Federal Records Act, the Freedom of Information Act (FOIA), or preservation obligations imposed by other federal laws. This *NIH Litigation Hold Policy* identifies the process for preserving potentially relevant information in the possession, custody, or control of the National Institutes of Health (NIH), an Operating Division (OpDiv) of the U.S. Department of Health and Human Services (HHS) when civil litigation has commenced or is reasonably anticipated.

1. **Filing Instructions:**

    - **Insert:** NIH Manual 1743-2 – *NIH Litigation Hold Policy*, dated 11/12/2020, Partial Revision: dated 06/26/2020

3. **PLEASE NOTE:**

    - To the extent that a new HHS Policy for Litigation Holds is put in place after the effective date of this policy; and if the HHS policy provides more stringent requirements, the new HHS Litigation Hold Policy will control and supersede existing NIH policy. To the extent that the *NIH Litigation Hold Policy* provides more stringent controls than the HHS Policy, the *NIH Litigation Hold Policy* controls.
    - For questions, comments, or concerns regarding Records Management content within this Manual Chapter, contact the Records Management Program, Division of Management Support (DMS), Office of Management Assessment (OMA), Office of Management (OM), Office of the Director(OD) at : nihrecordsmanagement@nih.gov or via 301-496-2832. Additional information on the NIH Records Management Program is found

at: https://oma.od.nih.gov/DMS/Pages/Records-Management.aspx

- For questions, comments, or concerns regarding NIH Policy Manual repository and official records policy, contact the Manual Chapter Program, DMS, OMA, OM, OD at: policymanual@nih.gov or via 301-496-4606. Additional information on the NIH Policy Manual Program is found at: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

The purpose of this *NIH Litigation Hold Policy* is to ensure preservation of potentially relevant information in the possession, custody, or control of the National Institutes of Health (NIH), an Operating Division (OpDiv) of the U.S. Department of Health and Human Services (HHS), when civil litigation has commenced, and/or when information suggests a credible probability of litigation, or circumstances that might lead to a conclusion that litigation is reasonably anticipated. The Office of the General Counsel (OGC), Office of the Inspector General (OIG), or the Department of Justice (DOJ) will issue litigation holds as appropriate.

When a litigation hold is issued, normal disposition schedules applying to impacted records are suspended until employees, volunteers, fellows, interns, covered contractors, or covered grantees are notified that the litigation hold has been lifted. When a litigation hold has been lifted, normal disposition schedules applying to impacted records resume.

B. Scope

This *NIH Litigation Hold Policy* applies to all NIH Institutes and Centers (ICs) and Offices within the Office of the Director (OD). Accordingly, any and all NIH personnel shall be responsive to a litigation hold. Scope includes all federal staff, covered contractors, volunteers, fellows, interns, and covered grantees involved in the creation, maintenance, and disposition of documents, records, electronically stored information (ESI), or Tangibles (such as equipment, laboratory samples, specimens, and photographs) in NIH's possession, custody, or control, irrespective of the information's physical or digital location, that are responsive to a litigation hold.

C. Policy

As an Operating Division of the U.S. Department of Health and Human Services (HHS), NIH has a legal obligation to preserve information that is potentially relevant to pending litigation or reasonably anticipated litigation, including documents, records, ESI, or Tangibles. Upon notice of a civil lawsuit or reasonably anticipated litigation, NIH will implement litigation holds following the *Responsibilities* section as described in (Section D) of the Policy. This *NIH Litigation Hold Policy* requires the preservation and retention of potentially relevant paper and electronic records for an indefinite period due to existing or reasonably anticipated federal litigation.

Accordingly, each NIH Institute and Center (IC), and Office within the Office of the Director (OD) is responsible for acting in compliance with the *NIH Litigation Hold Policy*. Compliance includes responding by the deadlines set in a litigation hold notification (and corresponding memoranda) describing the matter for which the litigation hold is being issued (or other instructions).

Failure to comply with a litigation hold could adversely affect the interests of NIH and the United States and could subject individual staff and NIH to sanctions and penalties.

Noncompliance with this policy or litigation hold may also result in adverse personnel action.

The Office of Management Assessment (OMA), Office of Management (OM), Office of the Director (OD), is responsible for implementing, disseminating, and managing the *NIH Litigation Hold Policy* upon receiving a litigation hold throughout the duration of the litigation and until receiving notice from the office who imposed the litigation hold (e.g. OGC, OIG, or DOJ) that the litigation hold has been lifted.

D. Responsibilities

1. **NIH Record Officer (RO):**

    a. Oversees the NIH Litigation Hold Process as described in (Subsection 2 of Section D) the *Responsibilities* section of the Policy.
    b. Immediately reports to the office who placed the litigation hold (e.g., OGC, OIG, or DOJ) any and all unlawful or accidental destruction of any records placed under a litigation hold.[1]

2. **Records Management Program (RM)/DMS/OMA/OM/OD/NIH:**

    a. Serves as the single-entry and dissemination point for all litigation holds received by NIH.
    b. Distributes non-EEO litigation hold notifications, memoranda, instructions, and certifications confirming receipt and agreement to comply to Executive Officers (EOs) of impacted IC and OD Offices and include office who placed the litigation hold (e.g., OGC, OIG, or DOJ) in correspondence.
    c. Distributes EEO litigation hold notifications, memoranda, instructions, and certifications confirming receipt and agreement to comply to Office of Equity, Diversity, and Inclusion (EDI) Director and Deputy Director within Immediate Office of the Director as well as Director of Resolutions & Equity Division and include office who placed the litigation hold (e.g., OGC, OIG, or DOJ) in correspondence.
    d. Receives signed certifications and list of additional staff to be included in litigation hold if applicable.

e. Provides signed certifications and list of additional staff with office who placed the litigation hold (e.g., OGC, OIG, or DOJ).
f. Provides list of individuals for email litigation hold to OCIO/CIT.

    - Receive OCIO/CIT concurrence of litigation hold.

g. Tracks the following:

    - Status of all litigation holds
    - Custodian names and positions
    - Confirmation of receipt and agreements
    - Litigation hold certificates received
    - Supplemental reminders
    - Continuous compliance
    - Lifting of litigation holds

h. Maintains a comprehensive list of all NIH litigation holds.
i. Prepares and distributes a monthly litigation hold update to appropriate parties.
j. Contacts the office who placed the litigation hold (e.g., OGC, OIG, or DOJ) to confirm status of litigation hold on an annual basis.
k. Promptly notifies all stakeholders when a litigation hold is lifted.

3. **Offices originating Litigation Hold Notice from within the Office of the General Counsel (OGC), Office of the Inspector General (OIG), or the Department of Justice (DOJ)**:

    a. Create the litigation hold notifications, memoranda, instructions, and certifications confirming receipt and agreement to comply.
    b. Identify in litigation hold notification, memoranda, or instructions individuals who are known at the time as potential document custodians to assist with document preservation and production efforts.
    c. Notify OMA via email to NIHLitigationHold@od.nih.gov of the litigation hold for distribution.
    d. Receive signed certifications, list of additional staff, and concurrence of email litigation hold.
    e. Respond to questions about the scope of the ligation hold.
    f. Provide OMA with routine updates on the status of active litigation holds, including supplemental hold requests, and promptly notify OMA when a litigation hold is lifted.

4. **NIH Office of Equity, Diversity, and Inclusion (EDI)**

    a. Process litigation holds in accordance with the *NIH Litigation Hold Policy.*
    b. Follow the instructions received within the litigation hold notifications and memoranda.
    c. Identify all NIH impacted staff (such as manager, supervisors, employees, volunteers, fellows, interns, covered contractors, and covered recipients) relating

to the litigation hold within the applicable IC or OD offices who may have documents, records, Electronically Stored Information (ESI), or Tangibles related to the litigation hold.

d. Distribute the litigation hold to all impacted staff.
e. Collect Litigation Hold Certifications from all impacted staff with responsive records; and return completed Certifications to OMA.
f. Notify OMA if a litigation hold notice comes from any office besides OMA.

5. **NIH Executive Officers (EOs) of NIH Institutes and Centers (ICs) and Offices within the Office of the Director (OD):**

a. Process litigation holds in accordance with the *NIH Litigation Hold Policy*.
b. Follow the instructions received within the litigation hold notifications and memoranda.
c. Identify all NIH impacted staff (such as manager, supervisors, employees, volunteers, fellows, interns, covered contractors, and covered recipients) relating to the litigation hold within the applicable IC or OD offices who may have documents, records, Electronically Stored Information (ESI), or Tangibles related to the litigation hold.
d. Distribute the litigation hold to all impacted staff.
e. Collect Litigation Hold Certifications from all impacted staff with responsive records; and return completed Certifications to OMA.
f. Upon notification that a litigation hold has been lifted, the EO will promptly notify impacted staff that the hold has been lifted and implement disposition instructions identified in applicable records retention schedules.
g. Notify OMA if a litigation hold notice comes from any office besides OMA and await guidance from OMA.
h. Notify OMA and the office who placed the litigation hold (e.g., OGC, OIG or DOJ) of departing impacted staff for additional guidance.

    - Interview or provide a questionnaire to identify the location of documents, ESI, and tangible things subject to the litigation hold;
    - Take appropriate steps to continue to preserve relevant information subject to the litigation hold after the individual's departure.

6. **All NIH Employees, Volunteers, Fellows, Interns, Covered Contractors, and Covered recipients (impacted staff):**

a. Comply with the *NIH Litigation Hold Policy*, applicable HHS Litigation Hold Policy, and instructions received by OMA for completing litigation hold certificates and preserving responsive documents, records, ESI, or Tangibles.
b. Retain and not alter, destroy, or otherwise dispose of potentially relevant information, regardless of format or physical location for as long as the litigation hold is in effect.
c. Preserve ESI in its original (native) file format to prevent alternation of metadata. Preserve ESI in its original location, whenever possible.

d. Notify managers and supervisors as soon as impacted staff are aware of information that suggests a credible probability of litigation or circumstances that might lead to a conclusion that litigation is reasonably anticipated. Managers and supervisors should immediately convey that information to OGC.
e. Contact the office that originated the litigation hold notice (e.g. OGC, OIG, or DOJ) with any questions regarding the scope of a litigation hold.

7. **NIH Office of the Chief Information Officer (OCIO) and NIH Center for Information Technology (CIT):**

a. Receive litigation hold notification, memoranda or information and initiate litigation holds on email accounts of NIH staff, contractors, fellows, interns, or volunteers. OMA will provide CIO/CIT with a complete listing of individuals involved in litigation holds, for action.
b. Removes litigation holds from email accounts of impacted staff once informed by the office who placed the hold (e.g. OGC, OIG, or DOJ) that the litigation hold can be lifted. OMA will provide CIO/CIT with a complete listing of individual accounts to be removed from litigation hold due to a change in the hold status.

8. **NIH Records Liaison (RLs):**

a. Receives litigation hold notifications, memoranda or information for awareness.
b. RLs must not initiate or approve any destruction of records, including records stored at the National Archives and Records Administrations (NARA) Federal Records Center (FRC), or NIH approved commercial off-site storage, that are responsive to an active litigation hold.

9. **NIH Freedom of Information Act (FOIA) Officer:**

a. Receives litigation hold notifications, memoranda or information for awareness and take necessary action as required by the FOIA.

10. **NIH Senior Official for Privacy:**

a. Receives litigation hold notifications, memoranda or information for awareness and take necessary action as required by the Privacy Act.

11. **Director, NIH Executive Secretariat:**

a. Receives litigation hold notifications, memoranda or information for awareness and take necessary action to notify or inform NIH leadership, as deemed appropriate.

12. **Office of Acquisition and Logistics Management:**

a. Receives litigation hold notifications, memoranda or information for awareness and take necessary action, as deemed appropriate.

[1] https://www.archives.gov/records-mgmt/resources/unauthorizeddispositionoffederalrecords

E. References

- 44 U.S.C. Chapter 33 – Disposal of Records (Federal Records Disposal Act)
- HHS Policy on Litigation Holds, November 29, 2016
- NIH Policy Manual 1743 – Keeping and Destroying Records, Appendix 1

F. Definitions

a. **Custodian** is an individual having possession, custody, or control of documents, electronically stored information or Tangles subject to a litigation hold.

a. **Covered Contractor** is an individual or entity under contract with NIH that has possession, custody, or control of potentially relevant documents, ESI, or tangible things. This term does not include contractors of recipients. The term "covered contractor" is used only for purposes of this policy, and is not intended to carry the same meaning as such term may have in other laws or HHS regulations.

a. **Covered Recipient** is a recipient of federal financial assistance to carry out an activity under an NIH program that has possession, custody, or control of potentially relevant documents, ESI, or tangible things. This term does not include contractors of recipients. The term "covered recipient" is used only for the purposes of this policy, and is not intended to carry the same meaning as such term may have in other laws or HHS regulation.

a. **Documents** include, but are not limited to, written material, in final or draft form, such as memoranda, reports, printed e-mails, maps, diagrams, correspondence, spreadsheets, presentation materials, or notes. This includes potentially relevant official or unofficial documents, all drafts, partial versions of documents, and duplicates.

a. **Electronically Stored Information (ESI)** is information created, manipulated, communicated, stored, and best utilized in digital form, requiring the use of computer hardware and software. This can include but is not limited to electronic files, digital content found on handheld computer devices (i.e., Blackberry, iPhone), internet websites (e.g., social network sites, intranet landing pages), network server information, voicemail messages; audio recordings, word processing files, spreadsheets, databases, digital images, computer animations computer simulations, back-up tapes, electronic messaging to include text and instant messenger messages, scanned paper; data produced by calendar software; and information management software. In addition to specific data that are electronically stored and readily retrievable, ESI includes data that may not be visible that is generated by computer hard-drive, email and instant messaging, information management software, handheld computer devices (i.e.

Blackberry, iPhone), telecommunications devices and back-up storage devices. ESI may be stored on different electronic devices and removable devices (i.e. internal and external drives, PDAs, smart phones, servers, laptops, backup tapes, thumb drives, CDs, DVDs) and may also reside at different locations (i.e. on the home or work systems, owned by NIH or personal systems in department files, etc.).

a. **Electronic messaging** means electronic mail and other electronic messaging systems (text messaging, instant messaging, chat, voicemail messaging, social media or mobile device applications) that are used for the purposes of communicating between individuals.
b. **Evidence** includes all records, whether electronic or paper form, created, received, or maintained in the transaction of NIH business, whether conducted at home or at work.

a. ***Legal Claim*** is an anticipated or pending lawsuit or other legal action against the Federal agency and an investigation or legal action by a governmental or administrative agency.

i. **Litigation** for purposes of this policy includes legal actions pending in federal court in which the United States, NIH, NIH component, or an NIH employee in an official capacity is a named party to the action and NIH's ESI, documents, or Tangibles may be subject to discovery under the Federal Rules of Civil Procedure. "Litigation" also includes civil matters in state courts or federal or state administrative proceedings in which the United States, NIH, NIH component, or an NIH employee in his/her official capacity is named and the matter appears likely to result in a federal court proceeding for which NIH's ESI, documents or Tangibles would be subject to discovery under the Federal Rules of Civil Procedure. Cases in which judicial review is limited to a defined record and cases in which OGC, in consultation with DOJ as appropriate, reasonably believes that NIH has no potentially relevant ESI, documents or Tangibles in its possession, custody, or control are outside the scope of this policy. "Litigation" does not include cases brought under the False Claims Act in which the United States either has declined to intervene or has filed a notice of no decision.

a. **Litigation Hold** stipulate that all records that may relate to a legal or Congressional oversight action involving NIH shall be retained. This requirement ensures that the applicable records are available for the discovery process prior to litigation. NIH shall preserve records when it learns of pending or imminent litigation, or when litigation is reasonably anticipated. Litigation holds prevent the spoliation (e.g. destruction, alteration, or mutilation) of evidence.

a. **Litigation Hold Certification is** written confirmation from each recipient of the litigation hold notice acknowledging that he/she has read, understands and will comply with the hold
b. **Litigation Hold Process** is the suspension of normal operation of document destruction polices for records that are relevant to pending litigation.

a. **Metadata** is data stored electronically that describes characteristics of ESI, found in different places in different forms. Metadata can be supplied by applications, users, or

the file system and can describe how, when and by whom ESI was collected, created, accessed, modified, and how it is formatted.

b. **Reasonable Anticipation of Litigation** means there is a credible probability that NIH, NIH component, or an employee in his/her official capacity will be party to litigation based on a good faith and reasonable evaluation of relevant facts and circumstances known to OGC at the time of its analysis. The analysis of whether there is a reasonable anticipation of litigation is fact specific. Some situations are clear—for example, serving or receiving a complaint filed in court, versus vague threats or rumors. Although it is important to realize that a check list approach is not appropriate in evaluating whether litigation is reasonably anticipated, relevant factors could include the specificity and clarity of the claim or threat, previous experience with the entity or individual making the claim, media coverage of the issue, and the existence of serious injuries or fatalities.

c. **Recorded Information** includes all forms of records, regardless of format or characteristics, including information created, manipulated, communicated, or stored in physical, digital, or electronic form, including metadata.

a. **Records** include all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the United States Government or because of the informational value of data in them. (44 USC 3101, Definition of Records).

a. **Records Disposition Schedules** are mandatory disposition instructions that provide continuous authority to dispose of recurring series or systems of records, or to transfer them to the National Archives and its national network of Federal Records Centers. These records disposition schedules are suspended during the duration of a litigation hold and resume once the hold has been lifted.

a. **Retention period** is the period that records are to be kept in accordance with NARA-approved records disposition schedules. Retention periods within records disposition schedules are suspended during the duration of a litigation hold and resume once the hold has been lifted.

a. **Tangibles** include, but are not limited to, equipment, laboratory samples, specimens, and photographs, models, light fixtures, removable computer storage media (e.g., hard drives, CD-ROMs, DVDs, tapes, discs, thumb drives, cards), and other physical objects.

b. **Preservation** is the process of retaining documents and ESI, including document metadata, for legal purposes and should include suspension of normal document destruction policies and procedure.