SMG 3205.1

FDA Staff Manual Guides, Volume III – General Administration

Information Resources Management

Information Governance

FDA Legal Hold Policy

Effective Date: 08/26/2025

1. Purpose

The purpose of this FDA Legal Hold Policy is to ensure preservation of potentially relevant information in the possession, custody, or control of the Food and Drug Administration (FDA), an Operating Division (OpDiv) of the U.S. Department of Health and Human Services (DHHS). This preservation requirement applies when civil or criminal litigation is pending or when information suggests litigation is reasonably anticipated. The policy also applies when other formal investigatory or oversight efforts require the suspension of records destruction schedules and preservation of FDA information.

When a legal hold is issued, normal records management disposition schedules and/or other disposal activities applying to impacted records and information are suspended until employees, volunteers, fellows, interns, covered contractors, and covered grantees (“impacted staff”) are notified that the legal hold has been lifted. When a legal hold has been lifted, normal disposition schedules and disposal practices applying to impacted records and information may resume.

2. Scope

This policy applies to all FDA Centers, Offices, and Programs (COPs) including all impacted staff involved in the creation, maintenance, and disposition of documents, records, electronically stored information (ESI), tangibles or physical artifacts (e.g., equipment, laboratory samples, specimens, and photographs) in FDA’s possession, custody, or control, irrespective of the information’s physical or digital location, that

are responsive to a legal hold. Accordingly, all FDA personnel shall be responsive to a legal hold.

The FDA Office of Chief Counsel (OCC), DHHS Office of General Counsel (OGC), the Department of Justice (DOJ), Office of the Inspector General (OIG), Office of Legislation (OL), and Agency Records Officer (ARO) will issue legal holds as appropriate.

3. Background

Historically, legal hold management had been carried out through independent email notifications issued directly by Agency/Department attorneys (or other authorized investigatory or legal entities) to individual custodians. Legal hold compliance had been the responsibility of individual custodians. FDA Information Technology system owners and administrators have not been uniformly engaged to implement supplemental preservation actions that may be useful for greater Agency legal hold consistency. Pursuant to the *HHS Policy on Litigation Holds*, the Division of Information Governance (DIG) has implemented the FDA Legal Hold Platform ("the platform") leveraging the DIG/eDiscovery Relativity review platform. This platform supports FDA in centrally managing legal holds and meeting DHHS policy requirements.

4. Policy

FDA has a legal obligation to preserve information that is potentially relevant to pending litigation, reasonably anticipated litigation, or other investigatory matters necessitating Agency information, including documents, records, ESI, or tangibles. Upon notice of litigation, reasonably anticipated litigation, or other investigatory matters, FDA will implement a legal hold following the *Responsibilities* section as described (Section 5) in this Policy.

This *FDA Legal Hold Policy* requires the preservation and retention of potentially relevant paper and electronic records for an indefinite period due to existing or reasonably anticipated litigation and/or investigatory matters. Accordingly, each FDA COP within FDA and all impacted staff are responsible for acting in compliance with the *FDA Legal Hold Policy*. Compliance includes responding by the deadlines and adherence to instructions set out in the legal hold notification (and corresponding materials) describing the matter for which the legal hold is being issued (or other instructions).

This Policy adheres to the processes required in the *HHS Policy on Litigation Holds* through issuance of all legal holds through the FDA Legal Hold Platform. The platform serves as a single-entry and dissemination point for all legal holds received by and/or issued by FDA. Reports generated by the platform may serve to validate Agency and/or individual compliance with this Policy and necessary certifications.

ARO or ARO designee may provide official certification of FDA legal hold compliance pursuant to system certification.

Legal hold issuances within the platform shall provide the following:

- a legal hold description, which includes the allegations, subject matter, and any relevant dates or issues,
- outline of documents, ESI, tangibles, or other material to be preserved,
- guidance on how to comply with the legal hold,
- points of contact for programmatic or legal questions, or technical assistance,

The FDA Legal Hold Platform shall support:

- formal issuance and closure of FDA legal holds,
- tracking of custodian confirmation of receipt and agreement to comply with the legal hold,
- maintenance of legal hold status and relevant guidance materials,
- issuance of supplemental reminders,
- necessary reporting and/or tracking of legal holds through their lifecycle.

Failure to comply with a legal hold could adversely affect the interests of FDA and the United States and may result in sanctions. Failure to issue holds through the FDA Legal Hold Platform may result in incomplete tracking and reporting and may undermine affirmative preservation efforts critical to avoid spoliation of relevant information and ensure legal defensibility.

Responsibilities for Legal Hold issuance, management, compliance and maintenance of ESI integrity under the *FDA Legal Hold Policy* are outlined in the *Responsibilities* section as described (Section 5) and will persist throughout the duration of the legal hold and until receipt of closure notification via the platform as directed by the Office who imposed the legal hold (e.g. DHHS OGC, FDA OCC, DOJ, OIG).

5. Responsibilities

A. FDA Agency Records Officer (ARO)

1. Oversees the FDA Legal Hold Policy.

2. Promptly reports all unlawful or accidental destruction of any records subject to a legal hold to the originating office and/or identified point of contact.

3. Certifies or designate certification authority as needed for legal hold issuance pursuant to FDA Legal Hold Platform.

B. Internal Originating Offices (FDA OCC, FDA OL)

1. Serve as primary authority on legal holds originating from within FDA. Internal Originating Offices also collaborate as appropriate with External Originating Offices and DIG on the issuance, management, updating, and closure of externally originating legal holds applicable to FDA staff.

2. Identify custodians, provide hold language, memoranda, instructions, or other materials necessary for issuance of the hold by DIG in the platform.

3. Work with COP records management staff to identify record locations, including transfers to the National Archives & Records Administration (NARA), Federal Records Centers (FRC), or commercial storage, as applicable.

4. Manage legal holds in the platform throughout the full hold lifecycle, e.g., hold issuance, custodian compliance tracking, certifications, reminders, updates, and hold closure.

5. Respond to internal FDA inquiries regarding the potential need for a specific new legal hold or the scope of existing holds.

C. External Originating Offices (DHHS, DOJ, HHS OIG)

1. Serve as primary authority on externally originating legal holds, providing guidance to Internal Originating Offices and DIG as necessary for hold initiation and ongoing management.

2. Collaborate with Internal Originating Offices in the issuance, management, updating, and closure of externally originating legal holds.

3. Work with COP records management staff to identify record locations, including transfers to NARA, FRC, or commercial storage.

4. Develop legal hold notification content, instructions, and scope, or other materials necessary for the issuance of holds.

5. When changes or updates to the hold need to be implemented, the External Originating Office will notify the collaborating FDA Internal Originating Office(s) to make such changes.

6. Respond to questions about the scope of the legal hold.

D. DHHS Office of Equal Employment Opportunity (EEO) and Strategic Engagement and Partnerships or other DHHS EEO Originating Offices

1. Collaborate with FDA Office of Equal Employment Opportunity (OEEO) in their issuance of holds within the FDA Legal Hold Platform.

2. When necessary, identify custodians, create memoranda, instructions, or other materials necessary for issuance of a legal hold within the platform.

3. Submit requests to create legal hold notifications within the FDA Legal Hold Platform to DIG.

4. Notify FDA OEEO when changes or updates to the hold need to be implemented.

5. Respond to questions about the scope of the legal hold.

E. FDA Division of Information Governance (DIG)

1. Manage the technological administration of the FDA Legal Hold Platform within Relativity.

2. Create legal hold notifications within the FDA Legal Hold Platform, upload materials, and validate user accounts, pursuant to requests submitted by Internal Originating Offices.

3. Provide training to internal and external legal hold originating office staff and authorized users on the capabilities, functionality, and use of the platform, necessary information, and requirements to comply with this Policy.

4. Manage the access and permissions of authorized users within the platform.

5. Support technical troubleshooting of the platform, resolving operational problems.

6. Generate reports for distribution as outlined in this Policy, on a monthly basis or ad hoc as necessary.

7. Collaborate with Office of Digital Transformation (ODT), and System Owners as necessary to effectuate affirmative preservation requirements pursuant to this Policy.

8. Support the creation of guidance materials and content for general distribution to FDA impacted users regarding legal holds and the platform, in conjunction with OCC and OL, as appropriate.

F. FDA Records Management Team (RMT)

1. Notify NARA of legal holds requiring preservation of FDA information stored at FRCs, or otherwise under NARA's possession, custody, or control.

2. Notify originating office point of contact in the event of any destruction, loss, or alteration of potentially relevant documents, ESI, or tangibles, or the discovery of potentially relevant documents, ESI, or tangibles not previously identified and reported or newly identified custodians.

3. Provide guidance to COPs, FDA Agency Record Liaison Officers (ARLOs), and impacted staff on preservation requirements for relevant documents, ESI, and tangibles by departing or transitioning staff.

G. FDA Agency Records Liaison Officers (ARLOs)

1. Receive legal hold notifications, memoranda, or information for awareness.

2. Aid offices issuing legal holds as necessary, or upon request, to identify responsive or potentially responsive records, custodians, or IT systems with possession, custody, or control of responsive or potentially response records in any format or location.

    a. ARLOs are not authorized to initiate or approve the destruction of records that are responsive to an active legal hold, including records stored at the FRC, FDA approved commercial off-site storage, or any other FDA locations.

3. Work with originating offices to determine if a legal hold requires preservation of records under FDA's possession, custody, or control.

4. Notify FDA RMT for communication with the National Archives in the event preservation is needed for records that are owned by NARA, and under the possession, custody, or control of the National Archives pursuant to a legal hold.

5. Notify originating office point of contact and FDA RMT in the event of any destruction, loss, or alteration of potentially relevant documents, ESI, or tangibles, or the discovery of potentially relevant documents, ESI, or tangibles not previously identified and reported or newly identified custodians.

6. Support FDA impacted staff leaving FDA or transitioning from their FDA position with preservation of potentially relevant documents, ESI, and tangibles.

H. All FDA Employees, Volunteers, Fellows, Interns, Covered Contractors, and Covered Grantees (impacted staff)

1. Comply with the FDA Legal Hold Policy, applicable HHS Litigation Hold Policy, and instructions sent from the Legal Hold Platform for completing legal hold attestation, certifications, and preserving potentially relevant documents, records, ESI, or tangibles.

2. Comply with FDA Records Management policies relevant to the ongoing management of FDA records, and appropriate treatment and notification prior to departure.

3. Retain and not alter, destroy, or otherwise dispose of potentially relevant information, regardless of format or physical location for as long as the legal hold is in effect.

4. Preserve ESI in its original (native) file format to prevent alteration of metadata. Preserve ESI in its original location, whenever possible.

5. Where relevant, implement and remove legal hold safeguards within applicable records repositories (e.g., RM Client, Documentum repositories) on potentially relevant information within the control of impacted staff.

6. Notify managers and supervisors as soon as impacted staff are aware of information that suggests litigation is reasonably anticipated. Managers and supervisors should immediately convey that information to OCC, via the Associate Chief Counsel for eDiscovery, any OCC litigator, or any OCC Manager.

7. Follow directions on legal hold notifications for questions regarding the scope of a legal hold.

8. Notify originating office point of contact and Center ARLO in the event of any destruction, loss, or alteration of potentially relevant documents, ESI, or tangibles, or the discovery of potentially relevant documents, ESI, or tangibles not previously identified and reported or newly identified custodians.

I. FDA Office of Digital Transformation (ODT) or Centers IT (as applicable)

1. Receive legal hold notification, memoranda, or information and initiate legal holds on IT accounts and assets (e.g., email, network shares, OneDrive, Teams, SharePoint, servers/laptops, mobile devices) of FDA impacted staff.

2. Remove legal holds from IT accounts of impacted staff once informed by the office who placed the legal hold (e.g., OGC, OIG, DOJ) that the legal hold can be lifted.

3. System Owners consult with DIG and OCC when a system is anticipated to be transitioned or decommissioned.

4. System Owners develop procedures when ESI must be transition to a different format and take reasonable steps to protect against data loss.

5. System Owners are responsible for notifying vendors about Agency holds related to their systems. Together they must take reasonable steps to prevent data loss, whether accidental or intentional, including the loss or deletion of files, metadata, or storage media.

J. Office of Acquisition & Grants Services (OAGS)

1. Ensure that preservation obligations of this Policy and the HHS Litigation Hold Policy are incorporated into contracts, federal assistance awards, or other agreements.

K. Director, FDA Division of Headquarter Freedom of Information (DHFOI)

1. Receive legal hold notifications, memoranda, or information for awareness and take necessary action as required by the FOIA.

L. FDA Senior Privacy Officer

1. Receive legal hold notifications, memoranda, or information for awareness and take necessary action as required by the Privacy Act.

6. Authorities

Statutes:

- 44 U.S.C. Chapter 33 – Disposal of Records (Federal Records Disposal Act)
- Title 36 CFR Part 1230 – Unauthorized Disposition of Federal Records

Policy:

- HHS Policy on Litigation Holds

- FDA SMG 3291.3 - Records Management Guidance for New and Departing FDA Personnel
- FDA SMG 3291.3a - Records Management Guidance for New and Departing Senior Officials

Guidance:

- FDA Records Schedules

7. Definitions

Authorized User – an individual within originating offices recognized and trained to access the FDA Legal Hold Platform for the purposes of legal hold oversight and management.

Custodian – an individual having possession, custody, or control of potentially relevant documents, ESI, or tangibles subject to a legal hold.

Covered Contractor – an individual or entity under contract with FDA that has possession, custody, or control of potentially relevant documents, ESI, or tangibles and who directly receives a legal hold. The term “covered contractor” is used only for purposes of this policy and is not intended to define this term used in other laws, regulations, or policies.

Covered Recipient – a recipient of federal financial assistance to carry out an activity under an FDA program that has possession, custody, or control of potentially relevant documents, ESI, or tangibles. 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 define this term used in other laws, regulations, or policies.

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

Electronically Stored Information (ESI) – 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 (e.g., Android, iPhone), internet websites (e.g. social network sites, intranet landing pages), network server information, voicemail messages, audio recordings, work processing files, spreadsheets, databases, digital images, computer animations, computer

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

Electronic messaging – includes electronic mail and other electronic messaging systems (e.g., text messaging, instant messaging, chat, voicemail messaging, social media, or mobile device applications).

Impacted Staff – includes all persons who may have potentially relevant documents, records, ESI, or tangibles related to a legal hold including but not limited to managers, supervisors, employees, volunteers, fellows, interns, covered contractors, and covered grantees.

Information – data held by a custodian concerning a particular fact or circumstance.

Legal Claim – an anticipated or pending lawsuit or other legal action filed against or by a Federal agency.

Legal Hold – also known as a “litigation hold”, “records hold”, or “freeze,” a legal hold stipulates that all records that may relate to a legal claim or Congressional oversight action involving FDA shall be retained. Once a legal hold is issued, it ensures that potentially relevant records will be available for discovery or in support of investigatory or oversight duty. FDA shall preserve records when it learns of pending or imminent litigation, investigation, or inquiry, or when reasonably anticipated.

Legal Hold Platform – FDA’s official system used by originating offices to manage the lifecycle of a legal hold. The platform enables the comprehensive oversight and management of legal holds, including issuance, custodial certification of compliance, hold description and scope, instructions, guidance and supplemental documentation, points of contact, reporting, etc. The platform is deployed and maintained by the Division of Information Governance eDiscovery Program leveraging their Relativity document review system.

Litigation – for the purposes of this policy, this includes legal actions pending in federal or state court or administrative proceedings in which the United States, HHS, FDA, FDA component, or an FDA employee in an official capacity is a named party to the action and FDA's ESI, documents, or tangibles may be subject to discovery under the Federal Rules of Civil Procedure or the Federal Rules of Criminal Procedure or otherwise potentially relevant. Cases (a) in which judicial review is limited to a defined record (b) in which OCC, in consultation with DOJ and/or DHHS OGC as appropriate, reasonably believes that FDA has no potentially relevant ESI, documents, or tangibles in its possession, custody, or control, or (c) which are third-party litigation, or qui tam cases, 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.

Legal Hold Certification – confirmation from each recipient of the legal hold notice acknowledging that he/she has read, understands, and will comply with the hold. Certifications are executed and tracked in the FDA Legal Hold platform.

Legal Hold Process – the suspension of normal operation of document disposition or destruction policies for records subject to a legal hold.

Metadata – data stored electronically that describes characteristics of ESI, found in different places in different forms. Metadata can be supplied by applications, users, or the filesystem and can describe how, when, and by whom ESI was collected, created, accessed, modified, and how it is formatted.

Originating Office(s) – federal offices, internal to FDA (e.g. OCC, OL) and/or external (e.g. DOJ, DHHS), that manage litigation, investigations, Congressional inquiries, or other activities requiring the preservation of FDA data and issuance of a legal hold to ensure suspension of records disposition schedules.

Reasonable Anticipation of Litigation –The analysis of whether there is a reasonable anticipation of litigation is fact specific. Some situations are clear (e.g., receipt of a complaint filed in court naming FDA as defendant), others are less clear (e.g., vague threats or rumors of future litigation). Relevant factors 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.

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.

Records – includes 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 the data in them. (44 U.S.C. 3301, Definition of Records).

Records Disposition Schedules – 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. Records disposition schedules are suspended during the duration of a legal hold and resume once the hold has been lifted.

Retention Period – 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 legal hold and resume once the hold has been lifted.

System Owner - A person or group from either ODT or COPs who are responsible for the procurement, development, integration, modification, operation, maintenance, and disposal of a system.

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

Preservation – the process of retaining documents and ESI, including document metadata, for legal purposes and suspending normal document disposition policies and procedure.

8. Document History - SMG 3205.1, "FDA Legal Hold Policy"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	08/22/2025	N/A	OMES/DIG	Hilary Wanke, Director, DIG

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