

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0167-2025-0002

Status: APPROVED
Date Approved: 07/15/2026

General Information

Agency or Establishment	National Institute of Standards and Technology
Record/Scheduling Group	0167 - Records of the National Institute of Standards and Technology
Records Schedule Applies To	Agency-wide
Schedule Subject	Research Protections Office Records
Additional Schedule Information	The Research Protections Office (RPO) coordinates and implements the NIST Human Subjects Protection Program (HSPP), which includes providing administrative support for the NIST Institutional Review Board (IRB). Human subjects research at NIST is guided by and adheres to the ethical principles set forth in the Belmont Report. These principles have been incorporated into federal regulation in the Department of Commerce's regulations at 15 CFR 27 and the Food and Drug Administration's (FDA's) regulations at 21 CFR 50 and 21 CFR 56. The objectives of the RPO are to: - Ensure the rights and welfare of human subjects are protected - Facilitate the timely review of NIST research protocols - Provide education and training to NIST staff participating in or reviewing human subjects-related research Pursuant to applicable regulations, the RPO makes determinations regarding whether a project is considered research, research not involving human subjects or exempt human subjects research. In addition, the RPO makes determinations as to whether NIST as an institution is engaged in non-exempt human subjects research. The RPO also provides advice and support to the NIST IRB, which reviews and, when appropriate, approves non-exempt human subjects research. In addition, the RPO conducts administrative reviews of documentation approved by non-NIST IRBs for non-exempt human subjects research and by non-NIST institutions for other determinations.
Is There a Classified Version of This Schedule?	No
Is consultation and coordination with Tribal Governments required?	No - the records covered by this schedule do not implicate Tribal interests

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Item Count

Total number of disposition items: 2

Number of Temporary disposition items: 2

Number of Permanent disposition items: 0

Number of Items with Disposition Not Approved: 0

Number of Inactive disposition items: 0

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Outline of Records Schedule Items for DAA-0167-2025-0002

Item #	Title	Disposition
0001	IRB Protocol Review Records.	Temporary
0002	IRB Administrative and Operational Records	Temporary

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Records Schedule Items

DAA-0167-2025-0002-0001		STATUS: Active
ITEM GENERAL INFORMATION		
Item Title	IRB Protocol Review Records.	
Item Description	-Non-Exempt Human Subject Research Files. Files maintained for all human subjects research protocols reviewed by the Institutional Review Board (IRB). These files include the following documents as appropriate/applicable: General Correspondence (e.g., protocol related correspondence between the IRB and the investigator(s), emails, letters) IRB official letters/memos (e.g., IRB official meeting outcome letter, IRB approval memo) Protocol reviews (e.g., consultant reports, reviewer checklists, Memoranda for the Record (MFR), responses to recommendations, MFR requesting final documentation or approval, Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) reports) Additional local IRB documentation (such as for multisite projects or collaborations with other institutions) as required by the applicable institutional agreement (e.g., IRB Authorization Agreement (IAA), memorandum of understanding (MOU), cooperative research and development agreement (CRADA), interagency agreement, etc.) Protocol (initial submission and all subsequent approved versions) Consent form (initial submission and all subsequent approved versions) Study instruments (e.g., questionnaires, case report forms, recruitment material) Recruitment materials (e.g., advertisements, email notifications) Scientific review documentation IRB readahead packets (includes items related to full IRB review of a protocol) Human subjects research protection training documentation and Conflict of Interest (COI) statements for all study team members Documentation related to continuing review Amendments (e.g., modification requests, including request for study closure) Documentation related to continuing review and/or annual reports	

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Adverse event (AE) reports, Serious Adverse Events (SAE) reports, and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) reports, and Research Monitor reports
Deviation reports

Any statements of significant new findings to be provided to subjects

Other related documents as appropriate, as determined by RPO, the PI and/or the Organizational Unit (OU)

Final study or study closure reports

Executed agreement documents (e.g., for NIST-funded grants, cooperative agreements, contracts, CRADAs or interagency agreements, statements of work (SOWs), etc.). These documents serve as duplicate copies only for purposes of RPO's human subjects review.

Note: The official agreement files are maintained by the OU's program office of record in accordance with the General Record Schedule 1.2

-Exempt, NR, NHSR (Files on Studies Determined to be Not Research (NR), Not Human Subjects Research (NHSR) or Exempt Human Subjects Research). Files of project materials submitted to the RPO are maintained for activities determined to not meet the definition of research or the definition of human subjects in accordance with 15 CFR 27.102, or determined to be exempt under one or more categories at 15 CFR 27.101(b) (15 CFR 27.104 after January 19, 2019), including documentation of the basis for the finding and the applicable exemption number. These files include the following documents as appropriate/applicable:

Scientific review documentation

Human subjects research protection training documentation, COI statements for all study team members (exempt human subjects research only)

Documentation related to annual reviews

Amendments (e.g., modification requests, including request for study closure)

Annual reports

AE, SAE, UPIRTSO reports

Deviation reports

Any statements of significant new findings to be provided to subjects

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Other related documents as appropriate, as determined by RPO, the PI and/or the OU.

Final study or study closure reports

Executed agreement documents (e.g., for NIST-funded grants, cooperative agreements contracts, CRADAs, or interagency agreements, SOW's, etc.) These documents serve as duplicate copies only for purposes of RPO's human subjects review.

Files related to studies determined to meet the criteria for NIST's Excluded Data/Specimens

Note: The official agreement files are maintained by the OU's program office of record in accordance with the General Record Schedule 1.2.

Note: The Technology Partnership Office (TPO) maintains any documentation regarding acquisition of the data and/or specimens, as well as the provider's terms of use in accordance with NIST and General Records Schedules.

-Files on studies approved by a non-NIST IRB or institution that are determined to be in accordance with applicable regulations through an RPO Administrative Review.

IAA, if applicable

General Correspondence (e.g., study related correspondence between RPO and the investigator(s), emails, letters, telephone call records)

Documentation approved by a non-NIST IRB for non-exempt research

Documentation approved by a non-NIST institution for other determinations (i.e., NR, NHSR, Exempt)

Executed agreement documents (e.g., for NIST-funded grants, cooperative agreements, contracts, CRADAs, or interagency agreements, SOW's that support a study etc.) These documents serve as duplicate copies only for purposes of RPO's human subjects review.

Note: All RPO Directives and Manuals and the IRB Charter are maintained by the Directives Management Coordinator within the Management and Organization Office in accordance with NIST Records Schedule Item 4.

-FDA regulated studies. Files are maintained for all FDA regulated human subjects studies reviewed by the NIST IRB when the NIST IRB is registered for performing FDA reviews. These files include the following documents as appropriate/applicable:

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General Correspondence (e.g., protocol related correspondence between the IRB and the investigator(s), emails, letters)
IRB official letters/memos (e.g., IRB official meeting outcome letter, IRB approval memo)
Protocol reviews (e.g., consultant reports, reviewer checklists, MFRs, responses to recommendations, MFR requesting final documentation or approval, DSMB or DMC reports)
Additional local IRB documentation (such as for multisite projects or collaborations with other institutions) as required by the applicable institutional agreement (e.g., IAA, MOU, CRADA, interagency agreement, etc.)
Protocol (initial submission and all subsequent approved versions)
Consent form (initial submission and all subsequent approved versions)
Study instruments (e.g., questionnaires, case report forms, recruitment material)
Scientific review documentation
IRB readahead packets (includes items related to full IRB review of a protocol)
CVs/biographical sketches, human subjects protection training documentation, COI statements for PI and key study personnel
Investigator's Brochure/device manual/product information and FDA Forms 1571-1572 and communications (as appropriate)
Documentation related to continuing review
Amendments (e.g., modification requests, including request for study closure)
AE, SAE, UPIRTSO reports, and Research Monitor reports
Deviation reports
Any statements of significant new findings to be provided to subjects
Other related documents as appropriate, as determined by RPO, the PI and/or the OU
Final study or study closure reports
Executed agreement documents (e.g., for NIST-funded grants, cooperative agreements, contracts, CRADAs, or interagency agreements, SOW's, etc.). These documents serve as duplicate copies only for purposes of RPO's human subjects review.
Documentation reviewed by the NIST IRB when NIST is the study sponsor, in terms of providing the test article or device to the study

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Note: The official agreement files are maintained by the OU's program office of record in accordance with the General Record Schedule 1.2.

Note: Investigators and study sponsors have separate retention requirements under 21 CFR 312.57 (sponsor) and 21 CFR 812.140 (d) for investigator and sponsor for investigational devices. These records are maintained by the OU and investigator in accordance with NIST Records Schedule Items 2532.

-Files on Studies approved by a non-NIST IRB registered to perform FDA reviews.

IAAs, if applicable. Additional study specific files include the following documents as appropriate/applicable:

General Correspondence (e.g., protocol related correspondence between the IRB and RPO, emails, letters)

IRB official letters/memos (e.g., IRB official meeting outcome letter, IRB approval memo)

Protocol (initial submission and all subsequent approved versions)

Consent form (initial submission and all subsequent approved versions)

Study instruments (e.g., questionnaires, case report forms, recruitment material)

Scientific review documentation

Investigator's Brochure/device manual/product information and FDA Forms 1571/1572 and communications (as appropriate)

CVs/biographical sketches, human subjects research protection training documentation, COI statements for PI and key study personnel

Documentation related to continuing review

Amendments (e.g., modification requests, including request for study closure)

AEs, SAEs, and UPIRTSOs reports, Research Monitor reports

Deviation reports

Any statements of significant new findings to be provided to subjects

Other related documents as appropriate, as determined by RPO, the PI and/or OU

Final study or closure reports

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Executed agreement documents (e.g., for NIST funded grants, cooperative agreements, contracts, or CRADAs, interagency agreements, SOW's, etc.). These documents serve as duplicate copies only for purposes of RPO's human subjects review. Documentation reviewed by the cognizant IRB when NIST is the study sponsor, in terms of providing the test article or device to the study Note: The official agreement files are maintained by the OU's program office of record in accordance with the General Record Schedule 1.2	
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	Yes
Superseded Items	
Superseded Item	Item Superseded Explanation in Part?
DAA-0167-2024-0002-0001	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cut off at the closure of the study.
Retention Period	Other: Destroy 5 years after cut off, but longer retention is authorized if required for business use. (15 CFR 27.115)
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0167-2025-0002-0002		STATUS: Active
ITEM GENERAL INFORMATION		
Item Title		IRB Administrative and Operational Records
Item Description		NIST IRB Membership Roster, Minutes of NIST IRB Meetings, NIST IRB Correspondence outside of protocol review, and Audio recordings of IRB Meetings.
		2.1 IRB Administrative and Operational Records

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NIST IRB Membership Roster. The RPO maintains a list of the IRB's primary members and alternates identified by name; earned degrees; representative capacity (including status as non-scientist); professional expertise such as board certifications, licenses, or other relevant experience showing each member's anticipated contribution to IRB deliberations; and any employment or other relationship between each member and NIST. Whenever the membership of the IRB changes, a new dated roster is produced. Minutes of NIST IRB Meetings. The minutes of NIST IRB meetings document the date meeting, the presence of a quorum, the times when the meeting is convened and adjourned, recusals due to conflict of interest, and separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB. The Common Rule (15 CFR 27.115) requires that the minutes of IRB meetings shall be recorded in sufficient detail to show: Attendance at the meetings. The list of attendees must include the names of primary members and alternates present and members participating through videoconference and/or teleconference, attaching the current IRB membership roster. IRB members may be categorized in the following manner: primary members participating, alternates participating on behalf of primary members absent, primary members absent, and any ex officio members present. The list of attendees also includes the names of all non-member persons attending any part of the IRB meeting and may list such attendees as guests, if appropriate.

Actions taken by the IRB.

Votes on these actions, including the number of members voting for, against, and abstaining, including reasons for any abstentions. The basis for requiring modifications, deferring review, or disapproving research.

A written summary of the discussion of controverted issues and their resolution.

Continuing education presented at IRB meetings.

Annual reports that may include unanticipated problems, reports of protocol deviation, non-compliance, suspensions or terminations. The minutes also record the findings where the regulations require specific findings on the part of IRB, including but not limited to:

Approving research with waiver of informed consent

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Approving research with waiver of the documentation of informed consent Approving research involving pregnant women or children or other vulnerable subjects Other NIST IRB Correspondence. Other correspondence to or from the IRB is retained. Examples of such correspondence include but are not limited to: findings or recommendations on general issues to the NIST Institutional Official (IO; official communications with FDA, the Office of Human Research Protection (OHRP), the Department of Defense (DOD), the Environmental Protection Agency (EPA), and other regulatory bodies or agencies that require institutional reviews of NIST activities funded by that agency; lists of protocols and protocol actions reviewed and approved by expedited review; and site visit reports from other regulatory bodies or sponsor agencies and responses from the site regarding any findings. 2.2 Audio recordings of IRB meetings Audio recordings may be used to assist the IRB Office with accurately documenting the conduct of the IRB meeting.		
Is this item media neutral?	Yes	
Is this item a Big Bucket?	No	
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS		
Does this item supersede existing disposition authorities?	Yes	
Superseded Items		
Superseded Item	Item Superseded in Part?	Explanation
DAA-0167-2024-0002-0002	No	
Is this item a deviation from the GRS?	No	
DISPOSITION INSTRUCTION		
Final Disposition	Temporary	
Cutoff Instructions	Other: Cut off at the closure of the study.	
Retention Period	Other: Destroy 5 years after cut off, but longer retention is authorized if required for business use. (15 CFR 27.115)	
ADDITIONAL INFORMATION		
Are any of the records covered by this item national security classified?	No	

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GAO Approval Required	No
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Signatory Information

Action	User	Date
Approve	Edward Forst (Acting Archivist)	07/15/2026



Office of the Chief
Records Officer for the
U.S. Government

This schedule was signed outside of the ERA system using Standard Form 115.

NARA staff updated ERA to reflect this approval, moving the record schedule into an approved status. The approved status allows for generation of a PDF indicating that the schedule has been approved, and allows an agency to use the schedule in ERA to create transfer requests. The approved date in the system and on the PDF version of the records schedule reflects the system actions.