Records Schedule Number: DAA-0167-2024-0002

Status: APPROVED
Date Approved: 09/20/2024

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	Human Subjects Protection Office Records
Additional Schedule Information	The Human Subjects Protection Office (HSPO) 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 HSPO 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 HSPO makes determinations regarding whether a project is considered research, research not involving human subjects or exempt human subjects research. In addition, the HSPO makes determinations as to whether NIST as an institution is engaged in non-exempt human subjects research. The HSPO also provides advice and support to the NIST IRB, which reviews and, when appropriate, approves non-exempt human subjects research. In addition, the HSPO 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-0167-2024-0002

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

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Records Schedule Items

DAA-0167-2024-0002-0001	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	IRB Protocol Review Records
Item Description	-NonExempt 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: o General correspondence (e.g., protocolrelated correspondence between the IRB and the investigator(s), emails, letters) o IRB official letters/memos (e.g., IRB official meeting outcome letter, IRB approval memo) o 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) o 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.) o Protocol (initial submission and all subsequent approved versions) o Consent form (initial submission and all subsequent approved versions) o Study instruments (e.g., questionnaires, case report forms, recruitment material) o Recruitment materials (e.g., advertisements, email notifications) o Scientific review documentation o IRB readahead packets (includes items related to full IRB review of a protocol) o CVs/biographical sketches for Principal Investigator (PI), human subjects research protection training documentation and Conflict of Interest (COI) statements for all study team members

o Documentation related to continuing review
o Amendments (e.g., modification requests, including request for study closure)
o Documentation related to continuing review and/or annual reports
o Adverse event (AE) reports, Serious Adverse Events (SAE) reports, and Unanticipated Problems
Involving Risks to Subjects or Others (UPIRTSO) reports, and Research Monitor reports
o Deviation reports
o Any statements of significant new findings to be provided to subjects
o Other related documents as appropriate, as determined by HSPO, the PI and/or the Organizational Unit
(OU)
o Final study or study closure reports
o Executed agreement documents (e.g., for NISTfunded grants, cooperative agreements, contracts,
CRADAs or interagency agreements, statements of work (SOWs), etc.). These documents serve as
duplicate copies only for purposes of HSPO'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 HSPO 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:
o Scientific review documentation
o CVs/biographical sketches for PI, human subjects research protection training documentation, COI

statements for all study team members (exempt human subjects research only)
o Documentation related to annual reviews
o Amendments (e.g., modification requests, including request for study closure)
o Annual reports
o AE, SAE, UPIRTSO reports
o Deviation reports
o Any statements of significant new findings to be provided to subjects
o Other related documents as appropriate, as determined by HSPO, the PI and/or the OU.
o Final study or study closure reports
o Executed agreement documents (e.g., for NISTfunded grants, cooperative agreements contracts,
CRADAs, or interagency agreements, SOW's, etc.). These documents serve as duplicate copies only for
purposes of HSPO’s human subjects review.
o 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 nonNIST IRB or institution that are determined to be in accordance with
applicable regulations through an HSPO Administrative Review.
o IAA, if applicable
o General correspondence (e.g., studyrelated correspondence between HSPO and the investigator(s),
emails, letters, telephone call records)
o Documentation approved by a nonNIST IRB for nonexempt research
o Documentation approved by a nonNIST institution for other determinations (i.e., NR, NHSR, Exempt)
o Executed agreement documents (e.g., for NISTfunded 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 HSPO's human subjects review.
Note: All HSPO 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 FDAregulated 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:
o General correspondence (e.g., protocolrelated correspondence between the IRB and the
investigator(s), emails, letters)
o IRB official letters/memos (e.g., IRB official meeting outcome letter, IRB approval memo)
o Protocol reviews (e.g., consultant reports, reviewer checklists, MFRs, responses to recommendations,
MFR requesting final documentation or approval, DSMB or DMC reports)
o 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.)
o Protocol (initial submission and all subsequent approved versions)
o Consent form (initial submission and all subsequent approved versions)
o Study instruments (e.g., questionnaires, case report forms, recruitment material)
o Scientific review documentation
o IRB readahead packets (includes items related to full IRB review of a protocol)
o CVs/biographical sketches, human subjects protection training documentation, COI statements for PI
and key study personnel
o Investigator's Brochure/device manual/product information and FDA Forms 1571/1572 and

communications (as appropriate)
o Documentation related to continuing review
o Amendments (e.g., modification requests, including request for study closure)
o AE, SAE, UPIRTSO reports, and Research Monitor reports
o Deviation reports
o Any statements of significant new findings to be provided to subjects
o Other related documents as appropriate, as determined by HSPO, the PI and/or the OU
o Final study or study closure reports
o Executed agreement documents (e.g., for NISTfunded grants, cooperative agreements, contracts,
CRADAs, or interagency agreements, SOWs, etc.). These documents serve as duplicate copies only for
purposes of HSPO's human subjects review.
o Documentation reviewed by the NIST 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.
Note: Investigators and study sponsors have separate retention requirements under 21 CFR 312.57 (sponsor) and 21
CFR 312.62 (investigator) for investigational drugs, 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 nonNIST IRB registered to perform FDA reviews.
o IAAs, if applicable.
Additional study specific files include the following documents as appropriate/applicable:
o General correspondence (e.g., protocolrelated correspondence between the IRB and HSPO, emails,
letters)
o IRB official letters/memos (e.g., IRB official meeting outcome letter, IRB approval memo)
o Protocol (initial submission and all subsequent approved versions)

	o Consent form (initial submission and all subsequent approved versions) o Study instruments (e.g., questionnaires, case report forms, recruitment material) o Scientific review documentation o Investigator's Brochure/device manual/product information and FDA Forms 1571/1572 and communications (as appropriate) o CVs/biographical sketches, human subjects research protection training documentation, COI statements for PI and key study personnel o Documentation related to continuing review o Amendments (e.g., modification requests, including request for study closure) o AEs, SAEs, and UPIRTSOs reports, Research Monitor reports o Deviation reports o Any statements of significant new findings to be provided to subjects o Other related documents as appropriate, as determined by HSPO, the PI and/or OU o Final study or closure reports o Executed agreement documents (e.g., for NIST funded grants, cooperative agreements, contracts, or CRADAs, interagency agreements, SOWs, etc.). These documents serve as duplicate copies only for purposes of HSPO's human subjects review. o 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 in Part?	Explanation
DAA-0167-2018-0002-0001	No	

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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-0167-2024-0002-0002	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 NIST IRB Membership Roster. The HSPO 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 of the 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: o 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. o Actions taken by the IRB. o Votes on these actions, including
the number of members voting for, against, and abstaining, including reasons
for any abstentions. o The basis for requiring modifications, deferring review, or
disapproving research. o A written summary of the discussion of controverted
issues and their resolution. o Continuing education presented at IRB meetings.
o 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: o Approving research with waiver of informed consent
o Approving research with waiver of the documentation of informed consent o
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-0167-2018-0002-0002	No
DAA-0167-2018-0002-0003	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Temporary. Cut off at the closure of the study.

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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

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Signatory Information

Action	User	Date
Approve	Colleen Shogan	09/20/2024