Request for Records Disposition Authority

Records Schedule Number	DAA-0167-2018-0002
Schedule Status	Approved
Agency or Establishment	National Institute of Standards and Technology
Record Group / Scheduling Group	Records of the National Institute of Standards and Technology
Records Schedule applies to	Major Subdivsion
Major Subdivision	Director's Office
Minor Subdivision	Human Subjects Protection Office
Schedule Subject	Human Subjects Protection Office Records
Internal agency concurrences will be provided	No

Background 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.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
3	0	3	0

GAO Approval

Outline of Records Schedule Items for DAA-0167-2018-0002

Sequence Number	
1	IRB Protocol Review Records.
1.1	IRB Protocol Review Records Disposition Authority Number: DAA-0167-2018-0002-0001
2	IRB Administrative and Operational Records
2.1	IRB Administrative and Operational Records Disposition Authority Number: DAA-0167-2018-0002-0002
2.2	Audio recordings of IRB meetings Disposition Authority Number: DAA-0167-2018-0002-0003

Records Schedule Items

Sequence Number	
1	IRB Protocol Review Records. Non-Exempt Human Subject Research Files maintained for all human subjects research protocols reviewed by the IRB, Exempt, NR, NHSR (Files on Studies Determined to be Not Research (NR), Not Human Subjects Research (NHSR) or Exempt Human Subjects Research), and FDA regulated studies files.
1.1	IRB Protocol Review Records Disposition Authority Number DAA-0167-2018-0002-0001 • Non-Exempt Human Subject Research Files. Files maintained for all human subjects research protocols reviewed by the IRB. These files include the following documents as appropriate/applicable: o General correspondence (e.g., protocol-related 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 check-lists, 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 multi-site 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 read-ahead 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 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 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 NIST-funded 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 non-NIST 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., study-related correspondence between HSPO and the investigator(s), emails, letters, telephone call records) o Documentation approved by a non-NIST IRB for non-exempt research o Documentation approved by a non-NIST institution for other determinations (i.e., NR, NHSR, Exempt) o 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 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 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: o General correspondence (e.g., protocol-related 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 check-lists, MFRs, responses to recommendations, MFR requesting final documentation or approval, DSMB or DMC reports) o Additional

local IRB documentation (such as for multi-site 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 read-ahead 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 NIST-funded 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 25-32. • Files on Studies approved by a non-NIST 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., protocol-related 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

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the closure of the study.
Retention Period	Destroy 5 year(s) after cut off, but longer retention is authorized if required for business use. (15 CFR 27.115)

Additional Information

GAO Approval	Not Required

2 IRB Administrative and Operational Records
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

Disposition Authority Number DAA-0167-2018-0002-0002

• 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.

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the closure of the study.
Retention Period	Destroy 5 year(s) after cut off, but longer retention is authorized if required for business use. (15 CFR 27.115)

	Additional Information	
	GAO Approval	Not Required
2.2	**Audio recordings of IRB meetings**	
	Disposition Authority Number	DAA-0167-2018-0002-0003
	Audio recordings may be used to assist the IRB Office with accurately documenting the conduct of the IRB meeting.	
	Final Disposition	Temporary
	Item Status	Active
	Is this item media neutral?	No
	Explanation of limitation	Audio recordings
	Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
	Do any of the records covered by this item exist as structured electronic data?	No
	Disposition Instruction	
	Retention Period	Destroy/erase upon final approval of written meeting minutes which capture requirements under 15 CFR 27.115.
	Additional Information	
	GAO Approval	Not Required

Agency Certification

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
09/10/2018	Certify	Donna Miller	Records Management Officer	Director's Officer - Management and Organization Officer
05/14/2019	Submit for Concurrence	Valerie Terray	Archives Specialist	National Archives and Records Administration - Records Management Services
05/16/2019	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
05/16/2019	Concur	Laurence Brewer	Chief Records Officer	National Records and Archives Administration - National Records and Archives Administration
05/18/2019	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist