

HRPP POLICY APPROVAL & IMPLEMENTATION
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 206

SOP Title: Maintenance of Records

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators,
IRB Chairs, IRB Administrators, Protocol Navigators**

Revision Approval:

Michael M.  Digitally signed by
Gottesman -S Michael M. Gottesman -S
Date: 2020.06.10
16:39:27 -04'00'

**Deputy Director for Intramural
Research**

Implementation date: 11/02/2020

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

POLICY

A. PURPOSE

1. Describes the requirements for maintaining adequate documentation of the human subjects protection activities of the Office of Human Subjects Research Protections (OHSRP) and the NIH Institutional Review Board (IRB) within the NIH Intramural Research Program (IRP) Human Research Protection Program (HRPP).
2. Describes the requirements for the content of NIH IRB Minutes.

B. SCOPE

1. This policy applies to the records related to the protection of human subjects held by OHSRP and its offices.
 - a. This policy applies to the Office of IRB Operations (IRBO) regarding maintenance of NIH IRB records (including records of the convened IRB, of expedited reviews, of limited IRB reviews, and IRB Minutes), as well as maintenance of records for exempt reviews.
 - b. This policy applies to OHSRP and NIH IRB records that are regulated by [45 CFR 46](#) and [21 CFR 56](#).
2. This policy applies to the Deputy Director for Intramural Research (DDIR) with regard to access to human subjects protection records held by OHSRP and the NIH IRB.
3. This policy does not address recordkeeping responsibilities for NIH investigators. (See *Policy 300 Investigator Responsibilities*.)

C. POLICY

1. The OHSRP will keep adequate records of the activities of the NIH IRB and the OHSRP, consistent with federal law, regulation and policy, including NIH policy (e.g., [45 CFR 46.115](#) and, as applicable, [21 CFR 56.115](#), [NIH Manual Chapter 1743 - Keeping and Destroying Records](#), and the [NIH Intramural Records Retention Schedule](#)).
2. Where applicable, OHSRP will treat as confidential its human subject protections records, including the records of the NIH IRB.
3. All OHSRP records, including NIH IRB records, will be controlled by the OHSRP Director, or designee.

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

4. The OHSRP Director will determine who should be allowed to view IRB and certain OHSRP records (e.g., human research protection investigations related to allegations of non-compliance or complaints). This determination will be based on documentation of a legitimate need and made in accordance with applicable federal law, regulation, and policy, including NIH policy. Any disagreements regarding access to records will be adjudicated by the DDIR.
 - a. Subject to applicable federal law, regulation, and policy, access to IRB records is limited to IRB members, IRB staff, authorized NIH and OHSRP officials, and officials of Federal regulatory agencies or oversight bodies. Each recipient must treat the records confidentiality.
 - I. Applicable IRB and OHSRP documents will be accessible for inspection and reproduction by authorized representatives of the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), in a reasonable manner. ([45 CFR 46.115](#) and [21 CFR 56.115](#), as applicable.)
 - II. Records and correspondence that are identified as confidential, and provided by OHSRP are not permitted to be shared or disclosed, particularly outside of NIH, without OHSRP permission, unless to another NIH Federal Employee for the same purpose for which OSHRP disclosed the record/correspondence originally.
 - b. Access to IRB files by non-NIH investigators or institutions will be granted consistent with the terms of any applicable agreements executed by the NIH, and with applicable law and policy.
 - c. NIH investigators and other authorized NIH staff (e.g. Protocol Navigators or IC Monitors) may be provided reasonable access to certain IRB files related to their work on NIH protocol(s).
 - d. Accreditation bodies, including their staff and accreditation site visitors, as applicable, may be provided access to inspect IRB records, e.g., during site visits, as needed, and as mutually agreed upon by the parties, and consistent with applicable agreements, law, regulation, and policy.
5. The minutes of the NIH IRB shall be in sufficient detail to show:
 - a. The quorum of the meeting, including the members who were present or absent, as well as any consultants or guests.
 - b. Determinations made by the IRB, including the basis for any changes required by the IRB, the discussion of controverted issues and the resolution thereof, or the basis for disapproval of the research.

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

- c. Actions taken by the IRB, including voting by members, both for or against, as well as abstained or recused due to a conflict of interest.

D. DEFINITIONS

- 1. *NIH Investigator* – An NIH federal employee (intramural or extramural), Special Volunteer, Intramural Research Training Awardee (IRTA) or Cancer Research Training Awardee (CRTA) who is conducting NIH human subjects research on behalf of the NIH. This may include a contractor in accordance with [Policy 100](#).

E. RESPONSIBILITIES AND REQUIREMENTS

1. OHSRP Records Responsibilities

- a. OHSRP is responsible for maintaining all records (paper and/or electronic) of its human subjects protection activities in compliance with applicable federal law, regulation, and policy, including NIH policy, including records such as:
 - I. The IRP Federalwide Assurance (FWA) and IRB registration;
 - II. Human Research Protection Program (HRPP) policies;
 - III. Reliance (authorization) or other human research protections-related agreements, executed by the OHSRP Director or the Deputy Director for Intramural Research (DDIR) on behalf of the Human Research Protection Program (HRPP).
 - IV. Human subjects protection investigations including allegations and findings related to non-compliance and subject complaints (See [Policy 104 Managing Research-related Complaints from Research Subjects](#), [Policy 802 Noncompliance in Human Subjects Research](#).);
 - V. Reportable Event Forms (REFs), e.g., including injuries to subjects, or non-compliance reports, Problem Report forms and related materials. (See [Policy 801 Reporting Research Events](#).);
 - VI. Regulatory reports to federal agencies, consistent with [Policy 801 Reporting Research Events](#);
 - VII. Formal written communications with OHRP, FDA, and other regulatory, oversight, or accrediting bodies, as applicable;

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

- VIII. Records of accreditation activities and quality assurance activities regarding the NIH IRB. (See *Policy 108 OHSRP Quality Assurance and Quality Improvement Program*); and
- IX. Educational records, materials and presentations, consistent with [Policy 103 Education Program](#).
- b. The OHSRP is responsible for protecting from unwarranted disclosure, and treating as confidential, its records as applicable (e.g., confidential correspondence, intellectual property, agreements, and investigational records).
- c. The OHSRP is responsible for ensuring that records under its control (including IRB records) are made available for inspection by OHRP when appropriate, and as applicable, by the FDA, consistent with [C.4.a.](#) above.
- d. The OHSRP is responsible for ensuring that applicable records under its control are made available for inspection to the accrediting body, including its staff and accreditation site visitors, consistent with [C.4.d.](#), above.

2. IRBO Records Responsibilities

- a. The IRBO is responsible for maintaining records (paper and/or electronic) of NIH IRB activities, consistent with federal law, regulation, and policy, including NIH policy (e.g., the NIH Records Retention policy). The IRBO will maintain records pertaining to the review of human subjects research while a project is active and then for a minimum of three years from the date of study completion or study cancellation (e.g., termination of IRB approval, or administrative closure by an IC). If the NIH records retention policy requires that such records should be maintained for a longer period of time than specified above, then the IRBO will maintain the records consistent with the NIH records retention policy. ([45 CFR 46.115](#), [21 CFR 56.115](#), and [NIH Manual – 1743 Keeping and Destroying Records](#) and the [NIH Intramural Records Retention Schedule](#).)
- b. The IRBO maintains its human subjects protection records in electronic systems, which must meet applicable federal standards (e.g., federal law, regulations or policies, including NIH policy).
- c. The IRBO is responsible for keeping confidential its human subjects research records (e.g., NIH IRB records, including IRB minutes and agendas, records of exemption reviews, and communications with investigators).

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

- d. The IRBO must maintain documentation of the date of transition for protocols transitioned from the pre-2018 Common Rule requirements to 2018 requirements and related documentation.
- e. The IRBO is responsible for ensuring that records under its control are made available for reasonable inspection by OHRP and the FDA, as applicable. ([45 CFR 46.115](#) and [21 CFR 56.115](#))
- f. The IRBO must maintain information used by exempt reviewers to make their determinations including, but not limited to: 1) materials in support of exemption requests, 2) exempt review determinations and documentation, and 3) correspondence with NIH investigators. (See [Policy 205 Requirements for IRB Submissions](#).)
- g. When the NIH IRB is the Reviewing IRB, the information used by the convened IRB, expedited reviewers, or limited IRB reviewers to make their determinations, must be maintained by the IRBO.
 - I. By federal regulation and policy, the following records of NIH IRB activities must be maintained by the IRBO:
 - i. Research proposals including: research protocols, protocol addenda and/or research plans, and information about the proposed research collected within the electronic IRB system;
 - ii. Scientific Review evaluations submitted by NIH PIs to the IRB, as applicable (See [Policy 106 Ancillary Reviews](#).);
 - iii. IRB-approved informed consent and/or assent documents, (e.g., consent forms, parental permission forms, assent forms, information sheets, verbal scripts), as applicable;
 - iv. Continuing review (CR) determinations by the IRB, including the rationale for conducting CR of research that otherwise would not require CR as described in [45 CFR 46.109\(f\)\(1\)](#) of the 2018 Common Rule, as applicable;
 - v. Progress reports, as applicable (including reports of injuries to subjects and subject complaints, if any, and significant new findings);
 - vi. Statements of significant new findings provided to subjects that may relate to the subject's willingness to continue participation in the research, as applicable ([45 CFR 46.116](#));

| | | |
|--|-------------------|-----------------------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | | Effective Date: 11/02/2020 |
| Maintenance of Records | Policy 206 | Version: 1.0 |

- vii. Minutes of IRB meetings, including protocol-specific findings and supporting determinations. (see [E.3.](#) below);
 - viii. Any additional documentation of findings required under federal regulation or policy, including NIH policy, or as deemed necessary by the convened IRB, expedited reviewer, or limited IRB reviewer.
 - ix. For research approved under the 2018 Common Rule, the rationale for an expedited reviewer's determination that research appearing on the expedited review list described in [45 CFR 46.110\(a\)](#), is more than minimal risk ([45 CFR 46.110\(b\)\(1\)\(i\)](#) of the 2018 Common Rule), as applicable;
 - x. Correspondence between the IRB and investigators;
 - xi. IRB rosters consistent with the requirements of [45 CFR 46.108](#) (See *Policy 201 IRB Membership and Composition.*);
 - xii. Written procedures for the IRB as described in [45 CFR 46.108](#); and/or
 - xiii. Any other IRB documents required by federal law, regulation and policy, including NIH policy.
- II. The IRBO must maintain materials submitted by investigators, including but not limited to:
- i. Materials in support of initial review and, as applicable, CR. (See [Policy 205 Requirements for IRB Submissions.](#));
 - ii. Materials in support of modifications to previously approved research (amendments); (See [Policy 205 Requirements for IRB Submissions.](#));
 - iii. Expanded access use reports. (See [Policy 502 Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices \(Test Articles\).](#));
 - iv. For multisite research, site-specific submissions and amendments and related materials; and/or
 - v. Any other protocol-related documents requested by IRBO.
- h. When the NIH IRB is the Reviewing IRB, the IRBO will maintain the records related to IRB meetings and correspondence including:
- I. Meeting Agendas, including:

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

- i. A list of expedited review determinations.
 - ii. A list of limited IRB review determinations, including documentation as required at [45 CFR 46.111\(a\)\(7\) and \(8\)](#) of the 2018 Common Rule.
 - iii. A list of expanded access use, including emergency use, of investigational drugs, biologics or devices determinations. (21 CFR parts, [50](#), [56](#), [312 \(Subpart I\)](#) or [812](#)) (*[Policy 502 Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices \(Test Articles\)](#)*.)
- II. Meeting minutes see [E.3.](#) below.
- III. All protocol-specific correspondence between the IRB, and the IRBO, and investigators, other authorized NIH staff (e.g. Protocol Navigators or IC Monitors), or other institutional offices as applicable, consistent with [C.4.](#) above). Notification to PIs of actions taken by the convened IRB, expedited reviewer, exempt reviewer, limited IRB reviewer or the IRBO including, but not limited to, the following:
 - i. Approval (initial or CR, and amendments);
 - ii. Approval with stipulations (initial or CR and amendments), or other conditions that must be satisfied by the PI, if any, for IRB approval;
 - iii. A deferred or disapproved study;
 - iv. Determination of serious or continuing non-compliance, or unanticipated problems to subjects or others;
 - v. Study closure;
 - vi. Suspension or termination of approved research;
 - vii. Frequency of CR, if applicable;
 - viii. Reminder of approaching expiration of IRB approval, or lapse in IRB approval; and
 - ix. Determinations of exemption, including the outcome of limited IRB review, as applicable.
- i. When the NIH is the Relying Institution, the IRBO will maintain records related to institutional review, consistent with federal law, regulation and policy, including NIH

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

policy, and the requirements of the IRB of record consistent with terms of any applicable agreement, whichever is longer.

- j. The IRBO will maintain IRB membership information and documentation consistent with federal regulation and NIH policy (*Policies 201 IRB Membership and Composition and 202 Board Member Conflict of Interest*) including:
 - I. Roster(s), including previous membership rosters (e.g., type of appointment, employment status and role on the IRB);
 - II. Notifications of appointment and re-appointment, including the member’s terms of service; and
 - III. CVs or resumes of members.
- k. The IRBO maintains records confirming that IRB members and Intramural Research Program (IRP) investigators have completed the IRP-required human subjects protection training ([Policy 103 Education Program](#)).

3. Minutes of the NIH IRB

The Minutes of the NIH IRB shall include, with sufficient detail, the following information:

- a. Attendance of members, consultants, and guests at convened meetings;
- b. The identity of a member who served as an alternate member, and for whom they were covering;
- c. Votes on IRB actions including the number of members voting for, against, and abstaining;
- d. The basis for requiring changes in, or disapproving, research;
- e. A written summary of the discussion of controverted issues and their resolution; and
- f. Determinations made, and actions taken, by the IRB as required by federal regulation (e.g., [45 CFR 46](#), and, as applicable, [21 CFR 56](#)), and by NIH policy. This includes but is not limited to:
 - I. Risk and benefit;
 - II. Consent procedures that waive or alter some or all of the elements of informed consent, or waive documentation of consent;
 - III. Vulnerable populations, including:

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

- i. Pregnant women, fetuses, and neonates described at [45 CFR 46 Subpart B](#) (See [Policy 400 Research Involving Pregnant Women, Human Fetuses and Neonates.](#));
 - ii. Prisoners at [45 CFR 46 Subpart C](#) (See [Policy 401 Research Involving Prisoners.](#));
 - iii. Children at [45 CFR 46 Subpart D](#) (See [Policy 402 Research Involving Children.](#));
 - iv. Adult subjects without capacity to consent to research. (HHS 45 CFR 46.111(b)) (See [Policy 403 Research Involving Adults Who Lack Decision-making Capacity to Consent to Research Participation.](#)); and
 - v. NIH staff as research participants. (See [Policy 404 Research Involving NIH Staff as Subjects.](#))
- IV. FDA regulated products, including:
- i. Drugs, biologics or nutritional products (See [Policy 500 Research Involving FDA Regulated Drugs, Biologics, and Nutritional Products.](#)); and
 - ii. Devices, including the rationale for Significant/Non-Significant Risk determinations for research devices. (FDA [21 CFR 812 Subpart D](#)) (See [Policy 501 Research Involving FDA Regulated Devices.](#))

F. REFERENCES

1. Federal Regulations:

HHS: [45 CFR 46](#),

FDA: 21 CFR parts [50](#), [56](#), [312 \(Subpart I\)](#), [21 CFR 812 Subpart D](#)

US Code 42 USC 289g-1/g-2

2. NIH policy:

[Policy 100 NIH HRPP](#)

[Policy 103 Education Program](#)

[Policy 104 Managing Research-related Complaints from Research Subjects](#)

[Policy 106 Ancillary Reviews](#)

Policy 108 OHSRP Quality Assurance and Quality Improvement Program

Policy 201 IRB Membership and Composition

Policy 202 Board Member Conflict of Interest

| | | |
|--|-----------------------------------|---------------------|
| NIH Intramural Research Program | | |
| Office of Human Subjects Research Protections | Effective Date: 11/02/2020 | |
| Maintenance of Records | Policy 206 | Version: 1.0 |

[Policy 205 Requirements for IRB Submissions](#)

[Policy 300 Investigator Responsibilities](#)

[Policy 400 Research Involving Pregnant Women, Human Fetuses and Neonates](#)

[Policy 401 Research Involving Prisoners](#)

[Policy 402 Research Involving Children](#)

[Policy 403 Research Involving Adults Who Lack Decision-making Capacity to Consent to Research Participation](#)

[Policy 404 Research Involving NIH Staff as Subjects](#)

[Policy 500 Research Involving Drugs, Biologicals, and Nutritional Products](#)

[Policy 501 Research Involving FDA Regulated Devices](#)

[Policy 502 Expanded Access, including Emergency Use of Investigational Drugs, Biologics and Medical Devices \(Test Articles\)](#)

[Policy 801 Reporting Research Events](#)

[Policy 802 Noncompliance in Human Subjects Research](#)

[NIH Manual Chapter 1743 - Keeping and Destroying Records](#)

NIH Intramural Records Retention Schedule:

<https://records.nih.gov/scheduleitems/category/28>

3. **Guidance:** NA

G. APPENDICES: NA

H. REVISION HISTORY: NA

I. SUPERSEDES DATE: 11/02/2020

SOP 4 Human Research Protection Program (HRPP) Documentation and Records