

Policy 206 Maintenance of Records – Policy Overview

<p>This document summarizes changes in Policy 206 Maintenance of Records (referred to as Policy 206 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.</p> <p>The policy 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).</p> <p>Describes the requirements for the content of NIH IRB Minutes.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
Policy 206 Maintenance of Records	SOP Superseded by Policy 206
Policy 206 fully supersedes	SOP 4 Human Research Protection Program (HRPP) Documentation and Records
<p>Applicability of Policy 206 - This policy applies to the records related to the protection of human subjects held by OHSRP and its offices:</p> <ul style="list-style-type: none"> • 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. • OHSRP and NIH IRB records that are regulated by 45 CFR 46 and 21 CFR 56; and • To the Deputy Director for Intramural Research (DDIR) with regard to access to human subjects protection records held by OHSRP and the NIH IRB. <p>This policy <u>does not</u> address recordkeeping responsibilities for NIH investigators. For more information see <i>Policy 300 Investigator Responsibilities</i>.</p>	
Policy Requirement	SOP Requirement
<p>Section C.1. – <i>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).</i></p> <p>AND</p> <p>Section E.1.a. – Review this section for a list of the types of records OHSRP and its offices will maintain in accordance with this policy.</p> <p>This requirement remains unchanged from SOP 4.</p>	<p>Section 4.2. – <i>The NIH keeps adequate records of its IRBs’ and the OHSRP’s activities. These records may be on paper or in electronic format and are stored in the IRB administrative office or on NIH servers.</i></p> <p>Policy 206 is unchanged from SOP 4 and is reorganized for clarity.</p>
<p>Section C.2. – <i>Where applicable, OHSRP will treat as confidential its human subject protections records, including the records of the NIH IRB.</i></p> <p>AND</p>	<p>Section 4.7. – NIH IRBs must protect the confidentiality of research information.</p> <p>Policy 206 has broadened this requirement to include records held by the OHSRP, reflecting the</p>

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<p>Section C.4.a.II. – <i>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.</i> AND Section E.1.b. – <i>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).</i></p> <p>Policy 206 is far more explicit about how records are held confidential and the conditions under which they will be disclosed.</p>	<p>change in the organizational structure of the NIH HRPP and the consolidation of the NIH IRB under OHSRP and IRB operations under IRBO.</p>
<p>Section C.4.a.I. – <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). See also Section E.1.c.</i></p> <p>This requirement is unchanged from SOP 4.</p>	<p>Section 4.2. – <i>IRB documents will be accessible for inspection and reproduction by the OHSRP, authorized representatives of the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), sponsors, and other NIH authorized entities.</i></p>
<p>Section C.4. – <i>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.</i></p> <p><i>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 confidentially.</i></p> <p>Policy 206 specifies that any disagreements about access to OHSRP, IRBO or IRB records will be adjudicated by the DDIR. Further, Policy 206</p>	<p>Section 4.7.C. – <i>Subject to applicable law and Federal policy, access to IRB records is limited to the Institute Clinical Director, the IRB Chair, IRB members, the IRB staff, authorized NIH and OHSRP officials, and officials of Federal regulatory agencies (OHRP, FDA, etc...). Appropriate accreditation bodies may be provided access to IRB records as needed.</i></p> <p>Policy 206 is expanded from SOP 4 to include the role of the OHSRP Director, who can determine who may access OHSRP and IRB records. This reflect the change in the organizational structure of the NIH HRPP and the consolidation of the NIH IRB under OHSRP and IRB operations under IRBO.</p>

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<p>specifies that any authorized recipient of IRB records must also hold these records as confidential.</p>	
<p>Section C.4.b. – <i>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.</i></p> <p>Policy 206 addresses multisite research and access by non-NIH investigators to NIH IRB records when the NIH IRB is the Reviewing IRB.</p>	<p>N/A</p> <p>SOP 4 was written before the implementation of the NIH sIRB Policy and the cooperative research provisions of the 2018 Common Rule (45 CFR 46).</p>
<p>Section C.4.c. – <i>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).</i></p> <p>This requirement is unchanged from SOP 4. However, it expands the group to include protocol navigators and NIH IC monitors.</p>	<p>Section 4.7.d. – <i>Research investigators may be provided reasonable access to IRB files related to their protocol(s). The IRB Chair or Institutional Official will determine if research investigators should be allowed to view IRB records (and to what extent). This determination will be based on documentation of a legitimate need and made in accordance with applicable laws and regulations.</i></p>
<p>Section E.4.d. – <i>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.</i></p>	<p>Section 4.7.c. – <i>Appropriate accreditation bodies may be provided access to IRB records as needed.</i></p>
<p>Section E.5. – <i>The minutes of the NIH IRB shall be in sufficient detail to show:</i></p> <ul style="list-style-type: none"> <i>a. The quorum of the meeting, including the members who were present or absent, as well as any consultants or guests.</i> <i>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.</i> <i>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.</i> <p>See also Section E.3. for what must be included in NIH IRB Minutes.</p> <p>These requirements are unchanged from SOP 4.</p>	<p>See Section 4.4.1.</p>

<p>Section E.2. – This section describes categories of IRB and IRB operational records that will be retained by the IRBO.</p> <p>The requirements for IRB records are unchanged from SOP 4. However, Policy 206 has been expanded to address 2018 Common Rule requirements and multi-site research, to include the following:</p> <ul style="list-style-type: none"><i>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.</i><i>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. (Note the expansion to include limited IRB determinations consistent with the 2018 Common Rule)</i><ul style="list-style-type: none"><i>I.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.</i><i>I.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. iv.</i><i>II.iv. For multisite research, site-specific submissions and amendments and related materials.</i>	<p>See Section 4.3.3.</p>
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