DOCUMENTATION AND DOCUMENT RETENTION

DESCRIPTION

The Institutional Review Board (IRB) records must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, which include but are not limited to, continuing reviews, modifications, reports of serious adverse events and unanticipated problems. All records regarding a submitted study must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, relying institutions, regulatory agencies, accrediting agencies, and institutional auditors at reasonable times and in a reasonable manner.

RESPONSIBILITY

The Human Research Protection Program (HRPP) staff is responsible for maintaining complete records on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements.

POLICY

Document Retention

The HRPP Office will retain all records regarding a protocol for a minimum of three (3) years. For all applications that are approved and the research initiated, the HRPP Office retains all records regarding that research for at least three (3) years after study closure or completion of the research. The HRPP Office retains all other records for three (3) years. If a protocol is cancelled without participant enrollment, IRB records are maintained for at least three (3) years after cancellation. For Veterans Affairs Medical Center (VAMC) research, records must be maintained and retained in accordance with Veterans Health Administration’s (VHA) Records Control Schedule.

IRB Administration Documents

The HRPP office must maintain and retain all records regarding IRB administrative activities that affect review activities for least three (3) years after completion or cancelation of a study. IRB records document the justification for exempt determinations. IRB records document determinations required by laws, regulations, codes, and guidance. In order to allow a
Human Research Protection Program Procedure

reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records must include:

- Protocols or research plans;
- Investigator brochure, if any;
- Scientific evaluations, when provided by an entity other than the IRB;
- Recruitment materials;
- Consent documents;
- Progress reports submitted by researchers;
- Reports of injuries to participants;
- Records of continuing review activities;
- Data and safety monitoring reports, if any;
- Modifications to previously approved research;
- Unanticipated problems involving risks to participants or others;
- Documentation of non-compliance;
- Significant new findings; and
- Relevant correspondence between the IRB and researchers.

IRB records for initial and continuing review of research by the expedited procedure will include the justification for using the expedited procedure, actions taken by the reviewer, as well as any findings required by laws, regulations, codes, and guidance to be documented.

For VAMC research, required records, including the research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA’s Records Control Schedule (RCS 10-1).
For VAMC research IRB records shall include:

- Correspondence between the IRB and VAMC’s Research and Development Committee;
- Correspondence between the IRB and researchers;
- Internal serious adverse events;
- Documentation of protocol deviations;
- A resume for each IRB member; and
- All previous membership rosters.

If a protocol is cancelled without participant enrollment, IRB records are maintained for at least five years after cancellation. Documents requiring retention beyond the UC IRB requirement are transferred to the VAMC. VAMC’s Research and Development Committee has access to all IRB records.
Destruction of Copies

All material received by the IRB, which is considered confidential and in excess of the documentation required to be retained in the IRB’s study file will be securely destroyed.

Applicable Regulations, Document(s):
45 CFR 46.115
21 CFR 56.115

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<thead>
<tr>
<th>Adoption Date:</th>
<th>Created by:</th>
<th>Date of Revision:</th>
<th>Revised By:</th>
<th>Summary of Revision:</th>
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<tbody>
<tr>
<td>03/2005</td>
<td>M. Belskis</td>
<td>07/2007</td>
<td>D. O'Neill</td>
<td>Extended the time for document retention from 3 years to 5 years. Updated IRB office staff terminology.</td>
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<tr>
<td>03/2008</td>
<td>M. Colbert</td>
<td>03/2008</td>
<td>M. Colbert per AAHRP</td>
<td>Department of Veterans Affairs- no longer a requirement for IRBs of academic affiliates to keep their records in accordance with VHA’s Records Control Schedule (RSC-10).</td>
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<td>10/2009</td>
<td>J. Gerlach</td>
<td>10/2009</td>
<td>J. Gerlach per AAHRPP</td>
<td>Added description- when protocol cancelled without participant enrollment, IRB records maintained for at least five years after cancellation.</td>
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<tr>
<td>12-2010</td>
<td>J. Gerlach</td>
<td>12-2010</td>
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<td>Revised document retention from 5 years to 3 years.</td>
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<td>5-2011</td>
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<td>Record retention from 5 years to 3 years. Corrected all retention periods.</td>
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<tr>
<td>9/2014</td>
<td>A. Braggs-Brown</td>
<td>9/2014</td>
<td>A. Braggs-Brown</td>
<td>Revisions include AAHRPP recommendations</td>
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Date Adopted: March 2015
Signature: signed copy on file