AAH RSPP GUIDANCE
IRB Record Retention

PURPOSE
The purpose of this document is to provide guidance on IRB record retention for studies overseen by the Advocate Aurora IRB.

Definitions of Italics words can be found in the AAH RSPP Glossary.

GUIDANCE

What human subject research studies are included in the IRB record retention policy?
Any
1) human subject research study that has undergone RSPP/IRB review and exempt
determination/approval or
2) a treatment protocol that requires per federal or institutional policy IRB review (expanded
access or HUD protocols)
is required to have records retained per federal regulations and AAH policy.
If a protocol is withdrawn/cancelled without subject enrollment, IRB records are maintained for
at least three years after cancellation.

How long are IRB records to be retained?
IRB records, including IRB meeting minutes, are required by the regulations to be retained for at
least 3 years after completion of the research that is the subject of the review (45 CFR
46.115(b)).
• Many sets of minutes will have records of review of multiple studies. Relevant portions of
the minutes must be retained until the regulatory retention period for each study is
satisfied.

IRB records must be accessible for inspection and copying by authorized representatives from
OHRP and/or FDA at reasonable times and in a reasonable manner.
• Institutions and IRBs can expect that representatives of OHRP conducting a compliance
oversight assessment, or representatives of FDA conducting a Bioresearch Monitoring
inspection, will review minutes and other appropriate IRB records to assess compliance
with the regulations.

AHC system policy 223 (Record Retention, Storage and Destruction) dictates that any IRB
records that contain HIPAA related documentation (e.g. records of waivers of authorization,
preparatory to research representations) must be retained for 7 years from the later of the date
created or the last effective date.
What types of documents are to be retained as part of the IRB record?
In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the human subject research study, the IRB record should include copies of the following, as applicable:

- Protocols or research plans;
- AAH IRB Submission applications;
- Investigator brochure;
- Scientific determinations/evaluations [e.g. radiations safety review, biosafety committee review, etc.] when provided by an entity other than the IRB;
- Recruitment materials;
- Consent/HIPAA authorization documents;
- Reports of injuries to subjects;
- Subject complaints;
- Records of continuing review activities;
- Data and safety monitoring reports;
- Changes to previously approved research;
- Reports of Unanticipated Problems;
- Reports of incidents of non-compliance;
- Significant New Information;
- Final Reports;
- All correspondence between the IRB and researchers.

What other documents should be retained?
Other documents will also be retained for the period outlined above:

- HIPAA determinations
- Copies of IRB authorization agreements
- Emergency Use reports

How are IRB documents stored?
Paper study files are stored in file cabinets/boxes within the locked RSPP office or a secure room in the Downers Grove (Illinois) office building.

Electronic study files are stored in electronic folders on secure RSPP shared drive(s) or in the electronic IRB Net environment. Access to the RSPP shared drive or IRB Net environment is restricted to those only individuals needing access.
Copies of IRB meeting minutes, meeting agendas, and IRB rosters are stored in paper format within the locked RSPP office or in electronic format on secure RSPP shared drive(s).

Older Significant Financial Interest disclosure forms and COI management plans are stored as paper documents within the locked RSPP office. Newer Significant Financial Interest disclosure forms and COI management plans are stored as electronic documents on a secure drive in the AAH Compliance department.

**How are IRB documents destroyed?**

Destruction of paper study files occurs after a minimum period of 7 years per Aurora system policy 233. Paper study files are sent to a secure shredding company as directed by AAH.

Destruction (deletion) of electronic files occurs after a minimum period of 7 years per Aurora system policy 233.

As required by policy 233, a destruction log is maintained by the RSPP office upon destruction of any IRB study files/documents.

**REQUIREMENTS**

- Common Rule Regulations: 45 CFR 46.15(b)
- FDA Regulations: 21 CFR 56.115(b)
- AAHRPP Accreditation Standards/Elements: II.5.A
- AHC System Policy 223 -
- AAH RSPP SOPs: #3, 7, 8, 9