AAH RSPP GUIDANCE
Study Closure & Researcher Record Retention

PURPOSE
The purpose of this document is to provide guidance on when investigators should submit a Final Report to close a human subject research study being conducted at Advocate Aurora Health.

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

GUIDANCE

When is my study considered ‘completed’?
Research studies should NOT be closed unless the study has been completed at AAH.

If any of the following conditions apply do NOT file a study completion report. Such studies must remain active and continue to receive ongoing IRB review and approval:

- Enrollment is on-going
- Research-related interventions and/or follow-up is ongoing
- Subject contact/follow-up is ongoing
- Biological specimens containing personally identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed.
- Data analysis or manuscript preparation that involves the use or access to personally identifiable information (including data that is linked/coded) is ongoing.
- If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

There may be other reasons for terminating a research study besides ‘study completion’ (see below). If any subjects were enrolled, the study should not be closed until all subjects have been notified (as needed) and final contact/data collection is completed, sponsor is made aware and agrees to study closure, and any data/specimens are de-identified.

- Loss of study funding
- The sponsor or FDA has permanently closed the study at all research sites.
- The research was never initiated at Aurora.
- The research was initiated but no subjects were ever enrolled at Aurora, and the sponsor has closed study enrollment;
- The local PI is terminating the research at Aurora prior to meeting intended goals/objectives;
- The local PI is leaving Aurora, and no one is available to take over the study.
Note that the need to close a study early – i.e. before it is completed as outlined in the IRB approved protocol – may be investigated by the IRB as an unanticipated problem (See SOP #7: UP Submission Requirements).

**How do I close my research study?**
Research studies may be closed by submitting to the RSPP Office an AAH Final Report (found on the RSPP website or in the IRB Net library). The Final Report should be submitted within 30 days of study completion/termination.

The submitter/PI will be asked to confirm that research activities have been completed at AAH. Once the AAH Final Report is received and processed by the RSPP, the research study will be closed with the RSPP/IRB and deactivated in the RSPP research database.

An acknowledged copy of the submitted Final Report will be returned to the study team for their records. The Advocate Aurora IRB will be made aware of study closure on a future IRB meeting agenda.

**What does study closure mean?**
Study closure means that the research study is not being overseen by an IRB, and therefore no research related activities may occur in that study. This includes: the collection of data about any subject enrolled in the study (even if only collecting information from his/her medical record), analysis or use of identifiable or coded/linked data or specimens, or the contact of research subjects to collect data points (even if only to ascertain whether the subject has experienced side effects from the research). Therefore, **take care not to close the research study too soon.**

After a study is closed with the IRB, there is no need for continuing review (if applicable to the study).

**Do I need to submit a Final Report for research being overseen by an external IRB?**
Research studies overseen by an external IRB will follow the study closure policy of that IRB.

However, once the research study is closed with the IRB of record, the study team/PI is required by AAH RSPP SOP #3 to submit an AAH RSPP Final Report to the RSPP office. The submission of the Final Report for ceded research alerts the AAH RSPP that the study is no longer being conducted at AAH. The submission of the Final Report will deactivate the study in the RSPP research database.

An acknowledged copy of the submitted Final Report will be returned to the study team for their records. The IRB will be made aware of study closure on a future IRB meeting agenda.
Can I use the data from a closed research study for another purpose?
Subsequent use of data from closed research, whether by the original investigator or other
investigators, may constitute human subjects research that requires IRB approval or an
Exemption Determination. Please contact the AAH RSPP office for guidance.

Can I contact the subjects of a closed study about participation in a future study?
Many investigators may want to “re-contact” research subjects to recruit for future studies. Since
it is important to protect the confidentiality and privacy of research subjects, it would not be
appropriate to re-contact research subjects in a closed research study about future participation
in another study unless they had previously agreed to such a re-contacting as part of the
consent process for the first study or if the IRB/Privacy Board could authorize a waiver of
consent/authorization for that contact as part of the new application.

What happens if I submitted a Final Report to close a study, and am asked by the study
sponsor to conduct further research activities?
Once you close the research study with the IRB it is no longer being overseen by an IRB.

If the study has been closed with the IRB, and you wish to conduct further research activities,
you may request that the IRB reopen the study. This may be accomplished in one of two ways:
- complete the continuing review process – the IRB will re-review the study ensuring that it
  continues to meet the regulatory criteria for approval; OR
- depending on the nature of the study, the research activities that will be done, and the
  length of study closure, the AAH RSPP may require that a new study application be
  submitted.

Again, take care, to the best of your ability, to ensure that the research activities in the study are
completed to reduce effort at a later date.

What if new information is received from the study sponsor after the research study is
closed that affects the safety and/or medical care of previously enrolled research
subjects?
The PI must report to the IRB any information learned after study closure that could affect
participant safety or care, including but not limited to serious adverse events or unanticipated
problems report by the Sponsor or other responsible for study monitoring.

If new information that may affect the safety or medical care of past-research subjects is
discovered or provided to the research team after a research study has been closed, the IRB
must be notified within five working days of the event or notification to the investigator of the
event. This information would be submitted on an Unanticipated Problem Report and reviewed
as a potential UPIRSO (see RSPP SOPs #7 and 8).
Should past-subject notification of the new information be required, it will be done as an institutional action rather than a research action. If the research sponsor wishes to collect further information from/on the past-subjects, the research study will need to be re-opened with the IRB. This would require a new submission to the IRB.

**How is collected research data to be retained, and for how long?**

You are reminded that data from the completed study should be stored and protected in the manner approved by the IRB and consented to by the research participant so as to maintain the privacy and confidentiality of the subjects. Whenever possible, the data should be permanently de-identified.

All records related to human subject research are subject to inspection by federal authorities and the institution. At a minimum, per federal regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), investigators must maintain research records for three years beyond the completion/termination of the study. Investigators should be aware that other laws and requirements (e.g., funding agency, ICH GCP, HIPAA Privacy Rule) may require a longer record retention period.

With regard to the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), if the research involves the use of Protected Health Information (PHI), the Privacy Rule indicates that the signed Authorization (or waiver of Authorization) must be retained by the covered entity for 6 years from the date of creation or the date it was last in effect, whichever is later. Aurora System Policy 223 (Record Retention, Storage, and Destruction) also outlines timeframes for record retention and destruction.

**What research records besides collected data should also be retained following study closure?**

AAH and federal regulations requires researchers to retain the following records related to the use of human subjects in research:

- Copies of the Human Subjects application forms and protocols,
- Notices of IRB approval, and
- Signed Informed Consent Documents and authorization documents (if applicable)

Per AARI SOP RM203 (Study closure and record retention), for clinical trials conducted at AAH, the retention of research records is managed by the ARI Clinical Trials Department. The SOP also outlines the processes for archiving of research records.

**REQUIREMENTS**

- Common Rule Regulations: 45 CFR 46; 45 CFR 160 and 164
- FDA Regulations: 21 CFR 56, 312 and 812
- AAHRPP Accreditation Standards/Elements: II.5.A
• AHC System Policy 223
• AAH RSPP SOPs: #3, 7, 8
• ARI SOP RM203