Research Subject
Protection Program
1020 N 12th St
Suite 3120
Milwaukee, WI 53233

T 414.219.7744
F 414.219.7477
IRB.office@aurora.org

www.aurora.org/IRB

News from the Advocate Aurora Health Research Subject Protection Program (RSPP) Institutional Review Board (IRB)

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IRB Help Information

Individuals from either Wisconsin or Illinois that have any questions or comments about the IRB process or for the IRB office, should not hesitate to contact us at the WI Office (414) 219-7744 or the IL Office at (630) 929-6151.You can email us at IRBOffice@aah.org or IRBmail@aah.org . These boxes are a great way to ensure that you get in touch with the appropriate individual at the Advocate Aurora Health RSPP offices. Using the group box will typically get you a much quicker response. If there is a topic that you would like addressed in a future newsletter, please send a detailed description of the topic to IRBOffice@aah.org. Past editions of the RSPP newsletter can be found on the RSPP website.

HIT Risk Review Authorization

Formerly known as 'Tech Reviews,' the Risk Review is the process in which various teams in Health Information Technology (HIT) come together to evaluate potential new, or existing technology related solutions. The Risk Review process although similar in name, is not a risk assessment. Risk assessments are performed throughout a solution's lifecycle, for more information check out HITs website: Risk Review (sharepoint.com).

A HIT risk review must be done prior to IRB submission for those studies that include the use of technology and that the Advocate Aurora IRB oversees. The HIT review will evaluate that the confidentiality of the data is maintained when using the technology. Additionally, the HIT review will identify any risks to the subjects that may occur with regard to the technology and that any risks to subjects are mitigated.

For studies that will be ceded to an external IRB, the Request to Rely on an External IRB form has been updated to ask the question if the protocol requires the use of technology, software and applications. It is recommended that a HIT Risk/Tech review be completed prior to study submission to the external IRB.

Examples of study-related technology that may require a HIT Risk Review are:

- Flash drives with PHI
- Internal/external data sharing on external drive (CD/DVD/…)
- Apps
- E consent
- Data transfer
- Email including PHI
- Some medical devices (especially those using Bluetooth/WiFi) (ex. Ultrasound)
- Medical technology using Bluetooth/WiFi
- Wearable sensors/trackers
- Tablets/Cell Phones/other technology used to collect PHI or share PHI
- E signatures
- Video/voice recordings

- Adding hardware (ex. MRI/CT scanner) or software (installing) to AAH network
- Cloud storage of PHI

Information on the HIT risk/tech review process may be found at: Risk Review (sharepoint.com). If you have questions you may also contact: AAH-HIT-SecurityRiskManagement@aah.org

Record Retention Procedures

With some offices being informed that they will be staying remote for the long term, we have received some questions about how this will affect IRB documents. What needs to happen with the study team's IRB documents that were kept in paper files in the office location. Can they be destroyed? Can they be brought home? Should they be converted to electronic files? All Advocate Aurora Health (AAH) System Policies as well as local and Federal regulations must be considered. That can be mind boggling to try to sort out. Here is a breakdown of the basics for IRB records data retention.

There are several factors in determining what needs to be done with the records. Is the local site the lead study site? Is there an IND/IDE related to the study? Do the files contain any subject identifiers? The response to these questions will lead us down different paths as to what is needed for keeping the files on and off site. Record keeping and retention regulations related to sponsor and the investigator can differ. The sponsor of a study may be a pharmaceutical company, a non-profit organization or the AAH PI. As a reminder, when the PI both initiates and conducts the clinical research study, the PI is considered the Sponsor-Investigator and assumes responsibilities of both the sponsor AND the investigator. If a study is industry sponsored, it is important to know the regulations that apply to a sponsor, as well. Some sponsors, CROs, or federal agencies may require that investigators keep additional documents, and it is helpful to ask questions and understand why.

Some general rules are:

- Drugs & Biologics: Under FDA regulation, essential documents and clinical trial records for drugs and biologics should be kept for a period of **two years** following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
- Devices: Under FDA regulations, essential documents and clinical trial records for devices should be kept for a period of **two years** after the latter of the following two dates;
    - The date on which the investigation is terminated or completed, or
    - the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
- Under ICH GCP E6, records should be retained until at least **two years** after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region; or at least **two years** have elapsed since the formal discontinuation of clinical development of the investigational product.
- HIPAA Authorization/Consent must be archived for **6 years** from date of IRB closure approval.
- If a protocol is withdrawn/cancelled without subject enrollment, IRB records are maintained for at least **three years** after cancellation.
- IRB records are required by the regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)) to be retained for at least **3 years** after completion of the research. The AAH RSPP office recommends that these records be kept for **6 years** because many contain HIPAA documents (e.g. records of waivers of authorization, preparatory to research representations).
- Destruction (deletion) of electronic files occurs after a minimum period of **6 years** per Aurora system policy 63000.

As required by system policy 63000, a destruction log should be maintained upon destruction of any study files/documents.

See AAH system policy 63000 (Record Retention, Storage and Destruction) for further information.

Research records should be maintained for the longest amount of time specified to meet the requirements, not the shortest. In the case of investigational drugs or devices, it often takes much longer than six years to reach marketing approval, thus the federal requirement for two years after marketing approval trumps the six-year policy. However, consideration should be given to maintaining the records longer than required. Records should be destroyed as soon as is reasonably practicable following the expiration of the applicable retention period. Justification should be documented for records that are maintained outside of the duration provided by AAH policy. The AAH RSPP office recommends that any IRB related records kept longer than 10 years after completion of the research should include a justification.

Often the deletion of electronic files should be brought to the attention of AAH HIT to ensure the proper destruction of these records. Destruction methods should be used that ensure the records, whether paper or electronic, are rendered essentially unreadable, indecipherable, and otherwise not capable of being reconstructed.

AAH Team Members should follow department procedures and AAH policies for maintaining study files in a location other than an AAH facility or on AAH owned devices.

Keep in mind when establishing a plan for your record retention for study files that applicable records must be accessible for inspection and copying by authorized representatives of HHS or the FDA at reasonable times and in a reasonable manner.

If study data storage and/or retention plan will be edited from what was originally presented to the IRB on the Protocol Submission Application (for example, moving from exclusive paper storage to electronic storage of study records), ensure the changes are communicated to the IRB through the submission of a change form.

Exempt Submissions – Protocol Requirement

To ensure that the RSPP Offices in both WI and IL have complete information about the Exempt research and processes, we are now requiring a protocol for all investigator-initiated research submissions including Exempt submissions. This is effective as of Friday June 4, 2021. During the conduct of the research, it is expected that the protocol be kept accurate and current. The preferred protocol template can be found here.

The revised Exempt Submission application has been revised to include the requirement to include a protocol as well as some additional questions about the collection and/or review of data and PHI. Watch your email and the RSPP website for the release of this new submission form.

As a reminder, the RSPP office should be notified when Exempt studies are to be closed. Closures may be made in the following manner: Advocate IRB via submission of a Continuing Review form (HRP-212); Aurora IRB via a Final Report form.

Form Revision: Request to Rely

The Request to Rely form has been updated and is available for use. Submitters in IL can find the new form loaded to IRB Net and those in WI can find the new form on the RSPP Website. Be sure to use the most current version of the form when submitting your initial requests/substantial modifications.

Significant Interest Disclosures

Interest Disclosures: Per AAH System Policy 2302, Investigators/key personnel must update their annual disclosure within 30 days of discovering or acquiring a new significant interest, and Investigators/key personnel have an obligation to notify appropriate reviewing bodies (including the IRB) and funding agencies of significant interests they believe are related to a project on which they are named. Significant Interests are those related to a research project that could directly and significantly affect a covered party's designing, conducting, or reporting of the research or Aurora's conduct, review, and/or oversight of the research. The disclosure questionnaire is available through Policy Tech, Aurora's on-line system. Please contact the RSPP office if you have questions on how to access the questionnaire to process a new or changed Significant Interest. In addition, if you wish to notify the IRB of a Significant Interest that you hold and you believe is related to a study on which you are participating, please send to the RSPP office email. Please do not include specific monetary values in the email.