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

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Contents

What's New?

- Please be aware that IT has made a small change in the RSPP website address. Check your bookmarks - the old RSPP website address will no longer take you to our website, and IT did not include re-direct instructions/links.

  The (new) RSPP website address is: www.aurorahealthcare.org/rspp-irb/ .

- **Newest version of forms** in the IRBNet Library - to be used immediately (submissions of older versions of forms may be returned to you):
  - All forms have been revised to include the new RSPP website address
  - SNI form- clarification to questions and RSPP processing workspace
  - UP reporting form - clarification to questions and RSPP processing workspace
  - NC reporting form - clarification to questions and RSPP processing workspace
  - Continuing Review form – minor edits to questions
  - Change forms (all three: exempt, ceded studies, AAH IRB studies) - updated student participation instructions
  - Request to Rely form - addition of student participation instructions and clarification to questions
  - IRB submission and Exempt submission applications - addition of student participation instructions
- **IRB SOP#3** - clarification to ceded study instructions post AAH authorization – specifically submission of UP reports in ceded research

- **Non-responsiveness Policy**. The AAH RSPP/IRB has been seeing more and more instances of submitter's non-responsiveness to requests from the AAH RSPP office or IRB for change, new information, etc. There are numerous examples of IRBNet packages (new human subject research (HSR) applications, requests for reliance on an external IRB, HSR determinations, Changes in approved research) that have been submitted to the AAH RSPP/IRB where individuals never respond to the requests of the AAH RSPP/IRB. These IRBNet packages remain in our review queue but do not get acted upon by the AAH RSPP/IRB.

  To prevent such packages from remaining in the review queue without action, and to make the RSPP/IRB's process more efficient, the AAH RSPP/IRB is implementing a Non-Responsiveness Policy. It should be noted that many other institutions have a similar policy when dealing with similar situations.

  - This policy will be enacted when submitters fail to respond to the AAH RSPP/IRB's request for clarification, further information, follow-up, or addressing IRB conditions of approval.
    - Non-responsiveness to requests for submission of Noncompliance Reports or required Continuing Review applications will be dealt with through the Noncompliance process or will be dealt with as a lapse in IRB approval.
  - If a submitter does not respond to a request from the AAH RSPP/IRB for clarification or action within **45** days, or make a formal request for an extension, the lack of action on the part of the submitter (ie. non-responsiveness) will result in the **administrative withdrawal** of the submitted AAH IRBNet package.
    - Withdrawal of the IRBNet package will mean that your submission (HSR submission, Change request, Continuing Review application, reportable event, HSR Determination) will not receive action/review by the AAH RSPP/IRB. NO human subject research activity (including a change in an approved HSR study) may occur without IRB approval.
  - Once an IRBNet package is marked as withdrawn in IRBNet it cannot be reactivated. A new package must be submitted.
  - The process to be followed in situations of non-responsiveness can be found in the **AAH RSPP guidance: *Non-Responsiveness to AAH RSPP/IRB requests for information/action*** located in the RSPP website.
    - Submitters may request an extension of the initial 45 day response time period. The submitter will need to provide to the RSPP office team member who requested the information/action a rationale for the extension and a plan of action to respond to the request for information/action. This request must be made in writing (an email will suffice).
    - The request for an extension will be considered by the RSPP Director and is not guaranteed. The extension will not exceed an additional 45 days – and will only be granted once.
    - If there is no response/action after the extension period (the second 45 day time period), the IRBNet package will be administratively withdrawn without further communication with the submitter/PI.
  - This new policy/process takes effect **April 1, 2023**. Those IRBNet packages that are currently past the 45 day deadline with no response will be notified of impending administrative withdrawal per the process outlined in the guidance.

Noncompliance and Unanticipated Problems in Ceded research – role of AAH

AAH RSPP has a different role in the review of Noncompliance (NC) and Unanticipated Problems (UP) in research that relies on an external IRB for oversight ('ceded research'). AAH IRB is not the IRB of record in these research studies, therefore we do not make the Unanticipated Problems Involving Subjects or Others (UPIRSO) or serious/continuing NC determinations. That responsibility lies with the IRB of record per the federal research regulations.

Per our reliance agreements with the external IRBs and institutional policy, the role of AAH in the review of UP or NC in ceded research is to ensure that there is nothing that the institution/local site needs to do immediately to remedy/remediate the situation, as well as protect AAH subjects. The RSPP is the responsible party at AAH for making the decision if immediate action is needed.

To ensure that the AAH RSPP has the information necessary to meet our responsibilities, research teams are required to report UPs and instances of NC to the AAH RSPP as noted in Section 5.3 of RSPP SOP #3.

For **UP reporting in ceded research** - the local site follows the external IRB's policies in determining when a possible UPIRSO has occurred. **IF** a UP is reported to the IRB of record, research teams are required per RSPP SOPs #3 and #8 to provide a copy of that report to the AAH RSPP using the Significant New Information form. [Do **NOT** report these problems on the AAH IRB UP Reporting form.]

- The SNI form and a copy of the UP report sent to the IRB of record must be uploaded in IRBNet. The RSPP will review the information to determine if immediate action is necessary to protect AAH subjects.

For **NC reporting in ceded research** – per RSPP SOPs #3 and #5 research teams are required to report all instances of noncompliance to the AAH RSPP no matter if the study is overseen by the AAH IRB or an external IRB. In the case of studies overseen by an external IRB, the study team will go on to report the incident of noncompliance to that IRB per their policies and process.

- The AAH RSPP will review the submitted NC report for ceded research to determine 1) if the incident is potentially continuing noncompliance; and/or 2) if immediate action needs to be taken to protect AAH subjects.

  Remember, continuing noncompliance is not only determined for incidents that are serious but can also be determined for incidents that are of a non-serious nature but are repeated within the research study, or that are repeated by the same member(s) of the research team but in different research studies.

  As most external IRBs do not require non-serious noncompliance incidents to be reported to them, the AAH RSPP is the only group outside of the research team that will be aware of non-serious NC incidents. If the RSPP determines the reported NC incident to be potentially continuing, the RSPP will instruct the research team to report the incident to the external IRB even if it does not meet the IRB of record's routine/required NC reporting criteria.

- The AAH NC report should be completed and submitted to the RSPP via IRBNet. The RSPP will review the information to determine if immediate action is necessary to protect AAH subjects.

In both UP and NC reporting, any **final decisions/determinations made by the IRB of record** must be reported to the AAH RSPP using the SNI form. The completed SNI form and the determination from the external IRB must be uploaded as a new package for the study in IRBNet.

Research Ceded to an External IRB – General Reminders

RSPP SOP #1 and #3, RSPP guidance: *Deferral Ceding of IRB Oversight to an External IRB* – all located on the RSPP website - are resources available to you on the reliance process at AAH. These documents include information on:

1) which studies meet automatic ceding criteria and how to request an exception when your study does not meet automatic ceding criteria (see Section 5.3 of RSPP SOP #1);
2) the process to be followed when requesting reliance on an external IRB;
3) instructions on what is required to be submitted following IRB of record approval (see Section 5.3 of RSPP SOP #3);
   a) Pay careful attention to the requirements for submission of external IRB approval, and submission of noncompliance and unanticipated problems that occur in ceded research;
4) Changes in research personnel participating on a ceded study must receive authorization from the AAH RSPP **before** these individuals begin research activities. Per our reliance agreements with external IRBs, AAH must ensure that the research team members have appropriate training in the conduct of human subject research and have no reported conflicts of interest with the research **before** they are included on the research study. Submit in IRBNet a Changes in Ceded Research form (located in the AAH IRBNet library) when changes to the research team in ceded research are to occur.
5) It is important to let the AAH RSPP know when a ceded study has closed at AAH. You **must** report a study closure by submitting an AAH Final Report form in IRBNet.

NOTICE to those who submit research studies to NCI CIRB: Advocate Health Care Network has been deactivated as an option in NCI CIRB submissions. Only Advocate Aurora Health remains as a submission option to NCI CIRB. All studies that were originally submitted under the AHCN_NCI CIRB platform have been transferred to the AAH_NCI CIRB platform.

General Reminders/Tips for all Research

- **REMEMBER to review emails sent from the IRBNet system.** Not only does IRBNet remind you when action items are due (for instance, continuing review notifications), but **IRBNet project email** is also used by the RSPP office to inform you when clarification/follow-up is needed, or that your final documents/letters have been uploaded into the system.

- See above for new RSPP policy on Non-Responsiveness. NOTE that outside of continuing review notices (which are generated directly by the IRBNet platform), repeated requests for action are not sent by the RSPP/IRB. It is not the policy or practice of the AAH RSPP to send 'reminders' that we are awaiting action.
- For the most part, the RSPP office does NOT communicate with researchers/submitters about IRBNet packages via personal email. All communication is sent within IRBNet project email.
- It is important to make sure that the IRBNet project is **'shared' with the PI** so that s/he is aware of activity surrounding the research study. In most cases, there will not be separate communication via personal email.

- **Only one Change is allowed per study at one time**. Multiple changes submitted at the same time are withdrawn by the RSPP office. These withdrawn Changes must be resubmitted to be acted upon by the RSPP/IRB.
- **'Lock'/'relock' your IRBNet submissions** - especially after you submit revisions. The RSPP does not receive notification of returned/revised submissions until the resubmitted package has been 'locked', and we do not take action on submissions that have not been 'locked'.
- **Unanticipated Problem and Noncompliance reporting**. Please make sure to provide the AAH RSPP with enough information to make required decisions on the incident. The information provided on the forms should:
  - be concise and complete;
  - not include too many uses of undefined acronyms or too much medical terminology – the reports should be in lay language;
  - address the questions on the form. Many times, we see the same answers repeated for different questions. This is not acceptable in most situations.

  Incomplete forms will be returned to the submitter for revision. Not only does this cause extra work for the submitter/research teams but for RSPP staff reviewing the incidents as well. Please be mindful and provide accurate, complete information the first time
- **Research Team composition**– It is the responsibility of the research team to keep an accurate list of individuals taking part in the research at any given time. Outside of the fact that the RSPP must be aware of who is currently working on a research project, an accurate personnel list allows the RSPP Office to share these lists with other departments, such as Compliance or AARI.

  The **Personnel Log** in IRBNet (sometimes called the 'delegation of authority log') should be considered the 'source of truth' by research teams – and should include all key research personnel (see definition in RSPP glossary – RSPP website) active on the research study. This is true whether your study is ceded to an external IRB or overseen by the AAH IRB. Additions or deletions of research personnel may be requested by uploading a Change form into IRBNet (see more later in this section).

  An individual is able to work on human subject research only after they are authorized/approved by the AAH RSPP/IRB. The IRBNet Personnel Log should be updated with the name of the new individual at the time that a Change form is submitted, but the person may only initiate research activities after RSPP/IRB authorization/approval.

  Changes in research team composition may be requested by completing one of the three Change forms located in the IRBNet Library. The Change form, once completed, must be uploaded into an IRBNet package. The type of Change form to be completed is dependent on the study type (for instance exempt, non-exempt human subject research, or research ceded to an external IRB). Also, the changes in personnel **MUST** also be documented on the **IRBNet Personnel Log** (see IRB submission guidelines document for instructions – located in the IRBNet Library).

  The Personnel Log in IRBNet must accurately depict the employment status of the research personnel (Aurora, Advocate, Aligned), a correct email address where the individual may be contacted, as well as the **research activities** that have been delegated to that individual by the PI. This last point is important to be aware of – the RSPP/IRB is looking for the activities that the individual will do in the research study. We often see, for example, research personnel listed as conducting physical exams, however the research study is a chart review. While conducting physical exams may be a responsibility of the individual in their every-day job, this would not be a research activity in a chart review study.

  Contact the RSPP office if you have questions on the Change process.

- **Additions of research personnel.** Additions to the research team must be approved/authorized **before** the individual takes part in the research. If research activities are conducted without RSPP/IRB authorization/approval, this is an instance of Noncompliance that must be reported per RSPP SOP #5.

  All individuals being added to a research study must have completed the AAH HSR education requirements, the AAH COI survey, and if needed, the Master Investigator Obligation Agreement (MIOA; to be completed by individuals who are not employed by AAH) **before** the RSPP/IRB will take action.

  It is possible that a reliance agreement may also need to be executed if the external institution is engaged in human subject research. Contact the RSPP office with questions.

- There are extra requirements for the inclusion of students on a research study. Information can be found on the submission or Change forms – or you may review instructions in the GME Research SharePoint site.

- **Removal of research personnel.** When research team members leave the study/AAH, they must be removed from the research study by completing and uploading the appropriate change form and updating the IRBNet Personnel Log.

- **Notify the RSPP immediately upon awareness that the PI will be leaving the study**/AAH. It is required by federal regulation and AAH system policy 2467 that every research study be overseen by an individual ultimately responsible for the conduct of that study, and the safety of the research subjects or the confidentiality of their data. Such an individual is called the 'Principal Investigator (PI)'. Studies that do not have an active PI fail to meet the regulations and system policy.

  System policy 2467 (IV.C.3.) notes that the RSPP Office must be notified of the departure of the PI prior to, or 'in no case later than seven (7) working days from departure'. If no replacement PI is designated, system policy allows for the termination of the study due to lack of oversight.

- **IMPORTANT! Be careful and accurate when preparing personnel logs**. **The RSPP does not take responsibility for, nor confirm the accuracy of, information provided on the research personnel logs/change forms.** If issues are found later related to the information that was provided by the study team on the personnel log, this may become an instance of Noncompliance that must be reported to the RSPP/IRB.

  The RSPP occasionally conducts quality or spot checks of the personnel logs, and we have found the following errors on submitted personnel logs.

  1. There have been occasions where research team members were added to Personnel Logs, but the changes/additions were never disclosed to the RSPP/IRB on a Change form. This means that the individuals listed on the personnel log were never properly vetted for COIs or completion of HSR training, nor were they approved/authorized for participation in the research study by the IRB/RSPP. **Individuals added onto a personnel log without the accompanying disclosure of their research participation on a RSPP/IB Change form are NOT approved/authorized by the IRB/RSPP as a research team member.**
  2. We have also noted incorrect disclosures of an individual's employment status on the Personnel Logs. In such cases, the individual was listed as being an Advocate or Aurora employee when they are in fact NOT AAH employed (instead, they are a student or 'aligned' personnel conducting research at AAH).

     It is important to eliminate employment errors on Personnel Logs. Not only must the RSPP have an appropriately executed Investigator Obligation Agreement (IOA) for aligned research personnel, but the researcher information is often used by other departments - so accuracy is imperative. For instance, Compliance uses the RSPP Personnel Log information as part of the annual COI disclosure process. In this situation, inaccurate information provided to the RSPP can cause inaccuracies to be transferred into the AAH Compliance COI software/process.

     REMEMBER: the use/provision of an AAH email address is not an indicator that the individual is employed by AAH. Be especially careful with the employment status of residents, fellows and medical students. Not all residents and fellows are employed by AAH, and most students are not employed by AAH – yet some are assigned AAH email addresses for use during their time at our institution. Contact the individual, or their 'one-up', to obtain accurate information on employment status.

  - What is an **Investigator Obligation Agreement (IOA)**? This document was created by AAH Legal and upon execution, holds non-AAH employed individuals to the same standards/responsibilities as AAH employed personnel relating to research participation. For instance, an executed IOA holds a non-AAH

employed researcher accountable for following AAH research policies and RSPP processes, federal HSR regulations, and the ethical research principles.

- The IOA is a 'master' document. This means that if an aligned investigator participates on more than one HSR study at AAH, they only need to complete the IOA once –not for every research study on which they participate. Currently, the Master IOA is good for 3 years.
- If you or one of your non-AAH employed research personnel need to execute this document (the RSPP Office checks to make sure it has been enacted when aligned persons are added to a research study) you can find it in the IRBNet library, as well as instructions on how to send the document to AAH Legal for final execution.

- **Use your assigned IRB study number on RSPP forms uploaded in IRBNet.** Remember that the IRBNet ID# or the legacy Advocate four digit number is NOT the AAH IRB study number. The AAH form functions as your record of IRB approval/action (ie. in lieu of an IRB Letter). Therefore, use of the IRB study number is important for tracking. The AAH RSPP/IRB does not include any other numbers in our correspondence.
- **Submit a Final Report when the study is completed.** Study closure documentation is needed for **every** research study conducted at AAH – **exempt, non-exempt human subject research, and studies ceded to an external IRB**. This action is necessary for several reasons:
  - It provides acknowledgment to the RSPP that the study is completed.
  - It allows the RSPP to close the study in our database - thereby allowing for an accurate record of open research studies and research personnel at AAH. This record of research studies/research personnel is used not only by the RSPP but by other departments in the organization (e.g. AARI and Compliance).
  - Research team members of studies closed in our system will no longer be flagged to complete annual COI disclosures.
- **Always check the IRBNet library for the most current form.** Most of our forms have undergone revision in the last month (see section above). Current versions of the RSPP/IRB forms must be submitted to us – if the current version of a form is not submitted there is a good chance it will be returned to you to be redone. All current forms can always be found in the IRBNet library.
- **RAPR/research service line leader authorization is required for each HSR submission and Change in PI** per AAH system policy. The RSPP will not take action on the submission until appropriate RAPR documentation has been received. Contact your research service line leader or the AARI RAPR office for more information on their process.
- The RSPP office has created a **Submission Guidelines** document that is available in the IRBNet library. Please take time to review this helpful resource.

Research Education requirements

- **ICH GCP**

  ICH GCP training is often required by NIH and sponsors when researchers take part in clinical trials/biomedical research.

  - In Wisconsin, ICH GCP modules have historically been part of the CITI based Biomedical education course. The inclusion of ICH GCP modules within the CITI Biomedical education course was a decision made by ARI leadership back in 2017.
  - In Illinois, ICH GCP modules were NOT a part of the CITI based Biomedical education course. Instead, a stand-alone ICH GCP course was available to researchers who needed to complete this education.

  In an effort to harmonize HSR education requirements across Advocate Aurora Health, the decision has been made to remove the ICH GCP modules from the WI CITI based Biomedical education course.

  This means:

  - The RSPP will no longer be tracking completion of ICH GCP education for researchers.
  - None of the AAH HSR training courses in CITI contain ICH GCP education.
    - A separate, stand-alone ICH GCP course is offered in CITI should the researcher need to complete it.

- ICH GCP CITI based education at AAH is valid for 3 years. Reminders are sent to researchers from CITI when the training is due to expire.
    - At expiration, a refresher ICH GCP course is required for your education to remain current. An ICH GCP refresher course is also available to researchers in CITI course offerings.
- Instructions on how to access CITI and the course options available to AAH researchers can be found on the RSPP website.

➢ **HSR Education Requirements**

Due to contractual issues, there are two CITI programs at AAH – however they both contain the same available courses, and each course now contains the same modules. Historically, IL researchers registered to the Advocate CITI program and WI researchers registered to the Aurora CITI program. As the education requirements are now the same, it does not matter to which program you register.

REMINDER all individuals who are key personnel on an active HSR study must have current CITI based HSR education before the RSPP will review the study/change. See AAH RSPP SOP #11 [see RSPP website] for information. This requirement is in effect for studies overseen by the AAH IRB as well as those ceded to an external IRB.

- The Advocate and Aurora CITI programs offer education courses in Biomedical and Social Behavioral (SB) human subject research.
    - The type of course that is required for a given study is dependent on the study design.
        - Some researchers may need to have completed both the Biomedical and SB education course depending on the types of research on which they participate. For instance, researchers who take part in both biomedical and social behavioral HSR projects will need to complete both the Biomedical and SB CITI-based education courses.
- CITI based education courses are valid for three years. CITI will alert the researcher that their education is due to expire. At that time, a refresher course will need to be taken. HSR education completion records can be accessed in CITI.
    - Advocate and Aurora researchers will receive notification from CITI when a refresher course is required. Notices are sent by CITI at 90 days, 30 days, and 7 days before expiration, as well as one day post expiration.
        - It is the responsibility of an Advocate Aurora Health researcher to ensure HSR education does not lapse, and that you remain compliant with HSR education requirements noted in RSPP SOP #11. Noncompliant research key personnel must be removed from all active research studies. See the RSPP SOP for instructions on removal of the individual from the research and the timeline that should be followed.
- Participation in human subject research without proper HSR education is an incident of noncompliance that must be reported to the AAH RSPP.

AREA OF FOCUS #1 - Use and/or disclosure of PHI in research: Preparatory to Research Representations

As a general reminder, one of the following requirements must be met in order for AAH to use and/or disclose, or allow a researcher to use and/or disclose, PHI for the purpose of research:

a) An Authorization is obtained from the research subject or their legally authorized representative for the use and/or disclosure of PHI for a specific research activity;

b) A waiver or alteration of the requirement to obtain Authorization meeting the requirements at 45 CFR 164.512(i)(1)(i) (A&B) is obtained from a privacy board or Institutional Review Board (“IRB”) for a specific research activity;

c) A representation that the use and/or disclosure of PHI for a review preparatory to research is obtained from the researcher;

d) A representation that the use and/or disclosure of PHI for research on decedents is obtained from the researcher;

e) The PHI disclosed is a Limited Data Set and AAH enters into a Data Use Agreement (DUA) with the data recipient in accordance with System Policy: Use and Disclosure of Limited Data Sets for Certain Purposes Policy; OR

f) The PHI is de-identified in accordance with 45 CFR 164.514(b) and the AAH System Policy: Disclosure of De-Identified Information Policy, and a data sharing agreement is in place.

This article discusses Preparatory to Research Representations.

Per the HIPAA Privacy Rule, for activities preparatory to research, covered entities may use or disclose PHI to a researcher without an individual's Authorization, a waiver or an alteration of Authorization, or a data use agreement. "However, the covered entity must obtain from the researcher representations that (1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research, (2) the PHI will not be removed from the covered entity in the course of review, and (3) the PHI for which use or access is requested is necessary for the research."

AAH permits a researcher who works for the covered entity to submit a representation to the IRB/Privacy Board for the following preparatory to research purposes:

a) Preparing a research protocol; determining if enough subjects are available to conduct the research;

b) Assisting in the development of a research hypothesis;

c) Aiding in research recruitment, such as identifying prospective research participants who would meet the eligibility criteria for enrollment into a research study.

An activated Preparatory to Research Representation permits the researcher to access and use PHI **excluding PHI related to mental health, developmental disability, and substance abuse information**, as long as the PHI does not leave AAH.

The first two Preparatory to Research activities (a & b above) are considered 'feasibility' activities. PHI is reviewed (not recorded) to create or finalize the research protocol or determine if there would be enough subjects at AAH to complete the proposed project. As long as no potential subjects are contacted and no PHI recorded, this activity may be completed prior to IRB approval of the research.

The third Preparatory to Research activity (c) is the one most often used by researchers at AAH. This activity allows researchers to screen patient PHI to determine eligibility of potential subjects. It is considered part of the recruitment process, and therefore patients can only be contacted for participation once IRB approval of the study has been secured.

With an activated Preparatory to Research Representation:

- Researchers may review the PHI of potential research subjects prior to IRB approval; however, the investigator may not contact potential subjects to ask for their participation in the research without first obtaining IRB approval of the research study;
- the Researcher is not allowed to record PHI or other identifiable information obtained from a review Preparatory to Research. If PHI must be recorded then IRB approval of the research activity is needed.
- PHI may not leave AAH.
    - Remote access to PHI by an AAH Workforce Member under the Preparatory to Research provision is not considered a removal of PHI from AAH as long as the Workforce Member does not print, download, copy, save, or retain the PHI including any temporary files stored on a device.
    - Researchers or individuals who are not AAH Workforce Members are not allowed remote access to PHI under the Preparatory to Research provision.

How to obtain a Preparatory to Research Representation at AAH?
There are two processes for submitting a Preparatory to Research Representation depending on the activity:

For **FEASIBILITY** activities, researchers should complete the Preparatory to Research Representation form (found in the AAH IRBNet Library) noting that the activity is for preparing a research study, developing a research hypothesis or determine if enough potential subjects are available at AAH. The completed form should be emailed to the RSPP Office [NOTE this is the only time that it is allowable to send a form through email and not use IRBNet]. The AAH IRB/Privacy Board will review

the completed form and determine if the activity is appropriate. If found appropriate, the submitter will receive a copy of the activated Representation by return email.

For **SCREENING/RECRUITMENT** activities, the most common manner to submit the Representation is as part of the research application package. The RSPP will accept Preparatory to Research Representations as part of the Change process as well – if the information initially provided by the study team is revised or if screening and recruitment using PHI is a new activity that is added after IRB approval. Researchers should complete the Preparatory to Research Representation form (found in the AAH IRBNet Library) noting that the activity is for screening/determining eligibility. The completed form should be uploaded as part of the initial submission package or a Change package. The AAH IRB/Privacy Board will review the completed form and determine if the activity is appropriate. If found appropriate, the submitter will receive a copy of the activated Representation as part of the IRBNet package.

> **In research ceded to an external IRB**, AAH has made the decision that AAH alone will authorize Preparatory to Research Representations. This means, if you are looking to identify prospective research subjects who would meet the eligibility criteria for enrollment into a research study being ceded to an external IRB, you must submit a Preparatory to Research Representation form with your Request to Rely on an External IRB package in IRBNet. The AAH IRB/Privacy Board will review the Preparatory to Research form and determine if appropriate.

NOTE a Preparatory to Research Representation must be activated before the patient's PHI is accessed. Patients **may not be contacted** about potential research participation until the research study is approved.

RESOURCES

HIPAA [Health Insurance Portability and Accountability Act] Privacy Rule – 45 CFR Parts 160 and 164

NIH website: Clinical Research and the HIPAA Privacy Rule

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule; DHHS e-book; NIH Publication Number 03-5388

System Policy: AAH Use and/or Disclosure of Protected Health Information for Research

System Policy: Use and Disclosure of Limited Data Sets for Certain Purposes Policy

System Policy: Disclosure of De-Identified Information

System Policy: AAH Accounting of Disclosures of Protected Health Information

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AREA OF FOCUS #2 – What is a Privacy Board, and how does its role differ from an IRB? How do researchers submit a request for a waiver or alteration of authorization at AAH?

An **IRB** is a board, committee, or other group formally designated by an institution to review research involving humans as subjects. IRBs have authority to approve, require modification to, or disapprove all research activities covered by the HHS and FDA Protection of Human Subjects Regulations.

A **Privacy Board** is a review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. A covered entity may use and disclose PHI, without an Authorization (waiver), or with an altered Authorization, if it receives the proper documentation of approval.

Under HIPAA, IRBs gained authority to consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. An IRB's role under the Privacy Rule is limited to acting on requests for a waiver or an alteration of the Privacy Rule's Authorization requirement.

Privacy Boards do not exercise any other authority granted to IRBs under federal Human Subject Research regulations.

In some circumstances, Privacy Boards and IRBs will coexist or, as at AAH, may be the same board. Where these boards coexist, the Privacy Rule requires approval of a waiver or an alteration of Authorization **by only one of them**.

Under the Privacy Rule:

- a covered entity may use or disclose PHI based on a waiver or an alteration of Authorization approved by 'any Privacy Board or IRB, without regard to the affiliation of the Privacy Board or IRB to the entity'. This means that an

IRB or Privacy Board approval of a waiver or an alteration of Authorization may be issued by a Privacy Board or IRB that is 1) unrelated to the institution conducting or sponsoring the research study, 2) unrelated to the covered entity that creates or maintains the PHI to be used or disclosed for research, or 3) different from the IRB responsible for overseeing the research study.

- This is especially important to note for those research studies that are **ceded to an external IRB for oversight**. A waiver or an alteration of authorization could be obtained from the single IRB overseeing a multisite research study or where the PHI necessary for the research will be used or disclosed by more than one covered entity.

- Authorization may be combined with the informed consent document for research. If the **informed consent document is combined with an Authorization**, Human Subject Research regulations would require IRB review of the combined document. However, **an IRB is not required to approve stand-alone Authorizations** (i.e., Authorizations that are not incorporated into the informed consent document).

  What does this mean for research conducted at AAH but overseen by an external IRB?

  - If the IRB of record allows the authorization elements to be combined with the research informed consent, that IRB will review the research authorization language.
  - If the IRB of record does not allow the authorization elements to be combined with the research informed consent, then the stand-alone research authorization created by AAH must be used without revision to obtain the authorization of the research subject.

Waiver or Alteration of Authorization Requirements

For some types of research, it is impracticable for researchers to obtain written Authorization from research participants. The Privacy Rule has established the criteria for approval of a waiver or alteration of the Authorization requirement by an IRB or a Privacy Board. In addition, the criteria for a waiver or alteration of the Authorization are consistent with the criteria for IRB waiver of the informed consent requirements contained in the Human Subjects Research Regulations. This means that an IRB is well positioned to make waiver/alteration of authorization decisions.

For a covered entity to use or disclose PHI under a waiver or an alteration of the Authorization requirement, it must receive documentation of, among other things, the IRB/Privacy Board's determination that the following criteria have been met:

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The research could not practicably be conducted without the requested waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

If the researcher wishes to request a waiver of authorization or alteration of authorization elements – including documentation of authorization – and the AAH IRB is the IRB of record for the research study **OR** the external IRB overseeing the research study does not agree to serve as the Privacy Board, a Waiver/Alteration of Authorization form (located in IRBNet Library) can be submitted to the AAH RSPP office via IRBNet. The Waiver/Alteration of Authorization form addresses the necessary criteria that must be in place for the AAH IRB/Privacy Board to make the necessary waiver/alteration of authorization decision. This document should be uploaded with the package in IRBNet.

RESOURCES

NIH: Privacy Boards and the HIPAA Privacy Rule; 25 September 2023

NIH: Institutional Review Boards and the HIPAA Privacy rule; 15 August 2023

IRB Help Information

Individuals from either Wisconsin or Illinois who have questions or comments about IRB processes or submissions in IRBNet should not hesitate to contact us at IRBOffice@aah.org. This is a great way to ensure that you get in touch with the appropriate individual in the AAH RSPP office. Using the group box will typically get you a timelier 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.

Significant 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 (SI) 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 AAH's conduct, review and/or oversite of the research.

Please contact the RSPP office if you have questions on how to access the questionnaire to process a new or revised 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. , ,