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

November 2022

Contents

What's new in the RSPP?

The following bullet points outline the forms/SOPs/processes that have been updated… Please take a moment to review as these new forms/SOPs/processes are now in effect.

- **Revised forms** – NOTE these revised forms are included in the IRBNet library.
  - All of the '**Change'** forms have revamped sections related to the addition of key personnel to your research study – including the addition of students which have some special actions required by the research team.
  - The AAH IRB Change form now includes a section where you can itemize the study materials that were translated for use with LEP subjects. The listed documents will be 'approved' by the AAH IRB with the approval of the Change form.
  - The **IRB submission application** and the **Request to Rely on an External IRB** form have been revised to remove investigational drug services (IDS) notification. IDS awareness is now part of the AARI RAPR process.
- **Updated guidance documents** – NOTE these guidance documents are available on the RSPP website. Please make it a point to review these updated documents.
  - *Deferral/Ceding Of IRB Oversight To An External IRB*
  - *Enrollment of subjects with Limited English Proficiency (LEP)*
- **Updated SOP 3** – NOTE the updated SOP is available on the RSPP website.

  Relative to Research that Relies on an External IRB (ie. ceded research) – section 5.3:

  1. **Documentation of continued oversight** by the external IRB (IRB of record) **is no longer required**.
     - Until receiving documentation from the IRB of Record and/or the AAH study team of the termination of IRB oversight or the closure of the research study at AAH, the RSPP will conclude that 1) the study remains open at AAH, and 2) the original IRB of Record continues to oversee the study for AAH.

- It is incumbent on the study team (and required by RSPP SOP 3) for you to notify the RSPP should the ceded research study be closed at AAH or IRB oversight terminated. This is to ensure that the RSPP has an accurate record of the research being conducted/open at AAH and overseen by an external IRB.

2. A time frame for compliance with the requirement for providing the AAH RSPP with **initial/approval documentation from the IRB of record** has been added to the SOP. Such documentation must be submitted to the RSPP **no later than 14 days after receipt** from the IRB of Record.
    - Failure to supply the RSPP Office with the external IRB's initial approval/oversight documentation within 14 days of receipt will be treated as an incident of Noncompliance per RSPP SOP 5 (failure to follow RSPP SOPs).
3. SOP 3 has also been revised to provide clarification on how to submit the IRB of record's final determination of local instances of Noncompliance and UPIRSO.

- ***New* - Operational changes**
    - Effective immediately, **only one Change form may be submitted at a time for a research study.** Submission of multiple change forms in a study can cause issues with study conduct – particularly if a later Change form is processed before an earlier one.
        - If a Change form is submitted for a study, and there is already a pending Change for that study, the second Change form will be withdrawn and will need to be resubmitted once the earlier, pending Change has been approved/acknowledged. Please plan accordingly.
    - **RUSH requests**. The RSPP has been inundated of late with requests for RUSH reviews. While it is understandable that things happen unexpectedly that necessitate a document/form requiring a rush review, the submitter must be aware that such requests cause a disruption and work-stoppage in the RSPP. An RCA must be pulled from the review of other items in his/her work queue to accommodate the RUSH request. This may mean that the review of another study's research actions, submitted before the rush request, will be paused and therefore delayed.
        - Effective immediately, any request for a RUSH review should be sent to the RSPP email mailbox [irboffice@aah.org] – do not include a request for a RUSH review in the IRBNet package as it will not get acted upon. The request must include a rationale for the rush review. The request will be sent to the RSPP Director and evaluated for merit.
        - The RSPP Director may ask the requestor to provide documentation of his/her leader's awareness of the rush request as well as the potential for pause/delay in the review of other research actions.
        - NOTE RUSH requests should be rare and may not always be granted. Please plan accordingly.
- **Updated informed consent templates –** NOTE the updated consent templates are available in the IRBNet library.
    - The Certificate of Confidentiality (COC) language in the research informed consent templates has been revised to include the exact COC language found on the NIH COC website. NOTE COC language must only be included in the research informed consent if a COC has been issued by NIH. See the NIH website for more information.

IRBNet Updates

The following points outline recent revisions/updates to IRBNet forms processes.

1. Cloning vs. Editing.

a) Am I able to create a Personnel Delegation Log using a different Log as a starting point for an NEW submission (AKA- Cloning)?

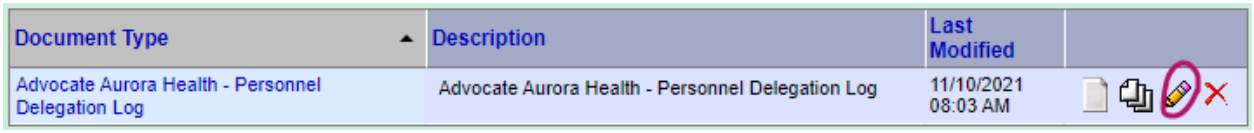
Yes. You are allowed to submit a personnel log in IRBNet by either creating a log from scratch or by cloning an existing log from another project.

IRBNet allows users to "clone" logs from one study project to another. This may be especially helpful when the project you are submitting includes many of the same researchers that were included on another project. While

the IRBNet program allows delegation log information to be duplicated and used in another project, it is the responsibility of the submitter to ensure that all information is accurate for the project that it is being used for. (Example: “Date Added”. While the Date Added or Start Date may have been accurate for the study the Delegation Log was cloned from, the submitter must ensure the Date Added/Start Date is accurate for the new project that it will be used for.)

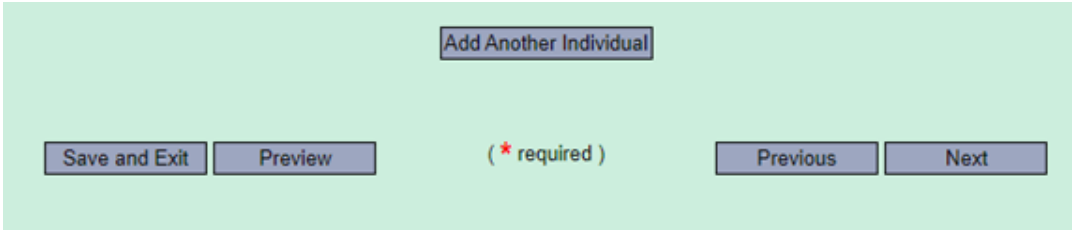
b) **So, I want to submit a MOD to change personnel on my study. Should I be cloning the existing Personnel Delegation Log when I want to make my changes?**

No. If you are planning on submitting a modification to add or remove someone to your study, you should create a new **version** (make a copy) of the existing Personnel Delegation Log. This is accomplished by clicking on the “pencil” icon found to the right of the most current Personnel Delegation Log located on the Designer page, which will allow you to update the existing document. (**Do not click on the Start a Wizard button**.)

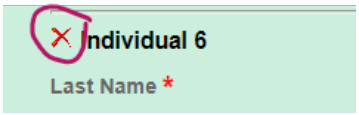


You are now able to ADD new people (or REMOVE people) from the existing Personnel Log.

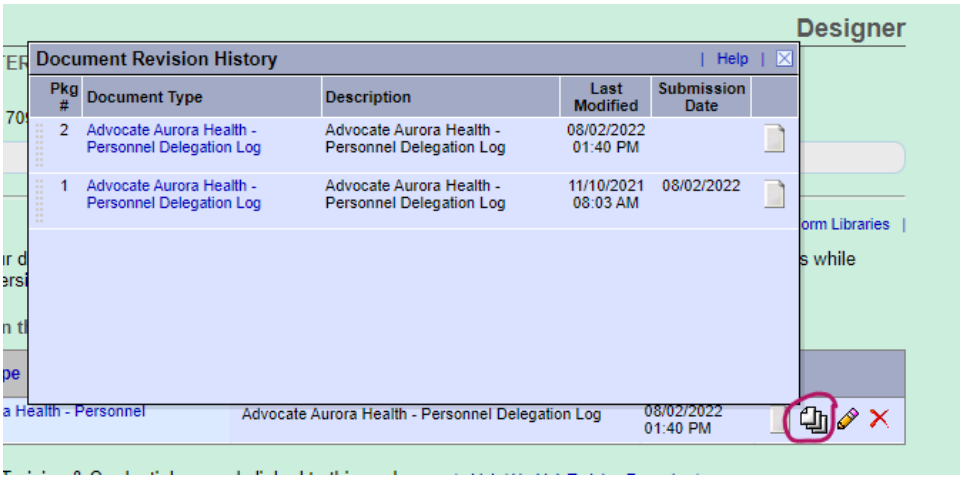
To **ADD** a person: Go to the end of the Log and CLICK on the “Add Another Individual “button”. Provide all required information. When you get to the DATE field, enter TODAY’s date.



To **REMOVE** a person: Find the person you wish to remove from the study. CLICK on the red “X” next to their name



Prior versions of the Delegation Log will remain available with the package in which it was submitted.



2. **Project Summary form updated.** The Participant Population(s) question was revised for clarity. The question now reads, 'Are you targeting any of the following special populations of participants in the project?'
3. **Personnel Delegation Log updated.** Two additional options have been added to the Employer section:
   - 'Non-AAH employee on a multi-site research study that's overseen by the AAH IRB' AND;
   - 'Other (e.g. students from outside institutions not employed by AAH etc.)' NOTE- If you do select OTHER, you will need to supply specifics. Even if OTHER does not apply to your situation, you must still enter N/A in that field so that no empty fields are present.

The **IRBNet FAQ** sheet is updated regularly and is a great resource for questions concerning IRBNet. If you have questions on how to use IRBNet, please review this document located in the Forms and Templates Library section of IRBNet. You can also contact the RSPP Office and one of our Super-Users will be glad to assist you.

Submission Reminders/Tips

How you can work with the RSPP office to get a faster turn-around for your submission…

- Make sure that ALL research personnel have completed: 1) HSR (CITI) education, 2) Financial Interest (COI) disclosure questionnaire **BEFORE** you submit your project/package to the RSPP. Until these items are completed for every individual on the Personnel Delegation Log, your submission will not be processed.
  - NOTE there is an additional requirement for 'aligned' (ie. not employed by Advocate Aurora Health) physicians/staff as well as students who are being included on your study as key research personnel. A Master Investigator Obligations Agreement (MIOA), drafted by AAH Legal, must be completed prior to approval of this individual on the research team. MIOA templates and a MIOA guidance document are available in the IRBNet library. The inclusion of students on your project may also have other requirements. Contact the Graduate Medical Education Research (GMER) team (GMER SharePoint site) for more information.
- Check your submission for accuracy and completeness.
  - Many submissions to the RSPP have missing responses/documents. Missing information causes a delay. You will be required to provide the missing document/response before the RSPP review will begin. A quick check to make sure you have included accurate responses on the application/all required documentation is a great start in avoiding a delayed review.
- To be fair to all submitters, IRB submissions/actions are processed/reviewed in a 'first in/first out" manner. If a submission is returned to you for being incomplete, there is a good chance that when you do return it other submissions will have been received. This means that your re-submission will need to wait until earlier-submitted actions clear the reviewer's queue – which will add time to the review/processing of your submission.
- Address **ALL** questions/comments from the reviewing RCA.
  - If the reviewing RCA's questions/requests are not addressed the first time, your submission will be returned to you AGAIN… further delaying your review. Remember, EACH time a submission is returned to the RSPP/RCA, it goes back into the review queue, which because of 'first-in/first-out' processing may add extra time to your review.
- If you receive questions/requests from the reviewing RCA, **ONLY** address/make the changes that have been requested.
  - Addition of new material or making changes that have not been requested by the RCA will add extra time to the review of your study as the re-submission will need to be re-reviewed in its entirety. **IF** you need to make changes that were not requested, or add new information, let the reviewing RCA know.
  - If the RCA is not made aware of additions/changes, the change/new information may get missed, and proper processing of those changes may not occur. You never know when revisions to your submission may have an effect on the IRB's approval decision. If information is missed, this may cause problems in the conduct of your study.

- Include tracked documents (protocols, informed consents, recruitment materials, etc) when submitting them as Changes to your approved study. Also, make sure to include a new version date on your revised materials.
- Separate IRBNet packages are required for different actions. For example, Changes, Noncompliance (NC), Continuing Review, unanticipated problems (UPs), etc. should all be submitted as separate IRBNet packages.
    - Different RCAs process different actions for the RSPP, and if several actions are mixed into one IRBNet package, one may get missed or it may take longer to process. For example, there is one RCA who reviews all Noncompliance reports. If the package contains a Change and a NC report, and the NC report is triaged to the RCA reviewing NC, the Change will take longer to process – especially if the NC needs to go before the convened board. We have also had the opposite occur… the Change was processed but the NC did not because it was not sent to the RCA reviewing NC.
    - You will be requested to separate out different actions into separate IRBNet packages during the triage process.
- In order for the RSPP office to properly track and assign packages, make sure to pick the appropriate "Submission Type" (New Project, Amendment/Modification, Continuing Review/Final Report, etc.) when creating your IRBNet package. Only use "**Other**" if there is no other choice available in the 'Submission Type' drop down menu. If all packages are designated "Other" neither you nor the RSPP will have any idea what has been submitted in the study unless each and every package is opened.
    - Submitted packages may be returned to you if the proper Submission Type category is not chosen.
- When asked to make revisions by the Office or the reviewing RCA, remember to **RELOCK** your package once you have finished making changes. The RELOCKing feature in IRBNet alerts the Office/RCA that the package has been resubmitted and is once again ready for review.
    - If you do not RELOCK your package after making revisions, there is a good chance that your package will sit in the IRBNet queue unattended as the office is not able to take action on unlocked packages. NOTE the RSPP cannot RELOCK packages.

The RSPP office has created a **Submission Guidelines document that is available in the IRBNet library. Please take time to review this helpful document. If you still have questions after reading this document, please contact the RSPP office for assistance.**

AREA OF FOCUS –

What does it mean when you say your data is de-identified?

The IRB considers there to be three general categories of datasets: Identifiable, Coded, De-Identified/Anonymous. The following describes each.

Identifiable data

Per the Common Rule (45 CFR 46), data is considered 'individually **identifiable'** when the identity of the subject is or may **readily be ascertained** by the investigator or associated with the information with information directly included in the dataset. Even if there are no direct identifiers associated with the dataset, it might still be possible to infer the identity of a subject via descriptors (i.e. indirect identifiers) such as age, gender, ethnicity, etc. – especially when dealing with a unique population or a small number of subjects.

Identifiers may be direct or indirect. A direct identifier is an element that can be used to directly ascertain the identity of the subject. Indirect identifiers, while not directly associated to the subject's identity, are elements that may become identifiers either alone or in combination with each other.

- Examples of direct identifiers may include: the individual's name or part of name or initials; identifying numbers (DOB, SSN, MRN, student record number, employee ID, driver's license number, account numbers, etc.); personal location information (street or work address, phone number, place/location of employment, IP address); physician's name; undisguised photos/video recordings or audio recordings, etc.

- Examples of indirect identifiers may include: journal or personal writings where descriptors can be lead to the identification of the subject; medical conditions or diagnosis (especially in a small or unique subject population); job title; marital status, household composition; names or other identifying characteristics of the individual's relatives or household members; etc.

HIPAA regulations specify 18 identifiers (see below). Inclusion of even one of these identifiers makes a dataset identifiable under HIPAA. When these identifiers are associated with the patient's medical/health information, that information becomes Protected Health Information (PHI), and subject research authorization or a wavier/alteration of research authorization is required.

It should be noted that different federal regulations define 'identifiable information' differently. The table below outlines what is identifiable data per HIPAA, the Common rule, and FDA [from "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule" DHHS]:

Area of Distinction	HIPAA Privacy Rule	HHS Protection of Human Subjects Regulations Title 45 CFR Part 46	FDA Protection of Human Subjects Regulations Title 21 CFR Parts 50 and 56
Identifiable Information	Defines PHI as individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records.	Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects. Individually identifiable means the identity of the subject is or may readily be ascertained by the investigator or associated with the information.	Title 21 CFR Parts 50 and 56 do not define individually identifiable health information.

This means that data can be considered identified under the Common Rule but NOT the HIPAA Privacy Rule (e.g. when limited data sets are used in the research – see below under De-identified data), and vice versa (e.g., when no HIPAA identifiers are included but the combination of data points could make subjects identifiable).

The presence of any subject identifier plays an important part in determining the level of risk in a study. If identifiers are included in the dataset, the IRB will look at the following in consideration of study approval (45 CFR 46.111(a)7): 1) how are data and identifiers kept confidential, 2) are data and identifiers being appropriately stored, 3) are identifiers being destroyed at the earlier possible time point, and 4) how are identifiers being destroyed.

Coded data

Coded data is NOT de-identified (see exception below when an honest broker is used). Coded data has been stripped of all subject identifiers, but each record has a code which is linked to identifiable information such as name or medical record number. This linking file must be kept separate from the coded data set, and may be held by someone on the study team (e.g. the PI) or by someone outside of the study team (e.g. a researcher at another institution).

Because the link to the subject's identity is retained, coded data is considered identifiable. Of note, the code itself may not contain identifiers such as subject initials or medical record number.

In their consideration of approval, the IRB will ask when the link to the subject's identity will be destroyed.

There is one exception to the rule that coded data is considered identifiable –that is when an '**honest broker**' is involved in the project. An honest broker is a neutral party (ie. not part of the study team), who is certified by the institution. The honest broker is allowed to access identifiable data for the researcher but agrees (in the certification process) not to provide the researcher with any identifying information.

While the information released to the researcher may contain a code that links the identity of the subject to the data, it is considered de-identified because the honest broker holds the linking file and is not allowed to provide any identifiable information to the researcher. The researcher may later request of the honest broker to provide updates to the dataset, and the linking code may be used by the honest broker to provide that information.

De-identified data/Anonymous data

Data is considered **de-identified** when ALL direct or indirect identifiers or codes linking the data to an individual subject's identify (outside of honest broker usage) are removed from the dataset. When a dataset has been de-identified, there is no way for the researcher to directly connect the data to any individual. [Sometimes called an aggregate dataset.]

HIPAA

If the dataset is subject to HIPAA regulations, covered entities may use or disclose health information as de-identified without restriction under the Privacy Rule. Covered entities seeking to release health information as a de-identified dataset must determine that 1) the information has been de-identified using either statistical verification of de-identification or 2) by removal of **ALL** 18 identifiers listed below. No subject research authorization or documentation of a waiver/alteration of research authorization is necessary if the data is de-identified.

If the dataset includes any of the HIPAA identifiers, the data is considered PHI. In most cases (see exception below for limited data sets) subject research authorization or documentation of a waiver/alteration of research authorization is necessary to use or disclose the dataset.

If a dataset includes any of the limited HIPAA identifiers (eg. geographic area smaller than a state, elements of dates (date of birth, date of death, dates of clinical service), and/or age over age 89), it is considered a "**limited data set**" under HIPAA. A limited data set is considered an identifiable data set, and therefore the data is PHI. The Privacy Rule permits a covered entity to use and disclose PHI included in a limited data set without obtaining subject research Authorization or documentation of a waiver/alteration of Authorization as long as a Data Use Agreement is executed between the covered entity and the data recipient.

Recommended Reading/Resources

Security and Privacy [HIPAA] Regulations (45 CFR164)

HIPAA Privacy Rule for Research (https://privacyruleandresearch.nih.gov/)

System policy 65253: AAH Use and/or Disclosure of PHI for Research

System policy 62942: AAH Honest Broker for Research

HIPAA identifiers per the Privacy Rule

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
   a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
   b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

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 oversight of the research.

The 2022 AAH Financial Interest Disclosure for Research is now available. You should have received an email from Policy Tech (WI) or Qualtrics (IL) asking you to complete your annual disclosure. Reminder that to continue to participate in research, it's required of all key personnel to complete this annual disclosure.

Both the Qualtrics and the Policy Tech COI Research questionnaires are the same – just different delivery mechanisms. A researcher only has to complete **ONE** of the two Research annual disclosures to be considered compliant with system policy 2302. If you happen to have completed your questionnaire 'across state lines' – that is, an IL researcher completes the Policy Tech questionnaire, or a WI researcher completes the Qualtrics questionnaire, can you please send a quick email to the RSPP office (IRB.Office@AAH.org) letting us know? We would hate to call someone noncompliant with system policy if you to have completed the other state's disclosure questionnaire.

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.

Coming Soon

- Watch for a Special Edition of the RSPP/IRB Newsletter where we'll cover an educational topic: Criteria for IRB Approval.