



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

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AAH merger with Atrium/Wake Forest School of Medicine – How this affects the IRBs

Advocate Health leadership has charged the Advocate Aurora Health RSPP/IRB and the Atrium/Wake Forest School of Medicine (WFSOM) HRPP/IRB with the task of creating a single enterprise IRB **by end of 2023**. Work has begun to identify similarities and differences in policies and procedures of the two IRBs. The eventual plan is to not only integrate the IRBs, but also the policies and procedures/processes of the two Human Research Protection Programs (HRPP). However, there is much work yet to do.

Current state:

- Aurora and Advocate combined their legacy IRBs into the Advocate Aurora Health (AAH) IRB in late 2021. Research studies overseen by the legacy Advocate and Aurora IRBs were transitioned to the AAH IRB by mid 2022, and legacy Advocate IRB was deactivated in July 2022. The AAH IRB oversees research for the Midwest region of Advocate Health.
- Atrium Health and WFSOM/Wake Forest Baptist Medical Center recently combined their legacy IRBs into the Wake Forest University Health Sciences (School of Medicine) IRB (FWA00001435). The [WFSOM IRB](#) oversees research for the Southeast region of Advocate Health.
- The AAH IRB is managed by the AAH RSPP Office; Wake Forest School of Medicine IRB is managed by the WFSOM IRB Office.
- The Advocate Aurora Health HRPP is fully accredited by AAHRPP - and includes both Advocate and Aurora facilities. The Wake Forest HRPP is currently undergoing AAHRPP re-accreditation. The re-accreditation process is adding Atrium which was not accredited previously. A final decision on reaccreditation of the Southwest region should be completed by end of 2023/early 2024.

We'll communicate new information as we progress in this initiative.

What's New?

- **Newest version of forms/documents** in the IRBNet Library - to be used immediately (submission of older versions of forms/documents may be returned to you):
 - AAH RSPP protocol template – minor changes to wording/instructions of the template
 - SNI form – minor changes to wording

Research Ceded to an External IRB – General Reminders

AAH RSPP SOPs #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.

Consent documents submitted to external IRBs. AAH RSPP does not require that the proposed consent document be submitted to the RSPP as part of the Request to Rely process. However, upon RSPP authorization of reliance on an external IRB, research staff must create a consent document to be submitted to the reviewing IRB.

It is required that the research team incorporate the AAH boilerplate research consent/authorization language for that reviewing IRB - yes, there are different boilerplates depending on which external IRB you use [see the IRBNet Library for copies]. The **consent/authorization boilerplate language** for that reviewing IRB must be included in your proposed consent document **WITHOUT REVISION**.

- There are 4 consent boilerplate documents included in the IRBNet library – one for: WCG, Advarra, NCI CIRB; as well as a boilerplate for all other external IRBs. All but the NCI CIRB boilerplate includes AAH research HIPAA authorization language.
 - NCI CIRB will not allow the consent document to include research authorization language. Therefore, if you are using the NCI CIRB to oversee your research study you must also have the prospective subject sign the AAH stand-alone research authorization document (found in the IRBNet library). The **stand-alone research authorization** must also be used **WITHOUT REVISION**.
 - As a reminder, if you do not have the subject sign the AAH stand-alone research authorization for NCI CIRB overseen studies you do NOT have the subject's permission to access/use their PHI in the research. Not only is this a reportable noncompliance event for the AAH RSPP but it should be reported to NCI CIRB as well. This is also a breach of privacy that must be reported to the AAH Research Privacy Officer.
- The consent/authorization boilerplate documents (including the stand-alone research authorization language) are to be used **WITHOUT REVISION**. The AAH boilerplate documents not only include header and footer requirements, but also AAH specific language about subject injury, research authorization, etc.
 - If you, the sponsor, or the external IRB wish to alter any part of the AAH boilerplate research consent/authorization or the stand-alone research authorization, you must obtain permission from the RSPP Director/designee before the document is used to enroll a subject at AAH.
 - How do you submit a request for alteration of language to the RSPP? Send an email to the [IRB office](#) inbox requesting an alteration in external IRB boilerplate language. Attach the external consent/authorization document(s) with the changes tracked. If the changes are not tracked, the request will be returned to you.
 - The request will be provided to the RSPP Director or designee. You will receive a return email for your records accepting or declining the change or instructing you to seek out permission from other research stakeholders (AAH Compliance or AARI Research Business Services).
 - The RSPP Director/designee will comment only on the revisions to the AAH research consent/authorization boilerplate language – any other revisions in the consent document are the purview of the IRB of record.
 - Be aware that revisions to the boilerplate may not be accepted – especially revisions to the research authorization.
 - If the revisions are accepted, retain the acceptance documentation in your regulatory binder in case of future need.

Research consent/authorization documents for ceded research studies are subject to review by the RSPP office to ensure that the research consent/authorization boilerplate language was used without revision. If the RSPP notes that changes were made to the boilerplate, you will be asked to provide documentation that you received permission from the AAH RSPP for the revision.

- Revisions to AAH boilerplate language made without permission of the AAH RSPP may result in this incident being reportable Noncompliance.

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.
 - 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 for audit purposes.
- 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.
- **'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'.
- **Always check the IRBNet library for the most current form/document.** Current versions of the RSPP/IRB forms must be submitted – if the current version of a form is not submitted there is a good chance it will be returned to you to be redone.
- The following resource documents can be found in the IRBNet library:
 - **Submission Guidelines**
 - **IRBNet FAQs**
 - **HSR Education_CITI FAQs**Please take some time to review these helpful resources.
- A research protocol is required for **every** research submission. A **protocol template** is available in the IRBNet library should you need assistance in creating your protocol.

AREA OF FOCUS: Levels of IRB review

All human subject research conducted at AAH must meet the ethical principles and federal, state and institutional regulations/policies that govern the use of human subjects in research. And each human subject research (HSR) study must be approved by an IRB prior to initiation of any research activity.

The type of IRB review is determined upon the degree of risk associated with the HSR study. There are three categories of IRB review (exempt, expedited and full board) as defined by the Federal Regulations for Protection of Human Research Subjects (45 CFR 46). The IRB makes the decision on the level of IRB review/oversight that is required of the proposed research project however, it is helpful for researchers to understand the types of IRB review so that they may choose the correct submission application to provide to the IRB. If you have questions on the level of IRB oversight required for your study or the correct submission application to use, you may always contact the [RSPP Office](#).

Human Subject Research falls into one of the following levels of IRB review:

- Exempt human subject research. This type of human subject research is less than 'minimal risk' (as defined by the regulations) and fits into one of the eight Exempt categories noted in the revised Common Rule (45 CFR 46.104) or FDA regulations (21 CFR 46.104). An example of exempt of research would be a medical record/chart review study where data is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained.

- This type of research does not require review at a convened IRB meeting and is accomplished most frequently by a member of the RSPP staff educated in the types of exempt research.
- It does not require continuing review per the federal regulations.

More guidance on this type of human subject research can be found in the [RSPP Guidance: Exemptions](#).

- Expedited human subject research. This type of human subject research is no greater than minimal risk and fits into one of the nine Expedited Review categories as noted in the Common Rule (45 CFR 46.110) or FDA regulations (21 CFR 46.110). An example of this type of research would be the use of a blood sample collected for research purposes - as long as the amount of the blood sample collected is within the prescribed methodologies and limits provided in the regulations expedited review and approval of the research study may be appropriate.
 - This type of research does not require review at a convened IRB meeting. Review is often accomplished by a single IRB member or in consultation with other members with expertise in the study design.
 - Based upon the revised Common Rule regulations, this type of human subject research may or may not require continuing review.

More guidance on this type of human subject research can be found in the [RSPP Guidance: Expedited Review](#).

- Full/convened board human subject research. This type of human subject research is greater than minimal risk, and fits into none of the regulatory exempt or expedited review categories. Research requiring full/convened board review includes all human subject research that has an IND, BBIND or IDE associated with it; clinical trials; studies with a randomization component; risks that are greater than those 'ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests. An example of this type of human subject research would be the use of an investigational drug, device or procedure in a research study.
 - This type of research will be reviewed at a convened IRB meeting (see IRBNet library for the AAH IRB meeting schedule).
 - Studies of this type require continuing review – at least until the research progresses to long-term follow-up status. Based upon the revised Common Rule regulations, only FDA regulated research that has not yet progressed to long-term follow-up status requires on-going continuing review.

NOTE there are other projects that use investigational agents for treatment purposes (e.g. Humanitarian Use Devices (HUDs), Expanded Access projects) that may also require full/convened board review. Contact the RSPP office with questions.

Common requirements for all HSR studies submitted to AAH IRB

- RAPR/AARI authorization
- Submission application – there are two different applications depending on the type of research: Exempt Application – for exempt research, and the IRB Submission application – for Expedited/Convened board studies (greater than minimal risk research). Each form outlines the ancillary information that must accompany the research submission application.
 - The most current version of these forms may be found in the IRBNet library. Submission must be made via the AAH IRBNet program.
- Research protocol. If you need to write a research protocol, the RSPP has a Protocol Template available in the IRBNet library.
- Completion of the two smart forms (Personnel Log and Project Summary) in IRBNet.
- Research key personnel HSR training/education (via CITI program)
- Research Significant Interest disclosure

It should be noted that the above information pertains to HSR that is **overseen by the AAH IRB**. If you wish to request that an external IRB oversee the research study, you will need to submit a Request to Rely on an External IRB application via IRBNet. See the [RSPP Guidance: Deferral Ceding of IRB Oversight to an External IRB](#) for more information on ceding of IRB oversight to an external IRB.

Significant Interest Disclosures

Per the [Conflicts of Interest in Research-Individual](#) policy, research investigators and key personnel must update their significant interest disclosures:

- Annually; and
- Within 30 days of discovering or acquiring a new interest

Research significant interests are financial and non-financial interests related to a research project that could directly and significantly affect a covered party's designing, conducting or reporting of the research or Advocate Health Care or Aurora Health Care's conduct, review and oversight of the research.

Also, investigators and 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.

New significant interest disclosure tool coming this year

- Disclosure Manager is a new disclosure platform replacing Qualtrics (used in IL), PolicyTech (used in WI) and Key Survey (used by teammates).
- The annual campaign to collect disclosures is launching on July 10 to align with the June 30 publication of CMS Open Payments data for program year 2022.
- Open Payments is a publicly available website that publishes payments that reporting entities, including drug and medical device companies, make to covered recipients such as physicians and researchers. Review this data as part of the disclosure process [Advanced Search | OpenPayments \(cms.gov\)](#).
- Collection of research and non-research related significant interest questions will be combined into a single questionnaire. However, if a teammate's job role changes during the year, an additional disclosure statement may be required.
- Those required to complete an annual questionnaire will receive an email invite from coi@aah.org.

NOTE: There has been **NO** change in the requirement that all individuals participating in human subject research at Advocate Health Care or Aurora Health Care must have a current significant interest questionnaire on file. Therefore, any research key personnel who doesn't complete the disclosure questionnaire by the deadline of Aug. 10 must be removed from all research studies on which they participate.

Watch your email and newsletters for additional information.

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](#).