



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

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## Revised Protocol Template

A protocol is required for most submissions to an institutional review board (IRB). If your study requires a protocol and the study sponsor has not provided one, please use the AAH RSPP provided protocol template. This template has recently been updated. The updated protocol template is intended to assist all AAH investigators in WI and IL in preparing a research protocol. The protocol should be submitted along with the appropriate submission application and required documents. The protocol template is located in the IRBNet library and the RSPP website found here: [Protocol Template](#). Please call the WI RSPP office at 414.219.7744 or the IL Office at 630.929.6148 if you have questions.

## Revised WI Delegation of Authority (DOA) log

The DOA log used by researchers submitting to the Aurora IRB side of the AAH RSPP has been revised and it includes a place for the legacy institution of employment for key research personnel. Using this form will help the AAH RSPP decipher which institution the key personnel are associated with so that [behind-the-scenes] IRB agreements can be established. This updated document can be found on the RSPP website. If you do not use the AAH RSPP template DOA, please revise your study team's template to include the institution of employment for the Key Personnel.

## System Wide AAH Clinical Trials and IRB Submission

A shared clinical trial is one that is conducted at both Advocate and Aurora locations, or by both Advocate and Aurora personnel. The AAH RSPP has started to see more submissions of shared clinical trials. Some tips for submitting shared clinical trials for IRB review are found below.

The first step when submitting an AAH IRB application of a shared clinical trial is to assign a PI for the study. This person is responsible for the conduct of this study throughout the AAH system. The application to the AAH IRB must be obvious that you are looking to conduct the study at both Advocate and Aurora sites as an IRB reliance agreement will need to be executed between Advocate and Aurora. A Delegation of Authority Log (DOA) must be submitted that includes personnel from the Advocate and Aurora sites (it is preferred that you note which individuals are from Advocate and which are from Aurora) who will conduct the study. You may designate an investigator from the other location(s) to assist the PI in the conduct of the study at the other sites.

If the shared clinical trial will be submitted to an external IRB, you need to complete a Request to Rely form that names the participating Advocate and Aurora sites and designates which external IRB will be the resultant Reviewing IRB/ IRB of Record. The Request form will outline how the study is going to be conducted at all AAH sites - so if there are any differences between how the study will be conducted at the Advocate and Aurora sites you must include that on the Request to Rely form. You must provide a DOA log that includes all personnel that will conduct the study at AAH (it is preferred that you note which individuals are from Advocate and which are from Aurora). You can submit the Request to Rely form to either the IL or WI office although it is preferable to submit to the office associated with the PI. The RSPP Office will complete the necessary reliance agreements between Advocate and Aurora, and the External IRB.





Let's say Dr. XX from Advocate's Christ hospital wants to include Dr. YY, and Aurora sites on his study. The study will ultimately be overseen by WIRB. Dr. XX will complete a Request to Rely noting the Advocate and Aurora sites/personnel on the Request and DOA log. WIRB should be listed as the external IRB that will oversee the study for all of AAH. Dr. XX will submit the completed Request to Rely to the Advocate RSPP office using IRB Net. The RSPP Office will execute the necessary reliance agreements (Aurora to Advocate and Advocate/AAH to WIRB). Once you obtain the authorization to cede from the RSPP Office, you may submit the study to WIRB for all AAH.

NOTE that the IL and WI AARI research preauthorization process is still not combined. The RSPP will need pre-authorization from both PRC (for IL) and RAP (for WI) designating that the research may be at both sites.

This guidance is relevant to all non-exempt Human Subject research system-wide, even if the study is not a clinical trial.

For Exempt research studies to be conducted at both Advocate and Aurora locations, you should include both sites/personnel on your Exempt application. Exempt studies are not ceded to an external IRB, therefore the exempt application should be submitted to the RSPP office of the lead PI. The submission must indicate if there are any differences in conduct between the research locations. The RSPP needs to be aware of participation of both Advocate and Aurora sites/personnel because a reliance agreement must be executed between the two legacy institutions.

In summary:

| Will the Advocate or Aurora IRB be the IRB of record for a system-wide study?   |   |
|---|---|
| Yes   | No  |
|    |    |
| <p>Submit to the AAH IRB that is associated with the PI named at the Lead site. Include research preauthorization from both PRC (for IL) and RAP (for WI)</p> | <p>Complete a Request to Rely form and submit to the IRB associated with the AAH PI named on the study. Include with the Request to Rely research preauthorization from both PRC (for IL) and RAP (for WI)</p>  |
|    |    |
| <p>All post-approval actions should be submitted to the IRB of record only. This is the IRB to which you submitted the initial submission.</p>                | <p>Post approval actions should be submitted to the IRB of record (external IRB) AND to the RSPP office associated with the AAH PI as needed.</p> <p>See RSPP Guidance: Deferral/Ceding Of IRB Oversight To An External IRB for more information on post approval actions that need to be submitted to the AAH IRB.</p> |

The above information is for new submissions. If you wish to add Advocate or Aurora locations to an already approved research study, contact the RSPP office for instruction.

## Ceding Submission Requirements

In addition to complying with the determinations and requirements of the external IRB and applicable AAH policies and AAH IRB procedures (see Deferral/Ceding Of IRB Oversight To An External IRB guidance), submit the following to the RSPP office to which the original Request to Rely application was submitted (via IRBNet or AAH's [RSPP Central IRB Office](#)):

- ✓ Noncompliance—Report all events or occurrences meeting the RSPP definition of Noncompliance - these can be serious, non-serious, continuing or non-continuing NC. These events must be reported to the RSPP Office within 10 days of discovery of the event.
- ✓ UPIRSOs—Submit a copy of any unanticipated problem involving risks to subjects or others (UPIRSO) that is submitted to the external IRB if the UPIRSO occurred at an Advocate or Aurora site. Submit to the RSPP Office at the same time reported to the external IRB.
- ✓ Re-approvals/Continuing Review Notices—Submit notification from the external IRB of study continuation which includes the re-approval date and the approval period. These should be submitted upon receipt.
- ✓ Changes in key personnel—Submit proposed additions or removal of investigators or key personnel before they are submitted to the external IRB using the *Changes in Key Personnel in Ceded Research* form. Wait for RSPP Office notification before submitting to external IRB.
- ✓ Study completion—Submit a *Final Report* when the study is closed with the external IRB. This should be submitted within two weeks of study close out.

The guidance on Reliance of IRB oversight is located on both the RSPP Website and the IRB Net library.

## CIRB Consents – Removal of IC process attestations

Due to changes mandated by the NCI CIRB, the following language (in red) has been eliminated from the NCI CIRB Informed Consent template:

From the “Signature of person(s) conducting the informed consent discussion” section:

**My signature below certifies the following:**

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

While gone from the NCI CIRB consent boilerplate, these attestations are still recommended by the RSPP as best practice, and required per AARI SOP (Research Informed Consent, section V, letter F).

Be sure to follow the requirements of the AARI SOP and provide documentation of the research consent process in the EMR and/or subject research record. Some tools available from AARI include EPIC Smart phrases and the AARI Documentation of Consent Process Form (Attachment C of the SOP) - although other options are allowable.

If you have questions about the AARI SOP please contact the AARI Research Educators.

## Substantial Modifications in Ceded Research

If any information provided in the initial Request to Rely submission form will be changing substantially, the AAH RSPP Office needs to be notified. This can mean changes:

- to the study itself (e.g. a change to the study title, change to study funding source), or
- to subject population (study now allows enrollment of children), or
- in how the study will be conducted at AAH (e.g. the study team now intends to utilize LAR to consent patients),
- in the consenting process (e.g. inclusion of e-consent platform), or
- in research location (addition or removal of a research site).

The PI/study team will need to complete and submit a new (previously un-submitted) Request to Rely form to the RSPP Office, checking the "Substantial Modification" box and provide the rationale for the revision in the text field provided. As part of the Substantial Modification submission process remember to:

- Place a check mark in the 3 attestation boxes that serve in place of the PI signature on the form.
- Complete all of Section I
- Complete any questions in Sections III and IV that are directly related to the proposed change. You will receive AAH RSPP authorization following review. You must receive AAH RSPP authorization and approval from the IRB of record before implementing these changes in the study, unless the changes are necessary to eliminate apparent immediate hazards to the subject.  
\*NOTE - Do NOT submit a revised Request to Rely form for changes in key personnel.
- Changes in either key personnel or PI MUST be made on the "Change in Key Personnel in Ceded Research" form. Per our IRB reliance agreement with external IRBs, the AAH RSPP office needs to verify that appropriate Human Subject Research education and a current Significant Interest disclosure is on file for the new personnel.
- RSPP verification of the Change in personnel must be authorized by the AAH RSPP before notifying the IRB of record (if necessary) of the personnel change(s) AND/OR the individual(s) begin conducting research activities.

### **The 21<sup>st</sup> Century Cures Act: Action needed by March 31, 2021**

On March 1, 2021 the AAH RSPP sent a global email notification to research teams of the need to revise the current research authorization language to address the new requirements of the Information Blocking Rule in the 21st Century Cures Act. This new Rule goes into effect on April 5<sup>th</sup> 2021 and allows for patients to have access to their treatment records at any time. The Rule includes an exception for clinical research (sub-exception 3): "An actor may deny access to an individual provided that the requested PHI is in a designated record set that is part of a research study that includes treatment (e.g., clinical trial) and is still in progress, provided the individual agreed to the temporary suspension of access when consenting to participate in the research. The individual's right of access can be reinstated upon completion of the research study."

*How has the Information Rule been addressed at AAH?*

- To address the requirement of the Information Rule, AAH Legal crafted language to be included in all research authorizations.
- Legal also wanted the same research authorization to be used throughout the organization. Therefore RSPP took this opportunity to integrate the research authorization template to address access/use of medical records for studies conducted throughout the organization.

Both of these requirements are addressed in the revised consent/authorization templates located in the IRB Net library or on the RSPP website.

*Action to be taken by research teams:*

- A. Authorization documents of currently-enrolling research studies, and all future research studies conducted at AAH that require subject authorization, must include appropriate Legal/Privacy approved authorization language.

If subjects were enrolled prior to the effective date of April 5<sup>th</sup>, no re-consenting is necessary. However, if locally enrolled subjects need to be reconsented because of new information, the subject is to resign the new consent/authorization. The authorization needs to be revised to include the Information Blocking language.

For studies that are currently enrolling research subjects:

1. Remove the current authorization language from your IRB-approved combined consent/authorization document, **and replace it with the NEW authorization section** from the revised combined consent/authorization template.

The new authorization language includes the following statement to address the Information Rule. However, the entire authorization section of the template should be used.

*If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.*

2. IF your IRB approved combined consent/authorization document includes the following language in the consent portion (NOTE not all studies include this language - you will need to search your document), you must add the language highlighted in yellow below:

[Include as applicable if the research collects/generates clinically relevant results.]

Clinically relevant research results [state what these are], including individual research results, [insert will or will not] be returned to you. [Include conditions under which they will be returned and include the following statement if applicable.] **Upon your request for personal research results, your research team can work with you to understand the type of data available to you.**

For new research studies:

1. Use the RSPP templates [either the revised combined consent/authorization template, or the revised external IRB boilerplate] located in the IRB Net library or on the RSPP website to create the informed consent/authorization document submitted to the IRB.
2. For those research studies approved to use a Stand-alone research authorization (these are limited studies – usually only studies that rely on NCI CIRB or Stroke Net IRB), the AAH stand-alone authorization has been revised to include the newly required language. NOTE this document has been translated into Spanish for those CIRB or Stroke Net studies that are approved to enroll Spanish-speaking subject.

**NOTE - NO REVISIONS can be made to the research authorization language.**

- B. **Submit** the revised combined consent/authorization document to the IRB using a Change/modification form OR the IRB of record for your externally ceded study. Remember to update the version date of the revised consent/authorization document so that you are able to track versions, and ensure proper use of the correct form.

For those CIRB or Stroke Net studies using a Stand-alone authorization you should check to see if the IRB of record must review this new version.

*When does this change need to occur?*

The Rule goes into effect on April 5, 2021. Therefore, it is recommended that should submit your Change/modification to the IRB no later than March 31, 2021 to ensure that you have an appropriate research authorization approved for use by the effective date.

**Research subjects enrolled into the research study prior to the effective date of the Rule do NOT need to re-sign/re-execute a new consent/authorization document.**

*What happens if I am not able to get the new research authorization language approved before the effective date (April 5, 2021)?*

You do not need to halt enrollment in your study. However, **any research subject enrolled on or after April 5, 2021 using the 'old' research authorization language will need to be re-consented/authorization re-executed once the new language is approved by the IRB.**

*Will the RSPP be monitoring that this change has been completed?*

No, however, audits may be conducted to ensure appropriate changes have been made. It is up to the research teams to ensure that they have obtained a valid research authorization from subjects. The change in research authorization language to comply with the Rule ensures that subject authorization is valid - and that the organization is not subject to

findings for noncompliance with the Rule. If it is found (e.g. during quality audit, continuing review, or other means) that the authorization obtained from research subjects does not include the revised (Information Blocking Rule) language, it will be reviewed as a noncompliance event that must be reported to the RSPP.

Additional education will be forthcoming from AARI and Compliance.

If you have questions on the necessary changes to the research authorization please contact the RSPP office.

### **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](mailto:IRBOffice@aah.org) or [irbmail@advocatehealth.com](mailto:irbmail@advocatehealth.com). 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 also 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](mailto:IRBOffice@aah.org). Past editions of the RSPP newsletter can be found on the RSPP website.

### **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.