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Special Edition - IRB Integration

Advocate Aurora Health Research Subject Protection Program (RSPP)/Institutional Review Board (IRB) Newsletter:

November 2023

With the merger of the AAH and Wake Forest School of Medicine IRBs happening in just a few short weeks this Special Edition of the RSPP newsletter is full of useful information on IRB integration! This edition supplements past editions of the RSPP newsletter. If you need to find to a past edition of the newsletter, you can look here - on the RSPP website.

If you have any questions on IRB integration, feel free to contact the AAH IRB office (IRBOffice@aah.org or 414-219-7744).

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How to contact the IRB office after integration?

There will be several ways to contact the IRB office after integration:

- The current AAH IRB email address and phone number will remain active for the time-being. You may continue to use IRBOffice@aah.org or 414-219-7744. Your question may be referred to someone at the Wake Forest office.
- A general email address for questions is available in the Wake Forest system: eirbhelp@wakehealth.edu. Inquiries directed to this email address are received by multiple Wake Forest IRB staff members.
- You may continue to contact the current AAH RSPP staff directly using their AAH email addresses OR contact the WF team member assigned to your submission.
- eIRB includes a ‘contact us’ link.

AAH IRBNet deactivation/integrated eIRB activation

****AAH IRBNet will be de-activated at end of business on November 30, 2023.****

Migration of AAH studies from IRBNet to eIRB will begin December 1, 2023.

Integrated eIRB will Go-Live December 6, 2023.

No actions can be submitted between 12/1 and 12/5. PLEASE PLAN ACCORDINGLY.

AAH submissions before IRB integration – DEADLINES [see calendar on last page of newsletter]

The following is information on deadlines for submission of actions to the AAH IRB/RSPP.

New Submissions

1. **Submissions of NEW human subject research studies to be overseen by the AAH IRB**
   - The deadline to submit a new Greater Than Minimal Risk research study to the AAH IRB **has passed**. **No new submissions for consideration by the convened AAH IRB are being accepted**.
   - Exempt and Expedited submissions will be accepted by the AAH RSPP **until November 3, 2023**.
     - Limited exceptions to this deadline may be considered by the RSPP Director, but acceptance is not guaranteed. Contact the RSPP office with requests.
2. **Submissions of NEW studies requesting reliance on an external IRB**
   - Submission of new studies requesting Reliance on an External IRB will be accepted **until November 13, 2023**.
3. **Submission of new HSR Determination requests**
   - Submission of new HSR Determination requests will be accepted by the AAH RSPP **until November 13, 2023.**

General Reminders HSR/HSR Determinations

- Finalization of incomplete submissions or submissions that require extensive revisions by the study team is not guaranteed.
- Revisions to incomplete submissions must be received in IRBNet **no later than November 24**, **2023**. Incomplete submissions will be withdrawn from the IRBNet system.
- Submissions not finalized before **November 30, 2023** will not be transferred to the integrated eIRB platform. These submissions will require re-submission in eIRB on or after December 6, 2023

Submission of Changes to Approved Research

- Submission of **Changes** – outside of research personnel changes - for any study overseen by the AAH IRB or ceded to an external IRB will be accepted **until November 13, 2023**. Adequate time for review and approval/acceptance must be allowed.
  - Limited exceptions to this deadline may be considered by the RSPP Director, but acceptance is not guaranteed. Contact the RSPP office with requests.
  - Changes that require convened board consideration will not be accepted – and must be submitted to the integrated IRB on or after December 6, 2023
- **Personnel changes** – for any study overseen by the AAH IRB or ceded to an external IRB will be accepted **until November 27, 2023**.

General Reminders - Changes

- Finalization of incomplete submissions or submissions that require extensive revisions by the study team is not guaranteed.
- Submissions not finalized before **November 30, 2023** will not be transferred to the integrated eIRB platform. These submissions will require re-submission in eIRB on or after December 6, 2023

Submission of Reportable Events (NC or UP)

- Submission of new **Reportable Events** for any study overseen by the AAH IRB or ceded to an external IRB will be accepted **until November 20, 2023**. Adequate time for review and approval/acceptance must be allowed.
  - Reportable Events that require convened board consideration will not be accepted – and must be submitted to the integrated IRB on or after December 6, 2023.
- It is understood that submissions of Reportable Events have deadlines per AAH IRB SOPs (#5 & 7). Between November 20, 2023 and December 6, 2023 these SOP submission deadlines will be waived. After December 6, 2023, the submission rules/deadlines for Reportable Events under the integrated IRB will be enforced.
- If there is a serious event that occurs or is discovered during the period between November 13 and December 6, 2023 that indicates that AAH research subjects are at immediate risk of harm, notify the RSPP office immediately. Do not wait until December 6, 2023 to report the event.

General Reminders - Reportable Events

- Finalization of incomplete submissions or submissions that require extensive revisions by the study team is not guaranteed.
- Submissions must be finalized by **November 30, 2023.** will require re-submission to the integrated IRB using the new eIRB system on or after December 6, 2023.

Submission of Continuing Reviews

If your study is due to receive continuing review before the end of 2023, you should have already been contacted by the AAH RSPP office for early submission of the continuing review application. If you have not been contacted by the office already, and believe your study requires continuing review by end of 2023, please reach out to Andree Lanera in the RSPP office.

- Review of any submitted/requested continuing review applications are underway and every effort will be made to finalize/approve the application prior to November 30, 2023.

Do NOT submit Continuing Review applications unless requested.

Transfer of AAH IRBNet materials to the integrated eIRB system

- **Only open/active studies/finalized actions will be transferred from IRBNet to eIRB.** Any action that is not finalized or approved will require resubmission in the integrated eIRB system on or after December 6, 2023.
- Documents related to closed studies will **NOT** be transferred to eIRB. IRBNet will remain accessible to research teams (for an undetermined period of time) so that study teams can access documents related to closed research studies and HSR determinations.
  - If you have not already done so, it is it is recommended that research teams begin **downloading IRB documentation (letters, forms) currently house in IRBNet, and not rely on IRBNet as your storage/retention system**.

Due to the large number of open AAH studies and the volume of related documents currently housed in AAH IRBNet, transfer of data to the eIRB system will be completed by IT **in phases**.

- By December 6, 2023, a study shell for every open study currently housed in IRBNet will be available in the integrated eIRB system. This study shell is expected to include the current versions of IRB approved documents.
    - This study shell will allow research teams to submit post-approval actions as needed (Changes/amendments, continuing reviews, reportable events).
- A 2nd and 3rd tier of data will be transferred into eIRB over the weeks following the initial transfer. It is hoped that data transfer will be completed by the end of December 2023.
- Midwest researchers may be asked to provide the IRB Office with missing material if needed (for example, a study Change has been submitted and the Investigator Brochure has not yet been transferred).

Study numbering under the integrated IRB

Once a study is transferred from IRBNet to the integrated eIRB system, it will be assigned a new IRB number using the naming convention of the current Wake Forest IRB: 'IRBXXXXX'. The 'X's are numbers that are ordered chronologically. Therefore, you will have two IRB numbers associated with your AAH study – the number assigned by the AAH IRB, and the number assigned by the integrated eIRB.

You should be prepared to use/provide both numbers for a while until all departments are converted to/comfortable with the new eIRB numbering system. It is expected that the AAH IRB number will be populated in the eIRB system for convenience purposes… likely in the 'short title' section of the eIRB application.

Submission to WCG IRB for studies that use them as the IRB of Record

If you currently use the AAH IRBNet platform to submit documents directly to **WCG IRB** that ability will end with the deactivation of the AAH IRBNet platform.

There is no direct link between eIRB and WCG IRB. Upon deactivation of AAH IRBNet, AAH research teams will use Connexus, the submission platform provided by WCG, to submit documents to WCG IRB. WCG IRB has been contacted for instruction on the Connexus system. We will share information as it becomes available.

Saving of AAH IRB Approval Documentation currently housed in IRBNet

Researchers are required by federal regulations and AAH system policy to retain copies of documents related to the conduct of research – including IRB submissions and approvals - for a minimum period of 3 years after the closure of the study.

Due to the imminent sunsetting of the IRBNet submission platform, if you have not already done so, it is recommended that you begin **downloading/saving IRB approval documentation (letters, forms) currently housed in IRBNet to another system/source**. It is unknown how long research teams will have access to documents housed in IRBNet.

Researchers/research teams should develop a plan to download and retain research documents that does not rely on the IRB office or access to the IRBNet system.

Keep in Mind….

- AAH RSPP/IRB Office will work to get as many submitted actions as possible finalized/approved before the November 30, 2023 deadline.
    - It is important to work with the RSPP Office/assigned RCA to address study questions or conditions of approval for actions that have been submitted in IRBNet.
    - **There is no guarantee that incomplete submissions or submissions that require extensive revisions will be finalized/approved by November 30, 2023**.

- The AAH RSPP will make every effort to contact research teams about actions that remain **pending in the IRBNet system**. Submissions not transferred to the eIRB system will require resubmission. Please log into your IRBNet account and see if there are actions that the RSPP team is waiting on you to complete.

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eIRB Training

Three TEAMS sessions have been created for eIRB training. All three sessions will have similar content and will be conducted by current Wake Forest IRB staff who are knowledgeable in the eIRB platform. **These sessions will be recorded for future use.**

The Teams meeting login information is provided below for each session. NOTE that the links are specific to one meeting.

Please choose the session(s) that best fit your schedule. You can copy and paste the meeting information to your Outlook calendar, Or, just click on the meeting link **below** on the date you wish to attend. If you have questions, please contact the IRB Office.

Wednesday November 15, 10am CST
Click here to join the meeting
Meeting ID: 258 696 189 776
Passcode: ZGVzP3
Download Teams | Join on the web
Join with a video conferencing device
615548708@aah.org
Video Conference ID: 119 530 415 6
Alternate VTC instructions
Or call in (audio only)
+1 414-292-9399,,654496208# United States, Milwaukee
Phone Conference ID: 654 496 208#

Tuesday November 21, 2023 1pm CST
Click here to join the meeting
Meeting ID: 233 380 992 829
Passcode: RC5cdB
Download Teams | Join on the web
Join with a video conferencing device
615548708@aah.org
Video Conference ID: 113 305 223 0
Alternate VTC instructions
Or call in (audio only)
+1 414-292-9399,,885798455# United States, Milwaukee
Phone Conference ID: 885 798 455#

Thursday November 16, 11am CST
Click here to join the meeting
Meeting ID: 210 257 346 355
Passcode: zaaqQj
Download Teams | Join on the web
Join with a video conferencing device
615548708@aah.org
Video Conference ID: 116 023 018 2
Alternate VTC instructions
Or call in (audio only)
+1 414-292-9399,,925707239# United States, Milwaukee
Phone Conference ID: 925 707 239#

In addition to Teams training sessions, eIRB training modules will be made available. These modules will include tips, glossary and examples of questions asked in the eIRB application. They are being updated to the integrated eIRB platform/questions. More information on the location/links for these modules will be provided at a later date.

Important Policy Differences Between the AAH IRB And the Integrated IRB

*This section will provide you with a list of important differences in policy between the AAH IRB and the integrated IRB. Bear in mind that this list is **NOT** exhaustive.*

Once the integrated IRB Policy & Procedure Manual is released, take time to review that document and familiarize yourself with the P/Ps of the integrated IRB. You are expected to follow the policies and procedures for the IRB of record that oversees your research study.

MW = Midwest region (Aurora and Advocate); SE = Southeast region (Wake Forest and Atrium).

CITI training/HSR education

- Only one human subject research education course will be offered to Enterprise researchers in CITI – this is the Biomedical course. This course must be completed by all key research personnel no matter the study design. Training remains valid for 3 years at which time the individual must complete a refresher course.
    - There will no longer be a need for investigators to complete the Social Behavioral (SB) CITI course if the study on which they are working is SB in design.
- A submission will not advance to IRB review until all key research personnel listed on the application have completed HSR education.
    - Researchers will be able to track/check CITI expiration within the eIRB system.
- Expiration of CITI training and the need for renewal will be identified at continuing review/annual check-in, at which time the researcher will need to complete CITI refresher training before the review is considered complete.
- There is no IRB requirement for the researcher to complete the ICH/GCP course, however ICH/GCP training remains available in CITI. The responsibility for monitoring/tracking ICH/GCP training belongs to the research team.

eIRB submissions

- The PI must officially submit the application.
- All sub-investigators must submit a CV within the application.
- All sub-investigators must complete and submit an attestation of awareness of their research participation, as well as disclose any potential conflicts of interest with the research study.
    - If the researcher's response indicates a possible COI with the study:
        - in the MW, the IRB office will review the researcher's annual significant interest disclosure. and provide relatedness documentation to AAH Compliance;
        - in the SE, the SE Compliance office will be automatically notified via eIRB of the researcher's potential COI with the study;
        - COI management plans, if needed, will be generated by the respective Compliance departments and provided to the IRB of record for consideration.

Noncompliance (NC)

- Definitions of continuing and serious NC are slightly different under the integrated IRB.
- Reporting requirements remain for all research conducted within the Enterprise – no matter the IRB of record.
- Requires immediate reporting (Safety Event Report in eIRB) ONLY if the event meets the definition of serious and/or continuing NC
    - Immediate reporting is required within 7 working days from date of discovery
- NC events that do not meet the integrated IRB's definition of serious or continuing are recorded on a Noncompliance log, and submitted at continuing review/annual check-in.
    - If events reported on NC log are found by the IRB to be of a serious or continuing nature, submission of CAPA will be required. Education of research staff on what meets immediate reporting criteria will be provided.
    - It is the responsibility of the study team to track NC events so as to determine when the event rises to the level of 'continuing' NC.

- Reports will undergo initial assessment by a Human Research Oversight Specialist (HROS) or designee.

Unanticipated Problems

- Definition is slightly different under the integrated IRB.
- UPs for studies ceded to an external IRB must be submitted to the integrated IRB if they: 1) occur at an Advocate Health site, and/or 2) are substantive, that is the event halts the conduct of the study generally or for that specific subject (e.g. the sponsor runs out of the drug, the subject becomes pregnant, or the subject becomes incarcerated).
- All UPs (as defined by the integrated IRB) must be reported within 7 working days of discovery.
- Reports will undergo initial assessment by a Human Research Oversight Specialist (HROS) or designee

Changes/Amendments to IRB approved research

- Submission of what constitutes a Change in IRB approved research is slightly different under the integrated IRB
- Personnel changes are separate in eIRB from other protocol/study changes
- The **timeline for implementation** of the change is immediate upon IRB approval. There will no longer be a 30-day delayed implementation.

Annual check-in/status report

- **Required** of any non-exempt Human Subject Research study conducted within the Enterprise (including research ceded to an external IRB) that does not undergo IRB-required Continuing Review.
- Very brief in content; submitted in eIRB
  - collects non-serious/non-continuing NC log;
  - checks for research personnel training compliance;
  - check on safety concerns;
  - checks to determine if study remains active.
- Lack of submission may result in administrative closure of study

Exempt HSR

- Like AAH, requires a protocol to be submitted
- Annual check-in **required** every 3 years
  - Lack of submission may result in administrative closure of study

Use of LAR in HSR

- Allowed in the Enterprise but different policies/laws depending on region

Reliance on an external IRB – (called a 'facilitated review')

- Initial review: There is no established criteria for 'automatic' ceding of research to an external IRB. The study team will be asked to submit to the integrated IRB a request to rely on an external IRB. The IRB Director/Chair/designee will review the request, and determine whether the study may be ceded to an external IRB. Consideration will be given to the subject population, local context issues, whether the study is federally funded, and the phase of research development.
- If the request to rely on an external IRB is granted, the local study team submits a facilitated review submission in eIRB.
  - Required submission in eIRB: facilitated review application; research preauthorization (AARI in MW); **documentation of approval from IRB of record**, privacy board requests (preparatory to research); **proposed consent document** (includes Enterprise boilerplate language).
  - Reliance agreement still required.
- Post approval required submissions in eIRB: **protocol modifications**, **consent revisions**, changes in personnel, **annual check-in/status report**, UPs or other safety events, NC - either submitted in real time (when potentially serious or continuing) or on the NC log submitted with the annual check-in/status report, annual summary reports.

Case report/series

- There is no specific number of case reports that determines when a project becomes HSR.
- It remains recommended that research teams submit a HSR determination request if they have questions about whether their project/use of case reports is HSR.

HIPAA Determinations

- Questions related to HIPAA determinations are part of the eIRB submission application. Separate application for HIPAA decisions are not needed.
  - When a researcher indicates that s/he will rely on recruitment of subjects using PHI/medical records, questions pertaining to eligibility assessment and Preparatory to Research Representations will auto-populate in the eIRB submission application.
    - Requests to conduct feasibility assessments are also submitted in eIRB. Questions related to Preparatory to Research Representations/feasibility will auto-populate.
  - If a researcher indicates their intention to waive or alter research authorization, questions on waivers of authorization will auto-populate in the application.
  - If your project is being conducted solely on decedents, questions related to the Decedent Representation will auto-populate.

HSR consent template

- The research consent template will continue to combine authorization language with research informed consent language.
  - If it is your intent to enroll subjects in both the MW and SE regions, two consent documents will be needed.
- A line to record the time consent was obtained has been added to the subject signature block.
- To account for regional differences, there will be two research consent/authorization templates available to the research community – one for research studies conducted in the MW and one for research studies conducted in the SE. It will be the study team's responsibility to choose the correct template consent/authorization template.
- Changes to the research authorization language will be allowed only in limited instances, and only with IRB and Privacy approval if needed.
- ICH GCP required language will continue to be included in the research consent template.

AdvocateAuroraHealth

November/December 2023

SUN	MON	TUE	WED	THU	FRI	SAT
			November 1	2	3 Last day to submit exempt or expedited studies to AAH IRB	4
5	6	7	8	9	10	11
12	13 Last day to submit HSR Determination requests and Changes to approved research	14	15 eIRB training session; 10am CST Click here to join the meeting	16 eIRB training session; 11am CST Click here to join the meeting	17	18
19	20 Last day to submit Reportable Events	21 eIRB training session; 1pm CST Click here to join the meeting	22	23 **Thanksgiving – IRB office closed**	24 Last day to submit revisions to incomplete submissions in IRBNet	25
26	27 Last day for submission of Personnel changes	28	29	30 **AAH IRBNet deactivated at end of business**	**DECEMBER** 1 **Data transfer of active/approved actions to integrated eIRB system begins**	2
3	4	5	6 **Integrated eIRB system Go-Live!**	7	8	9

NO submission to IRB December 1 through December 5 – Please plan accordingly.