



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

November 2016

Contents

- [IRB Help Information](#)
- [AAHRPP Accreditation Status](#)
- [RSPP Turn-Around-Time Initiative for Expedited Review Studies](#)
- [Preparatory to Research Activities \(Waiver of Consent and Authorization\)](#)
- [Article Review: Yet More Regulatory Myths](#)
- [Research Certification Expiration](#)
- [Submission Reminders](#)
- [Interest Disclosures](#)
- [Office Closure](#)

IRB Help Information

If you have any questions or comments about the IRB process or for the IRB office, do not hesitate to contact us at (414) 219-7744 or email us at IRB.Office@aurora.org. If there is a topic that you would like addressed in a future newsletter, please send a detailed description of the topic to IRB.Office@aurora.org. Past editions of the RSPP newsletter can be found on the [RSPP website](#).

AAHRPP Accreditation Status

The Aurora HRPP has received Full accreditation status from AAHRPP. Thank you to all that were involved with the process.

RSPP Turn-Around-Time Initiative for Expedited Review Studies

Turn-around-times are a measurement of efficiency. In the RSPP office, turn-around-time typically measures the amount of time from when a submission is received until the time that an IRB decision (i.e. approval) is communicated to the investigator. Many

factors contribute to turn-around-times. In an effort to improve RSPP turn-around-time remember to include the following with your submission materials when appropriate:

- RAP approval
- DOA
- subject materials
- protocol

If requests/questions/clarifications are required of the research team by the RCA or Expedited Reviewer, two reminders will be sent for the one month period following the date of initial contact. The reviewing RCA will send an e-mail notification to the PI and study coordinator within 48 hours of IRB study review notifying the PI/coordinator of the status of the review – approved, approved with conditions, deferred, or convened board review required.

RSPP turn-around-time is reported in the AAHRPP Annual Report and to the Council for Quality Assurance and Improvement in Research (CQAIR). Per [Aurora RSPP SOP 903](#), the Aurora IRB Steering Committee must evaluate on an annual basis the efficiency of the IRB review function. The Aurora IRB turn-around-time is used as a measure of this efficiency.

Preparatory to Research Activities/Pre-Screening: Waiver of Consent Requirement

At times, researchers would like to be able to access protected health information to identify potential research subjects. Obtaining and recording individually identifiable private information for the purposes of identifying potential subjects is considered to be Human Subjects Research by OHRP. The regulations call these recruitment/pre-screening activities PREPARATORY TO RESEARCH. Typically when conducting Preparatory to Research activities, investigators do not seek consent from the prospective subjects and therefore investigators must request a waiver of consent for these activities.

Historically, when submitting to the Aurora RSPP office (office of the Aurora IRB and Aurora Privacy Board for research) a representation was made for the preparatory to research activities. Investigators would provide the HIPAA Preparatory to Research information on the [form 502-A](#). The RSPP office, acting as the Privacy Board for research, would review these Preparatory to Research activities to assure compliance with the regulations [45 CFR 164.512(i)(2)(ii)]. Remember that the Protected Health

Information (PHI) used in these types of preparatory to research activities cannot leave the covered entity (i.e. Aurora).

To ensure that Aurora is compliant with regulations, investigators will also have to request a **waiver of consent** for the preparatory to research activities. The information that is needed to grant a waiver per 45 CFR 46.116(d) has been incorporated into the Aurora Form 502-A. This should be completed for studies using the Aurora IRB and external IRBs.

Investigators that are currently performing Preparatory to Research activities will be asked to submit a supplemental form to the RSPP office asking for a waiver of consent for these activities. This form can be submitted alone (no other forms needed with the submission) and will be processed by the RSPP office as a modification.

The RSPP office has created new guidance on this topic that can be found on the RSPP website ([here](#)).

SUMMARY:

- **For New Studies (both ceded studies and those overseen by the Aurora IRB):** For studies that involve Preparatory to Research Activities, Complete the 502-A form to request the consent waiver.
- **For On-going studies (ceded as well as those overseen by the Aurora IRB):** If the already IRB approved study is still conducting Preparatory to Research activities, investigators will need to complete the supplemental form to request a consent waiver for these activities.

UPDATE: This was rolled out in early November and since the roll-out there have been several questions asked of the RSPP office. Below is a summary of some of the responses to these questions:

- Research teams have asked if they need to request a waiver for the prescreening activity, indicating that they don't write down any identifiers when they are doing their subject screening activity. This is a reminder that, as indicated in the new guidance on the topic "recorded" also included department screening log entries, tumor board screening/logs, emails between researchers and screening staff on potential subjects.
- While rolling out this process, a separate modification form is not needed when submitting the Waiver Request form, even when submitted in Cyber. In Cyber,

attach the Waiver form to the MODIFICATION submission request. No separate MODIFICATION form is necessary.

- Researchers may submit ONE waiver request for MULTIPLE studies that are still enrolling subjects and are under the authorization of the same individual as PI. However, such submissions must be sent to the Aurora IRB office via PDF to IRB.Office@aurora.org— multiple studies cannot be included in a Cyber submission as Cyber associates the submitted document with ONE study only.

Article Review: Yet More Regulatory Myths

As part of Continuing Education, the RSPP office recently read an article by R. Bert Wilkins, JD, MHA, CIP titled “*Yet More Regulatory Myths*”. This article illustrates that while researchers and IRBs make their best efforts to comply with the regulations, occasionally what they are doing is not required and might even be contrary to the regulations. It is important to know which regulatory requirements are actually required, and which are just myths. The Aurora RSPP office would like to highlight a few of the myths noted in the article.

- **An IRB can accept an investigator’s determination that an investigational device study qualifies as a non-significant risk device without making its own analysis.**
FALSE. Responsibility for determining whether a device study qualifies as a non-significant risk (NSR) device study lies with the sponsor and the IRB. The IRB can agree with the sponsor’s or investigator’s rationale that a device qualifies as a non-significant risk device, but the IRB must evaluate the use of the device in the study and make its own determination. FDA has the final authority to determine whether a device is NSR.
- **A study that uses coded biosamples from an outside source is exempt from IRB review because the investigator does not have the codes to identify the donors.**
FALSE. To be exempt, the subjects cannot be identifiable, either directly or indirectly. In this case, the codes provide links back to the individuals who provided the samples. It does not matter that the investigator does not know their names. The 45 CFR 46.101(b)(4) exemption does not apply because the samples are indirectly identifiable.
- **The IRB is responsible for notifying the PI prior to any lapse of approval.**
FALSE. The IRB’s can notify the PI as a courtesy, but the FDA Guidance, “IRB Continuing Review after Clinical Investigation Approval” (2012), does not require

such notification: Investigators are responsible for ensuring that studies they conduct comply with applicable regulatory requirements. To ensure that the reviewing IRB can carry out its review prior to the expiration date of the current IRB approval, investigators should follow the IRB's policies and procedures for continuing IRB review of research (procedures required by 21 CFR 56.108(a)(1)), in particular by submitting materials and information required by the IRB. FDA encourages IRBs to make investigators aware of the IRB's procedures, for example, by enclosing a copy in correspondence informing the investigator of the IRB's decisions, or posting the information on a website.

The Aurora RSPP office encourages researchers to question and challenge the practice of the Aurora RSPP so that Aurora can have a strong and compliant research environment. Questions about regulatory requirements can be emailed to IRB.Office@aurora.org. A Research Compliance Analyst (RCA) will reply to discuss your concerns or questions.

The full article titled "*Yet More Regulatory Myths*" can be found in the Journal of Clinical Research Best Practices or by visiting the page found [here](#).

Research Certification Expiration

The RSPP office has implemented a new reminder process for expiring Research Certification which includes:

- The first reminder email will now be 8 weeks prior to the expiration. The email will remind the individual of the consequences of noncompliance with certification renewal.
- A second reminder will be sent 4 weeks prior to expiration. This email will include the following statement: "As of _____ [date of expiration] you will no longer be able to participate in research conducted at Aurora Health Care. You will be removed from all open research studies on which you are listed. Only after completing the requirements of Research Certification renewal will you be allowed to be added to any research study." This email will be copied to the individual's supervisor/director of the service line, administrative assistant if applicable, and the manager of the clinical trial(s) on which he/she is participating.
- If renewal is still not completed two weeks prior to expiration, a phone call will be made to the noncompliant researcher.

- After all reminders have been sent, should the researcher still not complete research certification renewal by the expiration date, he/she will be removed via modification (PI signature waived) - by the RSPP office - from all on-going research studies that include him/her as a key personnel. A copy of the modification removing the researcher will be sent to the study PI, the study contact/coordinator, as well as the researcher who has been removed. The PI of the study will be informed that he/she must find someone of equal training/status to fulfill the role of the researcher who has been removed – and that the new researcher must be added to the research study via modification that includes a revised Delegation of Authority log.

Submission Reminders

- When submitting a modification to add or remove personnel from a study, remember to include an updated Delegation of Authority (DOA) log with the submission materials. All key personnel added to a study need to have current Research Certification and COI SMART on file.
- When submitting a modification to add a facility, remember to include the facilities form.
- IDE Studies: FDA device regulations at 21 CFR 812.150(a)(4) require prior approval from the Sponsor of all planned exceptions, including administrative and Minor Exceptions. Planned exceptions of an IDE study must be submitted to the IRB on form 403-C ([Modification Form](#)), and approved by the Aurora IRB prior to implementation. A written copy of the sponsor's approval of the planned exception is required with submission of the form to the IRB.

Interest Disclosures

Interest Disclosures: Per System Policy 269, [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. To process a new or changed Significant Interest, please update your interest disclosure in COI Smart. 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.

Office Closure

Please Note: The RSPP Office will be closed on Thursday, November 24, Monday, December 26 and Monday, January 2.