Aurora Health Care

Research Subject
Protection Program
945 N 12th St
PO Box 342 W310
Milwaukee, WI 53201-0342

T 414.219.7744
F 414.219.7477
IRB.office@aurora.org

www.aurora.org/IRB

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

September 2018

Contents

Merger News

Plans are in the works to merge the Advocate and Aurora IRBs and offices. Care needs to be taken so that the policies/processes/practices of the combined human subject protection program (HRPP) meet AAHRPP accreditation standards. It is expected that final merger of the HRPP will occur by Fall 2019. We'll keep you informed as work proceeds.

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.

Retirement of COI SMART (Conflict of Interest Reporting System)

COI SMART is no longer being used by Aurora and a new system has not yet been established. See the posted article from Caregiver Connect here: COI Software will be turned off September 11 .

Until a new system is in place to make electronic interest disclosures, any new researcher/key research personnel that wishes to participate in human subject research, or individuals who must make revisions to their current research questionnaire, will need to complete a paper version of the Significant Interest Disclosure Questionnaire for Research. This form, as well as the required training noted in the form, can be found on the RSPP website under the Conflicts of Interest in Human Subject Research tab.

If you have questions please send an email to ResearchCOI@aurora.org.

IRB Review Fees

In order to alleviate any misperceptions/ misrepresentations under the Stark Law, it was requested by the Legal and Compliance Departments that the Aurora IRB begin to charge IRB review fees. IRB review fees will be charged to ALL research reviewed by the Aurora IRB – unless the study meets one of the established waiver criteria. Fees will be charged for initial review as well as on an annual basis. Studies ceded to an external IRB will be charged a one-time administrative fee unless the study meets a waiver criterion. A waiver/reduction of the established IRB fee will be granted if the research aligns with Advocate Aurora Health's (AAH) mission (as determined through the RAP process), and is one of the following [For exact language see Advocate Aurora Health (AAH) IRB Review Fee Schedule that will soon be found here]:

- Unfunded student research.
- Unfunded investigator initiated research led by an Advocate Aurora health team member.
- Research funded by a federal, state, or local government entity that doesn't allow inclusion of IRB fees or the amount of funds granted is limited.
- Clinical or non-research activity (i.e., Emergency Use, Compassionate Use, Expanded Access, HUDs).
- An activity funded solely by a not-for-profit group/entity and the group/entity either does not allow the charging of IRB fees or the amount of funds granted is limited.

When the research doesn't meet any of the noted waiver criteria, the fee policy allows for a waiver of or reduction in the IRB review fee under other extenuating circumstances. Such a request must be submitted in writing **to the Advocate Aurora Research Compliance Office**. APPROVAL by Compliance must be included with the initial IRB application.

Implementation of IRB review fees will begin **November 1, 2018** for all new submissions. Studies approved prior to 11/1/2018 will be charged the appropriate annual review fee at the next continuing review, and annually thereafter.

Waiver criteria will be added to all submission applications, the continuing review form, and the Ceding Request form. If a waiver is not requested in the IRB application, the RSPP Office will automatically generate an invoice **payable within 60 days**. Several attempts will be made to obtain payment before further action is taken.

Should an investigator/sponsor not pay the IRB review fee, the RSPP policy allows for a decision to be made by the RSPP Office, in consultation with Compliance and ARI, on the action to be taken.

Please take some time to review the IRB Review Fee document and let the RSPP office know if you have any questions. The IRB submission forms will soon be updated to capture information needed to assess the appropriateness of the IRB Review Fee waiver request.

Informed Consent Form Template Changes

In cooperation with the Aurora Research Institute management, there have recently been several changes to the Informed Consent Form Template. These changes include:

- Consent process tick boxes have been removed
    - These boxes were not required by regulations
        - The tick boxes were originally included in the consent template as a means to document that the consent process was appropriately completed
        - Removing the tick boxes eliminates the possibility of them being left blank. Blanks have proven to be an issue with monitors/auditors
        - Per ARI SOP, the consent process should be documented in the subject's research chart or in the electronic medical record
            - ARI has created several "dot-pharases" to help assist in the documenting of the consent process
- Addition of consent process bullets before coordinator signature line
    - To counterbalance the removal of the tick boxes, statements were added to the 'coordinator' signature block attesting to the completion of consent process activities

    - This langauge is intended to help those researchers who may not have access to EPIC in asserting that the consent process was properly completed
- Removal of ARI phone number for hurt/ill notification
    - The number in the old version of the consent template was being used by ARI personnel, and not manned 24/7. It was requested that only the investigator's 24 hour access number be included in the consent document. It is theRSPP's expectation that a subject be able to easily reach a live-person 24/7 should they experience a research injury.

Should the research team wish to revise a currently approved consent document to the above, a Change form must be submitted to the IRB. If you opt to keep the consent process tick boxes in your currently approved consent document, they must be completed (including signature). Failure to complete the tick boxes is reportable as noncompliance.

Waivers or Alterations of Authorization

Per System Policy 140 [USE AND/OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH], **Use** of PHI (protected health information) means the sharing, employment, application, utilization, examination or analysis of PHI within an entity that maintains such information. In the research context, a use of PHI would include the viewing (for example, looking in the patient's medical record), collection and/or analysis of PHI by a researcher or research team member.

The **Disclosure** of PHI is defined as the release, transfer, provision of, access to, or divulging, in any manner, of information outside the entity holding the information. In the research context, this would include the sending of PHI to a non-Aurora individual or entity.

When Protected Health Information (PHI) is **used/disclosed for** research, the researcher must obtain the subject's written authorization (included as part of the research informed consent/authorization template located on the Aurora RSPP website) or a waiver/alteration of authorization. If a waiver or alteration of authorization is requested, a 502.3 form [Waiver or Alteration of Authorization Request] needs to be submitted to the RSPP Office. Per HIPAA regulation, a detailed and study-specific justification needs to be provided to explain why the waiver or alteration of authorization is necessary.

1. A recent Compliance audit of the RSPP's processes for the granting of waivers and alterations of authorization unveiled that there is often a generic response provided by the research team to the question that asks:

    > Describe why the waiver or alteration of authorization is necessary and why it would not be practicable to conduct the research without the waiver/alteration.

    It was noted in the audit that more detailed and study-specific responses are needed as justification for the need of the waiver of authorization. The response to this question MUST include information that is appropriate to the design of the particular study. If the RSPP notices a too vague or inaccurate response to this question, the 502.3 form will be returned to the submitter so that additional, study-specific information can be entered.

2. A second question on the 502.3 form was also flagged for revision. This question asks submitters to:

    > List the HIPAA identifiers and patient information/data elements that will be used.

    A common response to this question is "the Patient's Health Care Records or the Patient's Medical Records". Such a response indicates that the entire medical record will be used to meet the objectives of the research. We know that this is typically not the case. Responses that imply that the entire patient medical record will be used to complete the research activity WILL be returned so that submitter can either: 1) add a justification for the need of the use of the entire medical record, or 2) edit the response to include general categories of data that will be used. **Remember** that only minimum necessary PHI must be used as part of the research activity. The researcher is attesting that the information being used in the research is minimum necessary by signing of the 502.3 form.

Watch soon for the release of a revised 502.3 form addressing these issues, as well as a guidance document to assist you in creating appropriate responses.

Using Third Parties in Research

The RSPP office has been seeing more questions about the use of third parties in research studies to help with recruitment efforts. Typically, we are finding that the individuals from the third parties are engaged in the research and therefore need to be named as Key Personnel on the Delegation of Authority Log. These individuals also need to complete the required Aurora COI disclosureand training requirements before their particpation in the study is approved by the IRB. These requirements are in effect for both studies overseen by the Aurora IRB as well as those ceded to external IRBs (see SOP 409). Contact the RSPP office with any questions on this issue.

WHAT'S NEW?

Form Updates

Make sure you are using the current version of all Aurora RSPP forms. Find Current forms here. If you do not submit the correct/current version of a form to the Aurora RSPP, your submission will be returned to you, and you will be required to resubmit using the correct version.

Forms that have undergone recent reivsion include:
Exempt submission Form (version date 8/6/18)

- Minor Edits
- Changes to ordering of the questions
- Language added to accurately document that the IRB has granted a waiver of authorization

Waiver or Alteration of Aurhorization Request Form 502.3 (version date 7/30/18)

- Minor Edits
- Citation Revisions
- Language added to accurately document that the IRB has granted a waiver of authorization

Application for Review of Medical Records and/or Databases for Research Purposes – MR Form (version date 7/30/18)

- This submission form now requires the researcher to submit a 502.3 to request a waiver of authorization. The waiver questions previously on the MR form have been removed (they were found not to be complete), and instead replaced by the requirement to submit a 502.3 form. This edit has been made to increase consistency and accuracy in IRB determinations.

Changes to Previously Approved Human Subject Research (version date 8/7/18)

- This form includes new documentation of approval (upper right corner), and a place on the last page for the RCAs/reviewers to document approval considerations. This section is bracketed off at the end of the form, and is FOR IRB USE ONLY.

Website updates

The RSPP presentation on the Noncompliance and Unanticipated Problems Reporting SOP has been placed on the RSPP website. These slides are a good refresher of what is expected with regard to reporting of events to the RSPP. The presentation slides have been placed on the RSPP guidance documents section of the website and can be found here: https://medicalprofessionals.aurorahealthcare.org/irb/art/rspp-sop.pdf

---

RESEARCH NEWS AND HOT TOPICS

The Who, What, and Why of IRBs

The Office for Human Research Protections (OHRP) has posted a new video on its public outreach website, **About Research Participation**, www.hhs.gov/about-research-participation. The video explains **Institutional Review Boards (IRBs)** to help prospective participants (or anyone interested in learning more about participating in research) understand IRBs' role, how they carry out their important function, and who serves on an IRB.

View the new video about IRBs at:
www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos

Revised Common Rule Educational resources

In preparation for the transition to the **revised Common Rule**, OHRP created a **series of videos** to help explain some of the new provisions and changes. The videos are intended to provide an overview of the major changes and supplement the other educational resources and guidance being developed. The first set of videos is now available on OHRP's website, with more to follow soon. Topics covered include the new and revised exemptions, and changes to IRB review under the revised Common Rule.

More information on how the changes to the Common Rule will affect the Aurora RSPP forms/templates/processes will be included in Special Editions of the RSPP newsletter published in the coming months. Please keep a look out for this information!

View the revised Common Rule videos at:
www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-videos

---

REMINDERS

Significant 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 complete the significant interest disclosure questionnaire found on the RSPP website. 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.

RSPP Investigator Manual

The Investigator Manual is designed to guide you through the submission process and policies and procedures related to the conduct of Human Subject Research that are specific to Aurora. You can access this manual by clicking on the following link: Investigator Manual

RSPP Office hours

Current office hours are 7:30 a.m. to 4:00 p.m. Monday through Friday (exclusive of holidays). You may reach the Aurora RSPP at phone number (414) 219-7744 or via email (irb.office@aurora.org) should you have any questions.