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)

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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.

Update on Common Rule

On June 18th the U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies issued a delay for an additional 6 months to the compliance date for the changes to the Common Rule. The delay allows for the use of three burden-reducing provisions during the delay. Stay tuned for future announcements on how the Aurora Research Subject Protection Program plans to handle the provisions and changes to the Common Rule.

The HHS announcement regarding the delay can be found here.

Ceding Research to an IRB Outside of Aurora

At times, researchers may choose to or be mandated to have research reviewed and overseen by an IRB outside of Aurora. The criteria for ceding research to an outside IRB can be found in RSPP SOP 409 and is summarized below.

For ceding consideration, studies must meet one of the following:

- federally funded; or
- any study that is no greater than minimal risk; or
- a study that involves an institutional conflict of interest as defined by Aurora system policy *Conflict of Interest in Research-Institutional*; or
- either a phase III or IV drug study, or a device study where there is evidence of safety and AHC is not the lead/coordinating site

There is an option for researchers to use when wishing to cede IRB oversight of a study when it does not meet these automatic criteria. In such situations, researchers should send an email noting the request, the name of the IRB where it is requested that the study be overseen, and the research protocol to the central IRB email inbox (centralirb.office@aurora.org). The RSPP Director in consultation with the Institutional Official will make a determination if this study can be ceded. Instructions on how to proceed will be provided to the researcher after the determination is made. NOTE: This email request should occur prior to submitting the Request to Rely on an External IRB form to the RSPP office. If it is determined appropriate to cede the study to the external IRB, researchers will then be expected to follow the ceding process as outlined in the SOP (ie. submission of the Request to Rely form, DOA log, etc.).

WHAT'S NEW?

Students and Volunteers as Key Personnel on Human Subject Research Projects

Summer is here and we have had many requests to add students to ongoing research projects being conducted at Aurora. The Aurora Research Institute (ARI) has revised its policy on when these individuals may be added to a research study. Here are some things to keep in mind:

- Volunteers are no longer allowed to be added as Key Personnel on Human Subject Research studies per ARI.
- Aurora-employeed Interns are allowed to be added as Key Personnel if they are getting college credit for their work through an agreement with the school (UW Milwaukee, Marquette, MSOE).

NOTE: Such student interns/Key Personnel must be added to an approved research study via a Change form (modification process). Approval of the participation of the student intern will not be granted by the Aurora IRB until he/she completes the Aurora required research certification and Significant Interest disclosure processes. Should the student intern require access to EPIC, you will need to work with the appropriate departments (e.g. compliance or medical records) to request such access. If you have questions about appropriate personnel, please contact ARI/RAP.

Using Healthy Volunteers in Research Imaging

The RSPP has received feedback on a common question – Can Healthy Volunteers be used to test imaging equipment being used on a research protocol?

Response: If a research team would like to use healthy volunteers for research required testing of equipment/processes, the testing must be part of the research protocol for it to fall under IRB oversight.

For sponsor required testing that is not included in research protocol, the research team will need to seek resolution with the department who oversees the testing (e.g. Radiology, Cardiology). This may require input by Risk Management, Compliance, Privacy, etc. Hospital-based (not research) consent and authorization may be required.

In a recent case where the healthy volunteer testing of the imaging process was not part of the research study, the issue was resolved by having de-identified results of recent patient tests sent to the sponsor. The study team/imaging personnel sent the data (de-identified) to the sponsor as part of a hospital operation so a waiver of authorization was not necessary.

Work is continuing by these other departments on creating a standard approach/guidance when the sponsor wishes confirmatory testing to be done that is not part of the research study.

System policy on Interpreter and Translation Services

The System Policy on Interpreter and Translation Services has been revised. The Aurora RSPP SOP 701 references this policy. Please read the new policy if your research includes patients using translated documents and/or interpreter services. A summary of the revision can be found on Caregiver Connect. The revised Assistance for Persons with Special Needs Policy #170 is posted in Policy Tech.

Certificates of Confidentiality (COC)

A clarification regarding the duration of the protections of a COC is available. The protection of a COC ends when NIH funding ends. Researchers may choose to separately apply for another COC after the funding ends.

Changes to the Human Subject Research (HSR) Determination Process

When a requestor completes the HSR Determination Request form, question 1 of the newly revised form (v. 5/16/18) will direct the submitter to send the HSR form to RAP (research.preauthorization@aurora.org) if Aurora caregivers are involved in any way in the project.

Based upon Aurora Research Institute (ARI) policy, RAP will decide whether a human resource determination is required in the project, and send an email response (a specific statement of human resource determination is expected/appreciated) to the submitter. The human resource determination needs to be included with the HSR Determination Form that is submitted to the RSPP office.

As a reminder, for projects that are determined to NOT be human subject research, oversight of the project is the responsibility of the individual and their home department. Should Protected Health Information (PHI) be involved in the project, the responsible party MUST seek out assistance from the Chief Privacy Officer. A reminder of this responsibility is included in the RSPP Determination Letter that is returned to the submitter. The letter also directs the submitter to seek out the approval of appropriate (as deemed by the project) Aurora administrative leadership before the project is begun.

If the project is determined to meet the definition of human subject research, the submitter will receive a letter from the RSPP office directing him/her to complete the RAP research process and an IRB submission before any proposed work is done. The RSPP forms can be found here.

RESEARCH NEWS AND HOT TOPICS

Article: Is a Vitamin D placebo trial in children with asthma ethical?
Craig Klugman, Ph.D.
http://www.bioethics.net/2018/02/is-a-vitamin-d-placebo-trial-in-children-with-asthma-ethical/
Full article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2897155/

REMINDERS …

Incomplete Submissions

The RSPP IRB Office has noticed an increase in incomplete submissions. Please take a moment to check all submissions for completeness and accuracy before submitting to the RSPP Office.

Reminder to Use New Forms

The RSPP forms are updated frequently. Access updated forms using the forms library in CyberIRB or by clicking here.

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 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.

New key research personnel need to complete an interest disclosure in COI Smart in order to be added to a research study. Please contact Angela Carpenter in the RSPP office (angela.carpenter@aurora.org) so that she can include the "researcher" role to their profile. If this is not done, the research questionnaire will not be included in the COI Smart profile, and therefore will not be able to be completed.

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.