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.

Annual Researcher Survey

On an annual basis, a short survey is sent to researchers asking them about their experience with the RSPP/IRB Office. The purpose of this survey is to improve the efficiency of the IRB meetings. Please take a moment to complete the anonymous survey by August 19, 2016, 2016 by clicking here. We appreciate your comments and suggestions.

Delegation of Informed Consent

At times, the RSPP office receives questions about who can sign the consent document. We hope to add some clarity on this topic in the following Questions and Answers as well as the excerpt from the May CTCC Newsletter.

> **Q: Can the PI delegate the informed consent duty?**
> A: The FDA regulations require that the PI ensure that the legally effective informed consent of subjects is obtained. If the PI delegates this responsibility, the FDA recommends that the individual to whom the responsibility is delegated

be qualified by education, training, and experience to perform this activity. The individual obtaining informed consent should be knowledgeable about the clinical investigation and have the appropriate training and credentials; and the PI should have a detailed plan for the supervision and oversight of the clinical investigation, including the informed consent process. Even when a task is delegated to another individual, the PI remains responsible for ensuring the clinical investigation is conducted according to applicable FDA regulations and for protecting the rights, safety, and welfare of subjects during the clinical investigation (21 CFR 312.60 and 21 CFR 812.100).
http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

Q: Who must conduct the Risk/Benefit/Alternative discussion with a research subject?
A: Based on Wisconsin law, a physician investigator must discuss the risk/benefit/alternatives of the study when a medical intervention is part of the research.

When there are no medical interventions as part of the research study, the entire consent process, including the discussion of risk/benefit/alternatives, may be delegated to another research team member. The submission application should detail this process, and the Delegation of Authority log must outline which key personnel have been delegated the duty of obtaining informed consent. These items will be reviewed by the IRB to ensure that the consent plan is appropriate.

DO NOT LEAVE BLANKS ON THE CONSENT DOCUMENT.
If there is a reason to leave a blank, it is recommended that it be documented why the blank was necessary.

Administrative Holds on Research

The Aurora RSPP SOP 403 has been revised relative to the process of placing studies on Administrative Hold. The specifics of the newly revised section of the SOP point out the differences between Administrative Hold and Study Suspension. A suspension of research made by the IRB necessitates external reporting per SOP 408. A voluntary administrative hold of research, made solely on the decision of the study PI, does not require external reporting. Remember Administrative Holds of research, when initiated by the PI, must be reported to the Aurora IRB on the modification form.

The updated SOP is available on the RSPP website's SOP page.

★Excerpt from the May 2016

Clinical Trials Communication Committee (CTCC) Newsletter★

By: Rachel Delaney, Corporate Counsel Research

Properly obtained informed consent is a key element of any research study or clinical trial. Here is a summary of best practice approaches and legally required approaches to obtaining informed consent:

1. What is the physician's duty in obtaining informed consent?

Wisconsin law requires physicians to perform the discussion of risks, benefits, and alternatives to obtain informed consent for clinical interventions (Wis. Stat. 448.30). Therefore, when a trial or study requires a clinical intervention, the physician must conduct the risks, benefits and alternatives discussion with the study subject for that intervention. If the trial or study does not require a clinical intervention, the risks, benefits, alternatives discussion may be done by a person qualified to do the discussion who is not a physician.

The Common Rule goes farther than discussion of risk, benefits, and alternatives for proper informed consent to be obtained. However, the Common Rule does not require that the additional elements of informed consent outside of the risks, benefits and alternatives discussion be done by a physician. Those additional elements may be delegated to a person with the right training and qualifications.

2. Can physicians delegate the risks, benefits, alternatives discussion to non-physician practitioners?

In Wisconsin, the risks, benefits, alternatives discussion must be done by a physician when there is a clinical intervention that will be ordered or performed by the physician. The physician cannot delegate this duty to a non-physician practitioner. However, a non-physician practitioner may conduct the risks, benefits, alternatives discussion with the patient for general consent to participate in the study, so long as the physician obtains separate consent for the specific clinical intervention that the physician is ordering or performing.

3. What is the appropriate timing of obtaining informed consent for research studies?

Informed consent must be obtained prior to screening the research study subject. Wisconsin law requires hospitals to obtain prior informed consent for the patient's participation in any form of research (DHS 124.05(3)(i)). Screening a patient is a form of research because it is a procedure required by the study protocol. FDA subregulatory guidance indicates that while an investigator may discuss the availability of and possibility of studies with a prospective patient without first obtaining consent, informed consent must be obtained prior to initiation of any clinical screening or procedures, including procedures performed to determine eligibility for participation in the study. Work that is done as preparatory to research may still be done prior to obtaining informed consent, as permitted by HIPAA.

The informed consent duty in Wisconsin has been elevated to a higher standard due to recent court interpretations of medical malpractice actions where negligent consent is claimed as a separate cause of action (See, Jandre v. Physician's Insurance Co. of Wisconsin). Documenting that informed consent was properly obtained is the best defense to show that consent was properly obtained by a qualified individual prior to initiation of any research procedures.

Submission Reminders

- Please remember to black-out the names of subjects when signed ICF's or subject medical notes are sent to the IRB Office. If you need to refer to a specific subject in a violation or continuing review, use subject initials or a study code/subject ID number.
- CyberIRB submissions require a PI signature on the 502-A.
- All investigator initiated studies need Research Administrative Pre Authorization (RAP) research.preauthorization@aurora.org prior to submitting a protocol to the RSPP/IRB Office – even those that are merely done via medical chart review.
- All Expedited and Full Committee submissions need to include a protocol and not only the RAP proposal. Please use the protocol template found on the Aurora RSPP website.
- All key research personnel (as identified on the Delegation of Authority (DOA) log) need to have completed their Research Certification application and Significant Interest disclosures in COI Smart (including the research questionnaires) prior to submitting the study to the RSPP/IRB Office.

Enrolling non-English Speaking Subjects

- The Aurora IRB is in the process of updating our guidance on the *Enrollment of Non-English Speaking Subjects (version 7.26.16)*. The revisions include instructions on the process for obtaining a valid, written (signed) HIPAA authorization when using the Short Form enrollment process (when you unexpectedly encounter a non-English speaking prospective subject). In summary, the person obtaining consent must have the Non-English speaking subject sign the English version of the IRB approved study Summary that includes the elements of authorization. There may be opportunity to obtain a waiver of authorization, but the conditions to approve such a waiver are hard to meet when you have direct contact with the prospective subject. The revised guidance details all of this new information. SOP 701 is also being updated to address the authorization issue. These documents will be posted to the Aurora RSPP website soon.
- In addition, the Accountable Care Act has recently issued stricter standards for individuals who can serve as a medical interpreter. This affects who can act as a

"qualified" interpreter for the verbal presentation of the study Summary when the Short Form process is used for enrollment of non-English speaking subjects.

- Please read the guidance on who can function as a qualified interpreter. You are also encouraged to read Aurora system Policy 170 on this topic.
    - The RSPP obtained clarification from the Aurora Cross Cultural Services department on who may serve as a qualified interpreter. All individuals who serve as a qualified interpreter must be vetted by Aurora Cross Cultural Services. This includes employees who speak a specific language and want to approach a potential subject and interpret an ICF for research purposes. Such employees must be vetted and approved by Aurora Cross Cultural Services. The vetting process includes testing on medical terminology and the different dialects for the specific language. The employee's department is responsible for paying for the cost of the testing.

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.