



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

February 2016

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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.

RSPP Reminders and Updates

- Please continue using most recent versions of the [Aurora IRB forms/spreadsheets](#). The latest versions of all forms/spreadsheets can be found on the Aurora RSPP website. If outdated forms/checklists are submitted to the Aurora IRB, these will be returned or requests will be sent asking the submitter to address missing questions.
- The new Human Subject Research Investigator Manual is available on the Aurora RSPP website. Please take a moment to review this manual found [here](#).
- The RSPP SOPs have been updated. A summary of the changes can be found [here](#).
- The RSPP has created new guidance on databases and repositories. This guidance can be found [here](#).
- The Research Compliance section of the Compliance and Integrity internal website has been updated. To review: Log into Caregiver Connect and make the Compliance and Integrity site one of your Quick Links for future reference, or go to My Places/Compliance and Integrity to view. The site includes educational materials, summaries of research-specific system policies, and numerous links to regulations, guidance documents and FAQs.
- 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.

Case Reports

It is the IRB's task is to review projects that involve Human Subject Research. Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. The Aurora IRB defines a systematic investigation as the implementation of rule-based methods, specified in the investigation plan, that are repeated with multiple subjects (or their data) in a consistent manner across the subjects. Alternatively, the method may be implemented according to specified rules with a single subject for certain types of investigations.

Case reports generally involve the following:

- a retrospective review of medical records detailing a medical treatment in a patient or a few patients with a unique treatment, disease course, or outcome
- a description of a unique diagnostic finding or uncommon presentation
- a report prepared by the clinicians who have personally provided care to the patients

Case reports generally do not involve the following:

- a predetermined hypothesis or research question
- plans for publication of the information about the patients' medical care prior to or during the patients' treatment

Journals typically require a letter or other acknowledgement from an IRB prior to publication of a single case report or a case series. Anyone asked by a journal to provide documentation of IRB review prior to publication of a submitted case report or case series should complete the Human Subjects Research Determination Form found [here](#).

The Aurora IRB will not make HIPAA determinations for projects that do not involve human subject research. HIPAA Privacy Rule requirements must be followed in most Case Study scenarios. Questions regarding HIPAA Privacy Rule requirements can be directed to Aurora's Chief Privacy Officer at 414.299.1713.

Research Certification Update

The term for Aurora Research Certification (per revised Aurora RSPP [SOP 102](#)) has been revised to be 3 years. This time frame is considered to be best practice by IRB consultants. Individuals due for renewal will be sent a notice 6 weeks prior to expiration.

These notices will be sent directly to the affected individual only. Upon expiration of the individual's research certification term, the individual must reapply. This obligation includes the requirement for completion of a refresher CITI course. If an individual does not reapply prior to expiration of research certification, his/her participation in human subject research at Aurora will be suspended until such time as he/she complies.

Compliance Update: Avoid privacy breaches – Safeguard patient health information during transport (Diane Austin, Compliance Officer - Research)

No doubt about it, Aurora caregivers are busy and we have job responsibilities that take place in lots of different locations. As a result, caregivers may at times transport patient health information as they move from place to place. When that's the case we need to be extra cautious and make sure we take appropriate steps to protect the patient health information.

In their annual report to Congress, the Office for Civil Rights identified that theft and loss of electronic media or paper records are the most common causes of privacy breaches. Some of these incidents have resulted in hefty enforcement actions to the organization involved, most notably the \$1 million penalty to the Massachusetts hospital when an employee, transporting health information to her home, lost the patient identifiable documents on the subway train.

Each of us is responsible to make sure we have safeguards in place whenever we transport or store identifiable patient health information. To avoid privacy breaches, penalties, and fines here are safeguards you are required to have in place:

- Limit the transport of patient information whenever possible, if it is not directly necessary to do your job then don't remove or transport patient information
- When transporting patient information from department to department, avoid unnecessary stops along the way such as the cafeteria or pharmacy for personal reasons
- When transporting patient information in a vehicle, secure it at all times. If you must leave the information unattended, lock it in the trunk or store in a hidden location out-of-sight
- Remove any patient information from your vehicle overnight

When using or maintaining patient information in a residence, secure it so that it is not accessible to others. If you must leave the information unattended, lock it in a briefcase or other storage location out-of-sight

**Safeguarding confidential patient information is
everyone's responsibility.
Handle with care!**

Submission Reminders

- The current Curriculum Vitae (CV; signed and dated) of the Principal Investigator (PI) must be submitted for initial review of human subject research or when the PI of a study changes. CVs of sub-investigators are not required.
- A Modification form must be submitted to the IRB Office when the study contact changes. The reason for the notification is to ensure that important information/reminders, such as CR notifications, are sent to the correct person.
- When a study has a Data Safety Monitoring board (DSMB)/Data Monitoring Committee (DMC), a copy of the most recent DSMB/DMC Report needs to be included with continuing review.
- Significant New Findings (SNF) Reporting: Note that with the latest version of RSPS SOP 403, the timeframes for reporting Significant New Findings have been revised. If the new information is reporting a problem/an event determined by the Sponsor to be an Unanticipated Problem as defined by RSPS [SOP 403](#), the SNF form must be submitted to the Aurora IRB within **5 working days** from receipt of the information. Information that does not meet the definition of an Unanticipated Problem should be submitted within **ninety days (90)** after receipt of the information from the sponsor, or investigator for investigator-initiated research. Reporting violations will be tracked by the Aurora RSPS office.
- Protocol Exceptions: Reminder- Protocol Exceptions should be submitted prospectively to the Aurora IRB per the criteria outlined in RSPS [SOP 403](#). A Protocol Exception is a one-time, intentional, time-sensitive action or process that departs (“deviates”) from the IRB-approved study protocol. Keep in mind that some protocol violations may be alleviated if you are able to request a prospective Protocol Exception from the sponsor/Aurora IRB. .

On the Horizon

- **MAY 9 – 10, 2016:** The date of the impending AAHRPP accreditation site visit has been set – May 9 & 10th. Individuals listed as key personnel may be asked by AAHRPP to be part of the site interviews. Individuals requested by AAHRPP will be contacted in late March/early April for availability. The Aurora RSPS office is preparing educational materials for those individuals chosen by AAHRPP. More information to come. If you have any questions contact us at (414) 219-7744 or email us at IRB.Office@aurora.org.
- The [IRB Protocol Submission Application](#) has been revised to include specific questions on study resource availability. These questions were added due to a noted omission by the Research Compliance Officer, and are to be used by the Aurora IRB when the research study is reviewed to determine if one of the regulatory criteria for approval (Minimization of Risk) is met. The newest version of the forms will be available soon – watch your email and the [Aurora RSPS website](#) for information.
- Cyber IRB will be revised within the next few weeksWatch for updated information to be sent via email.