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

May, 2017

Contents

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.

Common Rule Revisions by Diane Austin, Aurora Research Compliance Officer

Through your training and experience, you have likely learned a great deal about the requirements of the Federal Policy for the Protection of Human Subjects, referred to as the Common Rule. That Rule was recently revised and the revisions are fairly significant. Fortunately, the effective date is not until January 19, 2018 for most provisions of the revised rule. This article will highlight the major changes that are likely to affect research at Aurora. You will learn more about each of these changes through various educational offerings through 2017, including additional newsletter articles. Major changes include:

- Exemptions: The Rule includes several new and revised exemptions. Three of the new exemptions likely to have a big impact at Aurora deal with the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. These exemptions are a bit complicated, requiring specific criteria to be met, and in some cases, broad consent and a limited IRB review to assess protections for subject privacy and confidentiality of their data. But, these exemptions should reduce overall burden for both the IRB and investigators in regard to the depth of review and length of IRB oversight.

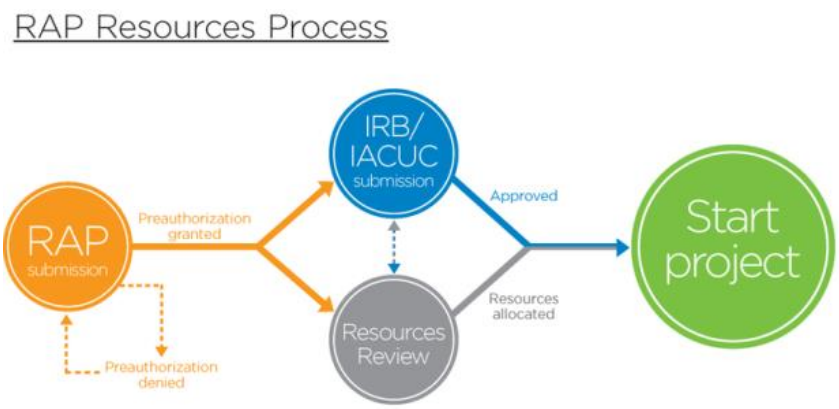
- Continuing review: The change to continuing review requirements will have a huge impact on relieving both IRB and investigator burden. No continuing review will be required if a study was initially reviewed via the expedited review process or once all interventional aspects of a study are complete and the only activities remaining are: a) observational follow-up of subjects in conjunction with standard clinical care; or b) data analysis.
- Informed Consent: Numerous revisions to informed consent requirements were made with the intent of improving the informed consent process. These include: a) a new requirement to provide a concise summary of key information at the beginning of the consent form to assist the potential subject in making a decision about whether or not to participate; b) an option of broad consent for storage, maintenance or use of identifiable private information or identifiable biospecimens; c) changes to the basic and additional (if applicable) elements of informed consent; d) an exception from informed consent for screening, recruiting or determining eligibility; and e) a requirement to post the consent form on a publicly accessible site after study enrollment closes.
- Single IRB Review: The Rule includes a requirement to use a single institutional review board (IRB) for federally supported multi-institutional research studies, with limited exception.

  Major changes that were proposed but did not make it into the final Rule include: 1) the scope of the Rule was not expanded to include all clinical trials, regardless of funding source; 2) the definition of "human subject" was not expanded to include all biospecimens, regardless of identifiability; and 3) the concept of “excluded” studies was removed.

Research Administrative Preauthorization (RAP)

Aurora Research Institute (ARI) has revised its procedure for reviewing and preauthorizing research projects conducted at Aurora Health Care – whether they are to be overseen by Aurora oversight committees (IRB or IACUC) or ceded to external oversight committees.

All principal investigators (PI) are still required to seek research administrative preauthorization (RAP) from ARI as a first step in the process of conducting research. RAP authorization must be secured prior to submitting the research proposal to the Research Subject Protection Program (IRB or IACUC). The new ARI review process includes a review of resources as detailed in the following image:



The intent of preauthorization is to ensure that all research projects at Aurora:

- Are meritorious and aligned with the priorities and mission of Aurora Health Care and ARI.
- Have clinical significance, scientific merit, feasibility, sufficient resources and anticipated outcomes.

RAP offers an opportunity for the investigator to obtain feedback before time and resources are spent writing an in-depth protocol or submitting to other review entities. It also allows for the possible allocation of resources, including study design expertise, data access/analysis, biospecimens, business contracting services, research coordinators, statistical support, publishing, etc.

The RAP process requires that the PI provide a description of the research with sufficient information for the RAP committee to adequately evaluate the project. The RAP submission documents/requirements must be sent to the RAP office (see below for RAP Office contact information and links to the necessary documents).

After RAP authorization, the ARI Resources Review Committee reviews the proposal in parallel with IRB/IACUC review to determine if adequate resources are available to the researchers, or if other resources are necessary for successful project completion. This parallel review assures that the project moves forward expeditiously but has the necessary resources. If resources are not identified or are insufficient, the Resources Review Committee will notify the PI and work with him/her to develop a plan of action and/or possibly direct the PI to potential funding sources in concert with the Sponsored Programs Office.

All submissions must be sent to the RAP Office at:
research.preauthorization@aurora.org.

Submission documents include:

- **RAP Form**
- **RAP Process**

Protocol Exception: What constitutes a protocol exception?

An exception to the currently approved protocol is a planned temporary change that has received IRB approval prior to its initiation.

An example would include enrollment of a subject who does not meet eligibility criteria or accommodation of a subject who moves out of the area for the remainder of his/her participation in the research.

If the change is granted as an exception it should not be reported as a violation.

External IRB Reminder

For studies ceded to an external IRB, the external IRB and the Aurora RSPP have a complementary relationship in the oversight of the research. You are encouraged to review

Aurora RSPP SOP 409 for the most current Aurora policies/processes relative to the ceding process.

In short, the external IRB oversees the approval and conduct of the specific study, but Aurora is still responsible for addressing compliance issues, quality assurance, and continuing education of its investigators. With regard to unanticipated problems and/or research noncompliance that occurs during the conduct of the ceded study, the external IRB reviews such events relative to the specific protocol, whereas the Aurora RSPP reviews the events in a more general context, focusing on issues at an institutional level.

Therefore, local investigators and research regulatory personnel who have research studies ceded to external IRBs are reminded that section 1.5.2.(i).1 of SOP 409 requires that any time potential Unanticipated Problems or Serious and/or Continuing Noncompliance are reported to the external IRB (follow that IRB's reporting policies) you MUST provide the Aurora RSPP with a copy of that report at the same time you are submitting to the external IRB.This concurrent review allows the Aurora RSPP to address any institutional issues relavent to the event. The external IRB will make a determination on the event based upon their definitions and policies (i.e. whether the event rises to the level of a UPIRSO or serious and/or continuing noncompliance) and will perform any necessary mandatory reporting to the sponsor, regulatory agencies, etc.

If you have questions on this process, please call the Aurora RSPP office.

What's new?

Forms

Please note that you should begin using the following revised forms and informed consent template ASAP but no later than May 15, 2017. Revised forms can be found here. The revised consent template can be found here.

Updated Forms:

- Significant Deviation/Violation Form v. 3/16/17
- Submission Form v. 4/10/17
- Exempt Submission Form v. 4/10/17
- Modification Form v. 4/10/17
- Request to Rely on an External IRB v. 2/6/17
- Informed Consent Template v. 4/10/17

If you are experiencing problems accessing the latest versions of the RSPP forms you may need to refresh your internet browser. The new forms are also available in the forms library in Cyber.

Revised Guidance Document and SOP

The RSPP office has released some new/updated guidance and SOP documents. Links to the documents are below:

- Guidance Document on the Use of Electronic Informed Consent in Clinical Investigations
- SOP 104 Conflict of Interest - Effective Date 3/27/17

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.

General Reminders

- When communicating with the Aurora IRB, please use the Aurora IRB study number and NOT the number assigned to the study by ARI. These two numbers are not the same – and the Aurora IRB only documents the study number that we assign, and not the ARI number.

  The use of the Aurora IRB number will ensure that there are no errors on our part in communicating information about a given study, as well as saving us time in searching for the correct study.

- RSPP Office hours have changed. Current office hours are 7:30 a.m. to 4:00 p.m. Monday through Friday (exclusive of holidays).