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

February 2018

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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.

Annual Researcher Survey: RESULTS

We would like to thank the 130 individuals that responded to our Annual Researchers Survey. Over half (52%) of the respondents indicated that they were interested in receiving additional educational topics from the RSPP office. In response to that result, we have added a section to the RSPP Newsletter entitled: RESEARCH NEWS AND HOT TOPICS. Under this heading we will provide links to articles that may be of interest to expand the Aurora research community knowledgebase.

Update on Common Rule Implementation - Delay

While most provisions of the revised Common Rule were scheduled to go into effect January 19, 2018, the Office of Management and Budget approved a requested **delay** until July 19, 2018. An additional six month delay has been requested but not yet approved.

Major changes in the delayed Common Rule include, but are not limited to:

- more studies will qualify for exemption status

- fewer continuing review requirements
- additional consent form requirements

Once the Rule goes into effect, studies reviewed and approved prior to the effective date will continue to follow the requirements in place prior to the Rule's revision unless and until those studies are transitioned by the Institutional Review Board/Research Subject Protection (RSPP) Office at continuing review time.

More information will be provided as the next implementation date nears.

WHAT'S NEW?

A Summary of changes to RSPP Forms, RSPP SOP's, RSPP Guidance and Aurora System Policy affecting Human Subject Research

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 CyberIRB.

Revised RSPP Forms

Revised forms can be found here and in the CyberIRB library

- (403) The modification form title was changed to: Changes to Previously Approved Human Subject Research Form
- (410) Unanticipated Problems Reporting Form
- (502.1) Representation for Reviews Preparatory to Research
- (601) Noncompliance Reporting Form
- Human Subject Research Determination Form
- The Main, Parental and Banking ICF's have been updated

Revised RSPP Guidance

Revised Guidance can be found here

- RSPP guidance on Issuance of Certificates of Confidentiality
- RSPP guidance on Subject Noncompliance Vs. Reportable Noncompliance
- Algorithm: Preparatory to Research
- Algorithm: Screening/Recruitment
- Updated RSPP Glossary found here

Revised RSPP SOP's

Revised SOP's can be found here

- (403) Changes to Approved Human Subject Research
- (408) External Reporting
- (409) Reliance on an External IRB
- (410) Reporting and Review of Unanticipated Problems
- (502) Privacy and Confidentiality in Human Subject Research
- (601) Noncompliance in Human Subject Research

Summary of Changes to the Aurora SOP's

SOP 403 was broken into the following three separate policies: Changes to Approved Research (new RSPP SOP 403), Unanticipated Problems (RSPP SOP 410) and Non-Compliance (RSPP SOP 601). The remaining SOP discusses Changes to Approved Research. In this revamped SOP, **t**he provision for protocol exception has been retained for changes related to a single subject's participation. All protocol exceptions require sponsor approval to be obtained even before submission to the Aurora IRB is allowed. If approval by the Aurora IRB is not obtained prior to the event taking place, the event becomes reportable as noncompliance since the approved protocol was not followed.

SOP 408 was revised to outline some minimal changes in the reporting process to external agencies (OHRP, FDA, grant agencies).

SOP 409 was revised to include reference to the revised NIH Policy on single IRB review of multi-site research. It also includes a brief outline of when the Aurora IRB will become the IRB of record for multi-site research.

SOP 410 was created in the break-up of SOP 403, and outlines the reporting of Unanticipated Problems (UP) in human subject research. Form 410 has been created for submission to the Aurora IRB of events deemed by policy requirements to be reportable UPs. Reportable UPs must be adjudicated by the PI, and submitted to the Aurora IRB within 5 working days of discovery. A summary of unreported UPs will no longer be accepted at Continuing Review.

The reporting of UPs for human subject research overseen by an external IRB does not follow Aurora RSPP SOP 410. The policy of the IRB of Record prevails as to whether an event is reportable as UP. Note that RSPP 409 requires that a copy of any UP reported to an external IRB be immediately provided to the Aurora RSPP.

SOP 502 was revamped to discuss all aspects of privacy and confidentiality in human subject research (HSR). Amongst other topics, the new policy discusses: the use of Honest Brokers in research; use of Protected Health Information (PHI) in HSR – including social security numbers, sensitive data and behavioral health and treatment records; clarification on Preparatory to Research activities, research authorizations and waivers of authorization; accounting of PHI disclosures; reporting of breaches of confidentiality; and Certificates of Confidentiality issued by NIH.

SOP 601 was majorly revised. The SOP remains centered on Noncompliance in human subject research, but changes include: there is no longer a distinction in the reporting of events that occur in research ceded to an external IRB v. research that is overseen by the Aurora IRB – all events that occur in human subject research must follow RSPP SOP 601 as far as reporting to the Aurora RSPP;; requirement for real-time reporting of all events that meet the policy definition of noncompliance (no longer will any noncompliance report be accepted at Continuing Review); subject-directed action/noncompliance is not considered by policy definition to be a reportable instance of noncompliance. A new submission form (form 610) has been created for the reporting of investigator noncompliance in human subject research. Form 601 will require the submitter to provide a corrective as well as preventative action plan. Note that the Aurora RSPP will **ONLY** accept at Continuing Review summaries of violations/noncompliance that occurred **prior to 12/15/17**. Events that occur after that date must be reported in real-time as noted within the revised SOP. Any event of noncompliance that occurs after 12/15/17, but is reported in summary fashion at Continuing Review, will itself be considered a noncompliance event.

UPCOMING CHANGES:

Signficant New Information – instruction on reporting of Significant New Findings (SNF) was originally found in SOP 403. With the revamp in policy, this information was removed from SOP 403. An SOP on Reportable Significant New Information will be released soon. You should continue to report significant new information (information that would/may affect a subject's willingness to continue in the research) on the current Significant New Findings (SNF) form until the new SOP and form are released.

Administrative Holds - instruction on reporting of Adminstrative Holds was originally found in SOP 403. Administrative Holds are still possible should the PI of an approved research study wish to voluntarily halt some or all research activities. Administrative Holds may be reported on the Changes to Approved Human Subject Research form (403). Information on placing a study on an administrative hold will soon be available in SOP 407.

A revised Continuing Review form will be released soon. The new form will include changes relative to the reporting of UPs and noncompliance.
Watch for e-mails announcing the releaseof new SOPs/forms.

Summary of Changes to the Aurora System Policies Affecting Research
****NEW** System Policy 811: Research Involving Humans or their Identifiable Data or Biospecimens**
This policy outlines authorities and requirements for the review and conduct of research that involves human subjects or their data or biospecimens. The RSPP Statement of Authority has been retired.

****NEW**System Policy 814: Designation and Responsibility of Principal Investigator (PI), Co-PI**
The Aurora Research Institute (ARI) has published a new system policy which designates and outlines who can serve as a PI of research. No longer will a facilitator be required in research as the system policy outlines that the PI of human subject research must be an Aurora caregiver.

REVISED System Policy 140: Use and/or Disclosure of PHI for Research

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Changes to the Human Subject Research Determination Process
To align with the new System Policy (#811) for Research Involving Humans or their Identifiable Data or Biospecimens, the RSPP office has changed some of the definitions on forms and the RSPP glossary. One of the updated forms is the Request for Determination of Human Subject Research Form. The main change related to the policy is the update to the definition of "generalizable knowledge". Guidance has not yet been provided by the RSPP office on what is considered generalizable knowledge, but it can be expected in the near future. Contact the RSPP office with questions.

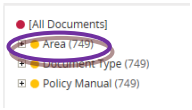
Additional changes to the form include an updated reporting process to the research administrative pre-authorization process (RAP). Reporting is needed prior to RSPP review when data is being sent out of Aurora or Aurora caregivers are included in the conduct of the project or it is a project being done as part of a student requirement. If one or more of these criteria are met, the determination form should be sent to research.preauthorization@aurora.org . RAP will send directly to the RSPP for review.

The new form can be found here.

Quick Tips for Using PolicyTech

As more System Policies are developed that will impact Human Subject Research at Aurora it is important for carevivers to know where to find them. Below the RSPP office provides a few tips for using PolicyTech.

- You can access Policy Tech through the Caregiver Connect Quicklinks
- In PolicyTech you can sort by area (e.g., Research) (see image on right)



- Policies can be marked as favorites by selecting the dropdown next to the icon.
- Favorites can be found under Documents on the left menu bar (★Favorites)

New OCR Guidance—Remote Access for Preparatory to Research Activities

The Office of Civil Rights (OCR) has issued new guidance on remote access to protected health information (PHI) for preparatory to research activities. The Health Insurance Portability and Privacy Act (HIPAA) allows researchers to access PHI for activities that are considered preparatory to research (i.e., assessing the feasibility of conducting a study, preparing a research protocol, or assisting in the development of a research hypothesis) after the researcher provides a representation outlining how the data will be used and protected. In this representation, the researcher certifies, among other things, that no PHI will be removed from Aurora Health Care. OCR guidance explains that remote access to PHI under specific conditions and with appropriate security safeguards is not considered a removal of PHI. However, if someone who has remote access retains or otherwise controls the PHI by printing, downloading, coping, saving, data scraping, faxing, etc., this is considered a removal of PHI and therefore is not allowed under a representation for activities preparatory to research.

The guidance goes on to state that in addition to ensuring standards for safeguarding PHI during remote access (e.g., access control, authentication, transmission security, etc.) are in place, Aurora must assess whether it is reasonable to rely on a researcher's representation that PHI will not be removed (i.e., physically taken, printed, downloaded, copied, saved, etc.). The guidance suggests that it is reasonable to rely on a representation from individuals who are employed by or under contract with Aurora because Aurora has the ability to manage these individual's behavior through employment arrangements/contracts and related institutional policies and procedures. The guidance also suggests, however, that it is not reasonable to rely on other researchers' representations that PHI will not be removed unless removal of PHI is managed in some other way to guarantee that the researcher will not physically remove, print, download, copy or otherwise control or retain the PHI.

In light of this guidance, Aurora has taken the position that remote access by Aurora Workforce Members will be allowed under a representation for reviews preparatory to research. See system policy #140-Use and/or Disclosure of PHI for Research for Workforce Member definition. The Workforce Member with remote access to PHI must certify that they will not print, download, copy, save, or retain the PHI even in a temporary manner. Other researchers or individuals who are not Aurora Workforce Members will not be allowed remote access to PHI under a representation for reviews preparatory to research. Non-Aurora Workforce Members who need remote access for preparatory to research activities will need to utilize another mechanism to meet Privacy Rule requirements (e.g., obtain authorization, request a waiver of the requirement to obtain authorization from the IRB, or use a Limited Data Set under a Data Use Agreement).

System policy #140-Use and/or Disclosure of PHI for Research as well as Research Subject Protection Program standard operating procedure #501-Privacy and Confidentiality in Human Subject Research and form #502.1-Representation for Reviews Preparatory to Research are being revised to reflect this position

and obtain the necessary certification from any Workforce Member who needs remote access to PHI for preparatory to research activities.

RESEARCH NEWS AND HOT TOPICS

Article: Enhancing Scientific Foundations to Ensure Reproducibility - A New Paradigm

Terry Hsieh, Max H. Vaickus, Daniel G. Remick

Abstract: Progress in science is dependent on a strong foundation of reliable results. The publish or perish paradigm in research, coupled with an increase in retracted articles from the peer-reviewed literature, is beginning to erode the trust of both the scientific community and the public. The NIH is combating errors by requiring investigators to follow new guidelines addressing scientific premise, experimental design, biological variables, and authentication of reagents. Herein, we discuss how implementation of NIH guidelines will help investigators proactively address pitfalls of experimental design and methods. Careful consideration of the variables contributing to reproducibility helps ensure robust results. The NIH, investigators, and journals must collaborate to ensure that quality science is funded, explored, and published.

Article: Views of clinical trial participants on the readability and their understanding of informed consent documents

Rita Sommers, Cornelius Van Staden, Francois Steffens

Abstract: Background: One of the ethical imperatives for a valid consent process in clinical medication trials is that the process be guided by and recorded in an informed consent document (ICD). Concerns have been expressed, however, about readability and participant understanding of ICDs, which are often 10–20 pages long. Objective measures of readability and understanding have been used to support these concerns in several articles, but surprisingly the voice of trial participants on ICDs has not been heard in previous studies. Hence, this study compares participants' subjective views on readability and their understanding of ICDs with those ICDs' objective readability scores. It also evaluates whether family, friends, and additional aids would foster better understanding of the ICD. Methods: Sixty current trial participants rated the readability and their understanding of deidentified standard ICDs. These had been sourced from two multicenter international Phase III trials on medication for diabetes mellitus and cancer. Results: Less than 10% of participants considered the ICDs difficult to read or difficult to understand in spite of objective readability scores at levels of about 12th grade education, but about a quarter considered the ICDs to be too technical. Participants gave mixed responses about friends or family members helping or the need for videos, pictures, additional reading material, and frequently answered questions (FAQ) sheets as an aid to their understanding. Conclusions: These findings suggest individual clinical trial participants should be engaged on their views of an ICD, for doing so is part of informed consent as a process rather than consent being merely focused on written information. Such participant-specific engagement should guide whether family and friends, videos, pictures, additional reading material, and FAQ sheets would be of assistance in improving understanding

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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 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.