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

November, 2017

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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

On an annual basis the RSPP Office sends a short survey to researchers. The purpose of the annual survey is to improve the efficiency of the IRB Committee Meetings and to inquire of your educational needs specific to Human Subject Research. The link to the survey was sent out last week. If you have not completed the anonymous survey, please take a moment to complete it by Friday, November 17, 2017 by clicking on this link: https://www.surveymonkey.com/r/Q2LSS2T

Update on Common Rule Implementation

Revisions to the Common Rule (the regulations that affect the conduct of IRBs and human subject research protections) were signed into law by President Obama several days prior to his departure from office. Most of the new regulation is to be implemented on January 19, 2018.

When President Trump took office he directed his staff to review all laws that were signed at the end of President Obama's tenure. No communication was disseminated to the public relative to the administration's review, and comment by the Department of Health and Human Services (HHS) has been

almost non-existent. This lack of communication has put IRBs and institutions in a terrible predicament: we need to assume that the revised Common Rule is effective this coming January.

However, on October 7, 2017, the federal Office of Management and Budget (OMB) regulation tracking website showed that a new rule request has been made by HHS to delay the effective date of the Common Rule by one year except for three unidentified provisions. The actual title of request is*: Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year*. No further details on the request or the three unidentified provisions have been made.

Generally OMB has 90 days to make a decision but one will need to be made much sooner since the current effective date is January 19, 2018.

We will provide more information on the OMB decision as we get it. But in the time-being, the RSPP office and Aurora research leadership are moving forward in revising policies and procedures to address the revisions to the human subject protection regulations (AKA the revised Common Rule). If OMB does not delay implementation, you will see a lot of changes coming from the RSPP office in the next two months. Stay tuned!

Common Rule Revisions - EXEMPTIONS
by Diane Austin, Aurora Research Compliance Officer

In a recent article on changes to the Common Rule for the protection of human subjects, I mentioned that one of the bigger changes in the revised Rule relates to exemptions. There are eight total exemptions, and this and future articles will provide an in depth explanation of those exemptions.

Three exemptions are for activities Aurora would be less likely to be involved in and therefore, won't be discussed in detail. Those three exemptions are for taste and food quality evaluation and consumer acceptance studies, research conducted, supported by or subject to the approval of the federal government that is designed to study, evaluate, improve or otherwise examine public benefit or service programs, and research conducted in established or commonly accepted educational settings involving normal educational practices.

While the type of research projects falling within an exemption category has been expanded, several of the exemptions now require a limited IRB review. This limited review is beyond the review to ensure exemption criteria are met, and the specifics of the limited review depend on the research being considered.

Exemption for educational tests, survey procedures or observations of public behavior. One revised exemption that may involve limited IRB review is the exemption for research that only includes interaction involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures , or observations of public behavior (including visual or auditory recording) uninfluenced by the investigator. For this exemption to apply, one of the following criteria must be met:

1. The information obtained is recorded in a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subject;

2. Any disclosure of responses outside the research would not reasonably place subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement or reputation; or
3. The information obtained is recorded in a manner that the identity of the subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited review to assess that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The first two subparts of this exemption (items 1. and 2. above) may be applied to research involving children if the research involves educational tests or observation of public behavior and the investigator does not participate in the activities being observed. All aspects of the exemption may be applied to research involving pregnant women, and neonates if the conditions of the exemption are met. All aspects of the exemption may also be applied to research that only incidentally includes prisoners.

The preamble to the revised Common Rule makes several additional points about this exemption:

- The term "survey" refers to information collected about individuals, not organizations or businesses, and "survey" does not include the collection of biospecimens. If a study includes collecting verbal or written responses to questions in addition to the collection of biospecimens, this exemption would not apply.
- Research falling under this exemption cannot include interventions. For example, research to determine whether respondents answer questions differently depending on the gender of the interviewer or research involving observation of public behavior when the investigator intervenes with the subject (e.g., offering a lost wallet to see if the subject will accept it) would not qualify for this exemption.
- Privacy and confidentiality provisions would be "appropriate" for those situations when the information collected is both identifiable and sensitive or potentially harmful.

The remaining exemptions will be discussed in future articles. Keep in mind these exemptions and other Common Rule changes do not take effect until January 19, 2018.

AUTHORIZATION

Using PHI for Research Purposes

The rules for the use and disclosure of Protected Health Information (PHI) for research purposes are distinctly different than those for using and disclosing PHI for treatment, payment or operations purposes. The HIPAA Privacy Rule allows a researcher to use PHI only under the following circumstances:
1. The Health information is **de-identified**—all 18 HIPAA-defined patient identifiers are removed.

2. With the patient's written **authorization**—the patient signs an authorization, often incorporated into a research consent form, that describes what PHI will be used/disclosed and to whom. The authorization must contain specific elements in order to be valid.

3. After securing an **authorization waiver** from an Institutional Review Board (IRB) or Privacy Board—certain criteria must be met in order for an IRB or Privacy Board to approve a waiver including that it would not be practicable to conduct the research without the waiver. This option essentially "waives" the need to obtain the patient's specific written authorization.

4. After signing a **Data Use Agreement** (DUA)—this option is limited to situations where a researcher only needs access to a Limited Data Set (LDS) instead of fully identifiable PHI. The DUA outlines the

permitted uses and limitations. A LDS is health information containing only the following patient identifiers: city, state, zip code, dates.

5. After signing a **representation**—a representation is a researcher's certification to protect and use or disclose PHI in a specific manner. There are two types of representations:
a. **Representation for Reviews Preparatory to Research**—under this representation, PHI may only be used/disclosed to assess the feasibility of conducting a study, to prepare a research protocol, or to assist in the development of a research hypothesis.

b. **Representation for Research on Decedents**—this representation certifies that the PHI is solely used/disclosed for research on deceased patients.

If PHI is disclosed under an authorization waiver or under a representation to someone who is not an Aurora Workforce Member, Aurora must account for the disclosure. Disclosure accounting is the tracking of when and what PHI is disclosed. A patient has a right to request an accounting of certain types of PHI disclosures, including those for research purposes.

See system policy Use and/or Disclosure of PHI for Research for more details on each of these provisions as well as related procedures. Contact Compliance at 414-299-1708 with any questions.

AUTHORIZATION
Legally Authorized Representatives – no waiver of authorization required
We have received clarification from the Privacy Officer that a waiver of authorization is not required when a legally authorized representative (LAR) is used to enroll a decisionally incapacitated patient into research. A person documented as a Personal Representative per Aurora System policy [USE AND OR DISCLOSURE OF PROTECTED HEALTH INFORMATION] should be treated the same as the patient with respect to PHI.

Personal Representative means a person who has authority under state or other applicable law to make decisions related to health care about an Individual. A Personal Representative must be treated as the Individual with respect to PHI relevant to such personal representation. For purposes of Chapter 146 (patient health care records), an Authorized Person may also be the Personal Representative depending on the scope of authority. For purposes of Wisconsin Statutes § 252.15 (HIV test results), an Authorized Representative may also be the Personal Representative depending on the scope of authority.

AUTHORIZATION
Disclosure Accounting Email
Remember, if you are disclosing (*Release of information to a non-Aurora workforce member*) PHI in your research study via a wiaver of authorization or representationyou need to track the disclosures and the patient information for Privacy purposes (accounting of disclosures). A template spreadsheet has been created for this purpose. This email is provided as part of the IRB approval process but can also be obtained from researchdisclosures@aurora.org . The completed spreadsheets should be sent to this email inbox where the patient information is compiled for Aurora Privacy use.

New Certificate of Confidentiality policy in effect 10/1/17
The NIH has recently updated their policy on Certificates of Confidentiality (COC), effective October 1st. The notice for the policy change can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Research studies that are federally funded should check with the study-wide PI/oncology cooperative group to determine if a COC has been issued for your research study.Studies affected by this change should include the COC language in their next consent amendment. The COC language can be found in the Informed Consent Template document here:
https://medicalprofessionals.aurorahealthcare.org/irb/informed-consent.asp

What to do with signed consent?
Recent quality reviews have found that there is some confusion about how signed consents should be kept. If a study collects the signed (original) informed consent, this is considered an essential document and must be kept in the study records. This includes the signed consent from individuals who are later considered to be screen failures. If a study team has a plan other than to keep original signed copied (i.e. fax/pdf), that plan should be outlined in the Submission Application to be reviewed by the IRB.

What's new?

Forms

Revised forms can be found here. Updated Forms:

- 502.1 Preparatory to Research v.10/19/2017
- 502.2 Decedent Representation v.10/19/2017
- 502.3 Waiver of Authorization v.10/19/2017

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 will have some new/updated guidance and SOP documents soon. An edition of the RSPP Newsletter will be distributed in December to outline those changes.

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

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).