Aurora Health Care

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

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Merger News

Plans are in the works to merge the Advocate and Aurora IRBs and offices. Care needs to be taken so that the policies/processes/practices of the combined human subject protection program (HRPP) meet AAHRPP accreditation standards. It is expected that final merger of the HRPP will occur by Fall 2019. We'll keep you informed as work proceeds.

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.

Compliance News

Reporting a Compliance Issue: Keep Calm and Call Compliance

Have a compliance related issue you would like to address? Team members, patients and families should now do so by calling **888-847-6331**. This hotline is staffed 24/7 and allows for anonymous reporting. And should you want to follow-up on your report, you will be given a case number that allows you to call back – still anonymously – and check the status of any investigation into your concern.

Reports can also be made anonymously online at www.advocateaurorahealth.ethicspoint.com.

Speak up and do the right thing by using this number or website to report potential compliance concerns. Almost half of all compliance issues are detected through tips and hotline reporting, and studies show that organizations experience 50% fewer losses when an effective reporting process is in place.

Thank you for your dedication to doing the right thing and making sure that Advocate Aurora Health remains focused on building a culture of compliance and integrity. It is through this culture that we are able to build the trust we need from team members and patients to help people live well.

Conflict of Interest Policies – Research by Susan Slimack, JD, MHA, Compliance Officer - Research
Advocate Aurora Health recently published new system policies related to Conflicts of Interest in Research: Research Conflict of Interest Policy – Individual and Research Conflict of Interest Policy – Institutional. In addition, survey questionnaires were distributed to researchers throughout Advocate Aurora Health as part of the annual research financial disclosure drive with the goal to have disclosures completed by March 1st.

The new system policies demonstrate that Advocate Aurora Health is committed to maintaining a research environment that promotes attention to the highest ethical standards for all sponsored and non-sponsored research. These policies are derived from regulations found at 42 CFR Part 50 (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors) which require disclosure and management of interest that have the potential to inappropriately influence the design, conduct or reporting of research. These regulations are applicable to Advocate Aurora Health as an institution that applies for or receives Public Health Service (PHS) funding and to many Advocate Aurora Health investigators who are responsible for designing, conducting or reporting PHS-funded research. While these regulations drive the policy, human subjects protection accreditation standards broaden the applicability of the regulatory requirements to anyone involved in the design, conduct or reporting of research. These policies are also aligned with best practices among other healthcare organizations involved in research.

To protect research subjects and maintain public trust, it is essential that certain interests (i.e. those determined to have a higher likelihood of creating a conflict of interest) be identified and, when necessary, managed. In addition, the policies offer protections for the individual holding the interest and the institution. Should something go wrong that is outside the control of the investigator or institution, appropriate management strategies help demonstrate that the conflicted individuals did not have the ability to influence the design, approval conduct or reporting of research.

One important change both policies have implemented is the process for determining whether a significant interest determined to be related to the research creates a conflict of interest with ongoing or proposed research. The Compliance and Integrity Department will now determine whether a conflict of interest exists and create a management plan while working with the conflicted individual and appropriate leader. The Research Conflict of Interest Committee will be utilized when the conflicted individual wants to appeal a management plan.

The Compliance and Integrity Department encourages all of those involved in research to review the new policies. They can be accessed via PolicyTech for legacy Aurora and Advocate Document System (ADS) for legacy Advocate.

WHAT'S NEW?

Form Updates

Make sure you are using the current version of all Aurora RSPP forms. Find Current forms here. If you do not submit the correct/current version of a form to the Aurora RSPP, your submission will be returned to you, and you will be required to resubmit using the correct version.

System policy 140 (PHI use in research) has been revised, the revised policy allows for the screening/eligibility determination to be conducted under a representation now rather than receiving a HIPAA waiver. 502 forms have been revised to meet the expectations of the system policy and are available in the RSPP website and in the Cyber library.

The submission of the Research Certifcation Application is no longer required. Research training is still required through CITI for all key personnel.

Website Updates

The RSPP website is going through a complete overhaul. Watch for a future announcement on this change.

RESEARCH NEWS AND HOT TOPICS

Article: Clinical research: Should patients pay to play?
Ezekiel J. Emanuel, Steven Joffe, Christine Grady, David Wendler and Govind Persad
http://stm.sciencemag.org/content/7/298/298ps16.full
Abstract: Permitting patients to pay for participation in clinical research threatens the principles of social value and fair subject selection as well as robust clinical trial design.

REMINDERS

PI Responsibilities for Exempt Studies

Per Aurora RSPP SOP #3 and federal regulations on Exempt research, continuing review and reporting of Noncompliance and Unanticipated Problems are NOT required of exempt research studies. However, you are REQUIRED to submit the following prior to implementation: any changes in investigator/key personnel or PI; and substantial changes in the study design/conduct. You may submit these changes via a *Changes In Exempt Research* form. Lastly, you must inform the Aurora RSPP when this study can be closed by submitting a *Final Report* form. Copies of RSPP SOPs and forms can be found here.

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. The disclosure questionnaire is available through Policy Tech, Aurora's on-line system. Please contact the RSPP office if you have questions on how to access the questionnaire to process a new or changed Significant Interest. 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.

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.