



Research Subject Protection Program 945 N 12th St PO Box 342 W310 Milwaukee, WI 53201-0342 T 414.219.7744 F 414.219.7477 IRB.office@aurora.org

www.aurora.org/IRB

News from the Aurora Research Subject Protection Program (RSPP) Institutional Review Board (IRB) January 2017

Contents

- IRB Help Information
- CyberIRB Training or Refresher Course
- RSPP Turn-Around-Time Initiative for Expedited Review Studies
- Interest Disclosures
- <u>Reminders</u>

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 <u>IRB.Office@aurora.org</u>. If there is a topic that you would like addressed in a future newsletter, please send a detailed description of the topic to <u>IRB.Office@aurora.org</u>. Past editions of the RSPP newsletter can be found on the <u>RSPP website</u>.

CyberIRB Training or Refresher Course

An electronic survey was recently sent to researchers inquiring of their experiences when using CyberIRB. Based on the responses, a number of individuals requested a training or refresher course. If you are interested in attending a 'Go To' meeting, please send an e-mail with your contact information to <u>IRB.Office@aurora.org</u>.

RSPP Turn-Around-Time Initiative for Expedited Review Studies

Turn-around-times are a measurement of efficiency. In the RSPP office, turn-around-time typically measures the amount of time from when a submission is received until the time that an IRB decision (i.e. approval) is communicated to the investigator. Many factors contribute to turn-around-times. In an effort to improve RSPP turn-around-time remember to include the following with your submission materials when appropriate:

- RAP approval
- DOA

Page **1** of **2**

- subject materials
- protocol

If requests/questions/clarifications are required of the research team by the RCA or Expedited Reviewer, two reminders will be sent for the one month period following the date of initial contact. The reviewing RCA will send an e-mail notification to the PI and study coordinator within 48 hours of IRB study review notifying the PI/coordinator of the status of the review – approved, approved with conditions, deferred, or convened board review required.

RSPP turn-around-time is reported in the AAHRPP Annual Report and to the Council for Quality Assurance and Improvement in Research (CQAIR). Per <u>Aurora RSPP SOP 903</u>, the Aurora IRB Steering Committee must evaluate on an annual basis the efficiency of the IRB review function. The Aurora IRB turn-around-time is used as a measure of this efficiency.

Interest Disclosures

Interest Disclosures: Per System Policy 269, <u>Investigators/key personnel</u> 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. <u>Significant Interests</u> 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 <u>RSPP office email</u>. 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.

Reminders

Modifications must be complete before being submitted to the IRB Office. All incomplete modifications will be returned to the submitter.