



## Special Edition Newsletter

# Aurora Research Subject Protection Program (RSPP) Institutional Review Board (IRB)

June 2016

Based on recent recommendations from AAHRPP, we have refined our process pertaining to the approval of research with conditions and administrative holds on research.

### Approval of Research with Conditions

The IRB can make several decisions: Approve, Approve with conditions, Defer, Disapprove. The Office for Human Research Protections (OHRP) has parameters for conditions of approval which are the only situations that we can include in our review of a research study that has been approved with conditions. If the IRB cannot determine that the criteria for approval are met or can be met under specified conditions, the IRB has no choice but to defer or disapprove the research study.

Please take a moment to review OHRP's guidance by clicking on the following link. This guidance represents OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word *should* in OHRP guidance means that something is recommended or suggested, but not required.

<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-irb-approval-of-research-with-conditions-2010/index.html#section-b>

### Administrative Holds on Research

The Aurora IRB has revised SOP 403 regarding Administrative Holds of research. The revised SOP language states that an administrative hold is a voluntary action by the Principal Investigator to temporarily or permanently stop some or all research activities as a modification to approved research.

Examples of when such a hold would be appropriate include: an investigator or research team's investigation into an allegation of noncompliance or unanticipated problem; unexpected or planned leave on the part of the Principal Investigator or other key personnel.

Although the Principal Investigator may discuss this action beforehand with an IRB chair, RSPP Director or the Institutional Official, the hold must be initiated voluntarily by the Principal Investigator and must not be used to avoid IRB mandated suspension or termination, or reporting requirements. During administrative hold, the research remains subject to continuing

review and requirements for reporting non-compliance and unanticipated problems involving risks to subjects or others.

An administrative hold of the research does not need to be reported to OHRP, FDA or other federal agency per normal reporting practices (SOP RR 408) but should not be confused with IRB suspensions or terminations of research (SOP RR 407).

Note that placement of a study on voluntary administrative hold by the PI does not in any way limit the IRB's authority to suspend or terminate a study.

Revised SOP 403 will be placed on the RSPP website shortly.

### **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](mailto: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](mailto:IRB.Office@aurora.org).