

<b>SOP: RR 402</b> <b>Version No.: 05</b> <b>Effective Date: 12/2/10</b>	<b>CRITERIA FOR</b> <b>IRB APPROVAL</b>	<b>Supersedes</b> <b>Document</b> <b>Dated: 7/1/08</b>
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Steering Committee approved 9/19/11

## 1. POLICY

All submissions (i.e. submission application and any documentation attached to the submission application) for studies that intend to enroll human subjects must meet certain criteria (which include ethics review coordinated with review of scientific or scholarly validity) before research-related procedures can be initiated. The criteria are based on the principles of justice, beneficence and respect for persons as discussed in the Belmont Report and are specified below. In addition, other criteria unique to Aurora Health Care and Aurora Facilities may apply and must be met as well.

The Aurora IRB shall review all research studies involving human subjects conducted at any Aurora Facility or any facility with which the Aurora IRB has entered an IRB Authorization Agreement. The IRB also shall review any research study that requires access to non-public information from patient health care records that are maintained by Aurora Facilities. Such review shall be in accordance with the procedures set forth in Policy SC 502 and Policy HI 1201. The Aurora IRB may, but need not, review a research study involving human subjects that is conducted by a medical staff member, or employee of any Aurora Facility, even if the research study will not be managed by Aurora Health Care or one of its departments or conducted at any Aurora Facility .

As a result of its review, the Aurora IRB may decide to approve or disapprove the proposed research activity, or to specify modifications required to secure IRB approval of the research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present at a fully convened meeting, except for those members present but unable to vote in accordance with the IRB's Conflict of Interest policies. When reviewed via expedited review, pursuant to Policy RR 401, the Senior IRB Chair or designee may make a determination to approve or approve with conditions but may not disapprove a study. A study may be disapproved only after review by the full IRB.

### Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

#### 1.1. IRB Determinations

The Aurora IRB may make one of the following determinations as a result of its review of research submitted for initial review (see Policy FO 301), for continuing review (see Policy RR 404), or for the review of modifications to previously approved research (section 1.3 of Policy RR 403). These determinations apply to research studies that qualify for either full committee review or expedited review (see Policy RR 401), except in the case of disapproval of a research study which requires a vote at a fully convened meeting.

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1.1.1. Approval: The protocol and accompanying documents may be approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or the IRB Chair or designee, and expires no later than one year from date of approval.

1.1.2. “Deferred” When the convened IRB has significant questions, or requests substantive clarifications or modifications regarding the protocol or informed consent documents, that are directly relevant to the determinations required by the IRB under DHHS and FDA regulations, IRB approval of the proposed research is deferred, pending subsequent review by the convened IRB of responsive material.

1.1.3. “Conditional” Approval:

“Conditional Approval” means that at the time the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of final approval that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings of the IRB regarding how the research will be conducted, or (c) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under DHHS and FDA regulations.

With respect to research reviewed and approved with Conditional Approval by the IRB at a convened meeting, note that because the IRB is able to make all appropriate regulatory determinations, the IRB may designate the RSPP Manager, Primary Reviewer, IRB Chair (and/or other individual(s) with appropriate expertise or qualifications) to review responsive materials and the investigator assess whether conditions have been satisfied, without judging whether the responsive materials meet the regulatory criteria for approval, and thereby further review by the IRB at a subsequent convened meeting is not necessary. The individual designated by the IRB for review of responsible materials for that specific protocol will be recorded in the IRB meeting minutes.

The IRB may require the following as conditions of approval of research:

- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children) or other aspects of the research;

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- Submission of additional documentation (e.g., certificate of training);
- Precise language changes to protocol or informed consent documents;
- Substantive changes to protocol or informed consent documents that don't affect or alter the regulatory criteria for approval, along with clearly stated parameters that the changes must satisfy.

In these cases, the investigator will be informed in writing of the required specific revisions and requested information, and must provide the IRB with the changes or information.

Where the convened IRB specifies conditions for approval of a protocol that are to be verified as being satisfied by the IRB Chair or another IRB member designated by the Chair, continuing review must occur no more than one year after the date the protocol was reviewed by the convened IRB, not on the anniversary of the date the IRB Chair or his or her designee verifies that IRB-specified conditions for approval have been satisfied. Subjects must not be recruited into the study until final approval has been issued.

1.1.4. Disapproval: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB.

## **1.2. Minimal Criteria for Approval of Research**

For review by the convened IRB, the Primary Reviewer takes the Aurora IRB through the criteria for approval as noted in RR 402-A. Using such criteria, the IRB will determine whether the research can be approved. They will also make any other required determinations.

For review using the expedited procedure, the Reviewer uses RR 401-A and 402-A to determine whether the research can be approved and to make all other determinations.

## **1.3. Special Considerations for Studies Involving Subjects Treated for Mental Illness, Alcohol or Drug Abuse, or Developmental Disabilities**

If research is being conducted on inpatients who are being treated for mental illness, developmental disabilities or alcohol or drug abuse, the IRB must assign a consent monitor who has the authority to be present during the consent process and to

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disenroll subjects whose rights under Wisconsin Statutes 51.61 have been violated or who withdraw their consent.

#### **1.4. Other Criteria**

The IRB may require verification from sources other than the investigator that no material changes have occurred since previous IRB review. The need to verify any information will be determined by the IRB at a convened meeting and documented in the meeting minutes. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

Third-party verification may be required for studies such as the following:

- Studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Studies that involve large numbers of subjects, or
- Studies conducted by investigators who have had incidences of noncompliance.

Projects that have been determined to need third -party verification will have such verification performed by the RSPP staff. Results of the verification will be reported to the IRB as necessary.

#### **1.5. Calculation of Approval Period**

The Aurora IRB may approve research for a defined period of time, but in no case greater than one day less than one year from the date of initial approval. The approval period is calculated based on the date of the convened meeting at which the Aurora IRB approved the study or approved the study with modifications, or the date the study was approved by expedited review. The Aurora IRB may approve a project for a period of less than one year, limit the number of study participants, or require periodic reports based on the number of subjects enrolled. The IRB approval automatically expires at 23:59 of the expiration date, or at the occurrence of an event set by the IRB (e.g. number of subjects enrolled). Both approval and expiration dates are specified on the approval letter sent to the Investigator. In determining the approval period, the IRB will consider the risks posed by the study intervention, the type of safety monitoring is provided in the protocol, and any other factors which affect the health and welfare of the study participants.

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**1.6. Compliance with HIPAA and Policy HI 1201.**

The IRB will ensure that Use and Disclosure of Protected Health Information related to the Research Study complies with Policy HI 1201 and federal and Wisconsin state privacy regulations.

**1.7. Reliance on Other IRBs for Review and Approval of Research Conducted at Aurora Health Care, Inc.**

Under authority granted by the Board of Directors of Aurora Health Care, Inc., the IRBs may enter into an IRB Authorization Agreement, to rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the Federalwide Assurance (FWA) agreements.

**1.8. Institutional Approval**

The Institutional Official, in consultation with the IRB Chair or the Site Administrator(s) of the Facility or Facilities where a research study will be conducted, may review a research study that has been approved by any of the IRBs and either disapprove or impose conditions on the conduct of such research study. However, neither the Institutional Official nor any Site Administrator shall have the authority to approve the conduct of a research study or any use of an investigational drug or investigational device at a Facility when the IRB has not approved the research study.

**1.9. Notification of IRB Approval or Disapproval**

1.9.1. The Principal Investigator will be notified in writing of the IRB’s decision as soon as possible after the IRB meeting. For conditional approval requiring additional or revised materials or responses from the investigator or sponsor, the Aurora IRB should receive the response or materials within 90 days of the date of notification. However, this period may be extended if the Principal Investigator communicates a need for an extension. If there is no communication by the Principal Investigator within 90 days, the RSPP office may withdraw the study. The Principal Investigator will be notified in writing.

1.9.2. The Principal Investigator will be notified in writing of the final approval. The Aurora IRB approved consent/authorization document will be dated with the period of approval and forwarded to the Principal Investigator (or his/her representative) via e-mail or Cyber IRB. Standard conditions for continued approval are included in the approval letter.

1.9.3. If the Aurora IRB disapproves the research study, the Principal Investigator will be notified in writing as soon as possible of the IRB’s decision.

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Correspondence will provide the reason(s) for disapproval and instructions for the Principal Investigator for appeal of such decision.

1.9.4. The Aurora IRB will notify the Institutional Official of all approvals or disapprovals of research studies.

**1.10. Investigator Appeal of IRB Action**

A Principal Investigator may appeal the revisions required by the Aurora IRB to the protocol and/or the informed consent/authorization document. This appeal must be in writing and submitted to the IRB Chair via the RSPP Manager. The Principal Investigator may also appeal an Aurora IRB decision to disapprove a study. Any such appeal must be in writing and must be reviewed by the full IRB at a convened meeting. The Principal Investigator may appear before the IRB at the meeting. If the appeal is denied and the study disapproved, the Site Administrator may not override the IRB’s decision.

**1.11. Notification of Suspension or Termination of IRB Approval For Cause**

The Aurora IRB may suspend or terminate approval of a research study when the research is not being conducted in accordance with the IRB’s requirements or the study has been associated with unexpected serious harm to subjects. Policy RR 407). If the Aurora IRB suspends or terminates IRB approval, the suspension or termination will be reported to regulatory agencies and institutional officials in accordance with the External Reporting policy (Policy RR 408).

**1.12. IRB Notification of Protocol Termination At Other Research Sites**

If an Investigator for a multi-site study becomes aware of a termination of IRB approval of the research study at other research sites, it is the Investigator’s responsibility to inform the Aurora IRB immediately. The reasons for the termination will be reviewed by the RSPP and Aurora IRB as appropriate. The Aurora IRB will notify the Principal Investigator of any decisions relative to the local study as soon as possible.

**2. SCOPE**

These policies and procedures apply to all RSPP staff and IRB members and to all research submitted to the Aurora IRB.

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**3. APPLICABLE REGULATIONS, GUIDELINES, AND STANDARDS**

45 CFR 46.103(b)(4) and (5), 46.109, 46.111, 46.112

21 CFR 56.108, 56.109, 56.111, 56.112

OHRP Guidance on Written IRB Procedures (January 15, 2007)

Wis. Admin. Code § DHS 94.13

Wis. Stat. § 51.61

AAHRPP Element I.1.F., Standard II-2, Element II.2.D., Standard II-3, and Elements II.3.A., II.3.B., and II.3.G.

**4. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 301

SOP 404

SOP 502

SOP 601

SOP 1201