

<b>SOP: FO 304</b> <b>Version No.: 05</b> <b>Effective Date: 2/10/11</b>	<b>IRB MEETING ADMINISTRATION</b>	<b>Supersedes</b> <b>Document</b> <b>Dated: 7/1/08</b>
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Steering Committee approved 4/6/11

## 1. POLICY

Except when an expedited review procedure is used or a study is deemed exempt, the IRB will review proposed research at convened meetings at which a quorum is present. The IRB will meet at established meeting dates as discussed in section 1.1 of this Policy. The Senior IRB Chair may call a “special meeting” at which the IRB will convene to address issues that the Senior IRB Chair believes requires IRB consideration before the next scheduled meeting.

### Specific Policies

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

#### 1.1. Meeting Schedule

1.1.1. Each IRB has established-meeting dates, and a tentative meeting schedule for the year that is determined in early fall of the previous year. The schedule is distributed to all IRB members in their meeting packet. The schedule is also placed on the IRB web site, along with a listing of protocol submission deadlines.

1.1.2. It is sometimes necessary to change a previously scheduled meeting date. IRB members are notified by e-mail, phone or fax of such changes. A notice is also placed in the meeting packet if applicable. A notice of meeting date change is also placed on the IRB web site.

1.1.3. It may be necessary to hold a “special meeting” to address issues that the Senior IRB Chair believes requires IRB consideration before the next scheduled meeting. IRB members are notified by e-mail, phone or fax of the date of the “special meeting”. A notice will also be placed in the meeting packet if applicable.

#### 1.2. Quorum

1.2.1. Quorum is defined as:

- (i) a majority (more than half) of voting members;
- (ii) at least one member whose primary concerns are in scientific areas;
- (iii) at least one member whose primary concerns are in nonscientific areas;
- (iv) at least one member who represents the general perspective of research subjects will attend at least 80 percent of IRB meetings held per calendar

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year (accreditation standard)

(v) at least one unaffiliated member will attend at least 80 percent of IRB meetings held per calendar year (accreditation standard); ; AND

(vi) when research involves the enrollment of subjects who are vulnerable to coercion or undue influences, at least one member who is knowledgeable about or experienced in working with such subjects. When research involves the enrollment of subjects who are inpatients in a hospital and are being treated primarily for conditions related to mental health, developmental disabilities, alcoholism, or drug abuse, there shall be one member who is or has been a consumer of such services and one who represents an organization or agency that advocates the rights of such inpatients. When research involves prisoners, the prisoner representative shall be present.

1.2.2. An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above, provided that the alternate is given all meeting materials in advance of the meeting with sufficient time to review.

1.2.3. If quorum is lost during an IRB meeting, the IRB will not conduct business requiring a vote, until quorum is restored.

### 1.3. Primary Reviewers

Prior to the meeting, the Senior IRB Chair will designate a Primary Reviewer for each research proposal based on the committee member's expertise and the experience on the committee. The RSPP Manager or alternate will also review the members scheduled to be present at the meeting and ensure that:

- When research involves the enrollment of subjects who are inpatients in a hospital and are being treated primarily for conditions related to mental health, developmental disabilities, alcoholism, or drug abuse, at least one member who is or has been a consumer of such services and one who represents an organization or agency that advocates the rights of such inpatients will be present at the meeting.
- When research involves the enrollment of subjects who are vulnerable, at least one member who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
- The IRB is otherwise constituted with the appropriate expertise.

If the RSPP Manager determines that appropriate membership will not be present at a particular IRB meeting, he/she will inform the IRB Chair who will defer the review of the

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study(ies) to another IRB meeting that will have appropriate expertise, or obtain an outside consultant to review the protocol for the IRB.

The Primary (and Secondary, if assigned) Reviewer duties are described in Policy OR 202.

#### **1.4. Meeting Materials Sent Prior to IRB Meetings**

All IRB members or their alternates will be sent a meeting packet prior to the scheduled IRB meeting. The meeting packet will contain the meeting materials required for review of all actions to be considered by the IRB, and will be sent sufficiently in advance of the meeting to allow time for adequate review. The meeting packet will include:

1.4.1. Agenda: a meeting agenda will be prepared by the IRB Coordinator (or designee) and distributed to IRB members prior to each meeting. A copy of the agenda will be maintained on file with the meeting minutes.

1.4.2. The voting ballot: The voting ballot will include all actions upon which the IRB must vote. It also includes a reminder for members to declare, at the outset of the meeting, any Significant Financial Interest or Significant Non-Financial Conflict of Interest that they may have with the research to be considered, and for them to absent themselves from the meeting room during discussion and voting on that particular protocol, except to provide information to the IRB. The IRB minutes will specifically reflect such recusals that occurred during the meeting.

If the IRB Chair has a Significant Financial Interest or Significant Non-Financial Conflict of Interest, another IRB member will preside over the meeting. Any issues related to whether a Significant Financial Interest or Significant Non-Financial Interest exists with respect to the IRB Chair shall be resolved by the Institutional Official.

1.4.3. Study materials for initial review.

(i) For each study to be initially reviewed by the fully convened IRB, all IRB members will receive, at a minimum, a copy of the following:

- A completed IRB Submission Form (FO 301-A)
- Proposed informed consent document(s) and/or script as appropriate
- Recruitment materials (Advertising) intended to be seen or heard by potential subjects, including e-mail solicitations, physician recruitment letters, and clinical trial web sites

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- Sponsor's sample informed consent, if applicable
- Subject materials (questionnaires, surveys, diaries, etc.), if applicable
- Any documentation (e.g. approval letter or conditional approval letter) from FDA related to a study with an IND or IDE
- Delegation of Authority log, if applicable.

(ii) In addition to the items listed in 1.4.3.i, for each study he/she is assigned to review, a Primary Reviewer will receive the following:

- Full Investigator's or Sponsor's protocol (including appendices, if applicable)
- Copies of letters of assurance or cooperation with research sites
- Most recent Investigator Brochure or device manual (if applicable)
- Any adverse event reports submitted by the study sponsor with the protocol
- Checklist for Reviewing Protocols (form RR 402-A) and any additional checklists for reviewing research involving vulnerable populations (e.g. pregnant women, prisoners, or children), or for making specific determinations about the research study (e.g., use of a surrogate decision maker in research)
- Grant Application: Regardless of funding source, if Aurora is the funding recipient ("awardee"), a copy of the grant application will be sent to the Primary Reviewer for review. The Primary Reviewer will review the grant application to ensure that the research described in the IRB proposal is consistent with the grant application. The IRB may require the Investigator(s) to: (i) summarize, and cross-reference to the application, specific information contained in the grant application; (ii) identify any IRB-approved protocols that describe the proposed research; and (iii) either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.

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- IRB Review of NIH-Approved Informed Consent Documents for NIH-Supported Multi-center Clinical Trials: If available, for NIH-supported multi-center clinical trials, the IRB must receive and review a copy of the NIH-approved sample informed consent document and the full NIH-approved Investigator's protocol as a condition for review and approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the Investigator, approved by the IRB, and reflected in the IRB minutes.

#### 1.4.4. Study materials for review of modifications.

(i) For each study undergoing modification review by the full IRB, all IRB members will receive, at a minimum, the following:

- the completed modification form, including a detailed summary of the changes to the study (a separate summary of changes to the protocol may be appended);
- other modified documents (e.g. consent document, submission application, recruitment tools, etc.) as applicable.

(ii) For each study undergoing review of modifications by full committee, the Primary Reviewer will also receive at a minimum, the following:

- the annotated version of the revised protocol
- other revised documents as necessary (e.g. revised Investigator Brochure or Device Manual, etc).

#### 1.4.5. Study Materials for Continuing Review.

(i) For each study-undergoing continuing review by the full IRB, all IRB members will receive, at a minimum, the following:

- A completed Continuing Review Form (RR 404-A)
- Any submitted materials to address questions on the Continuing Review Form
- The current consent document (if applicable).

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(ii) For each study undergoing continuing review by the full IRB Primary Reviewers, and Secondary Reviewers as assigned, will also receive, at a minimum, the following:

- The complete protocol that includes any protocol modifications previously reviewed by the IRB.

1.4.6. Any other materials to be discussed by the full committee, including forms RR 403-A and RR 03-B,RR403-F, or RR403-G, and IRB member education materials.

## 1.5. Minutes

Minutes will accord with the federal regulations for the protection of human subjects [45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2)], which require that “Minutes of IRB meetings ... shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.”

The Aurora IRB meeting minutes will also address a research study’s compliance with HIP AA's privacy standards.

1.5.1. Recording: The RSPP manager or designee will take minutes of each meeting using the IRB Agenda/Minutes Template (Form FO 303-A). Minutes will be written in sufficient detail to show the following:

- The names of all individuals attending any part of the meeting, including status of each attendee (regular or alternate member, consultant, guest, etc.);
- If an alternate member attends a meeting in place of a regular member, the meeting minutes will reflect that name of the regular member that the alternate is replacing
- The establishment of a quorum including the number of non-scientific members present;
- When a member is not present for discussion of the entire protocol and the fact that he/she does not vote;
- Actions taken by the IRB on each agenda item requiring full IRB review, including the basis for requiring changes in or disapproving the research, the protocol or the informed consent document;

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- “Conditional approval”: The IRB may request that investigators make specific changes to the research protocols or informed consent documents or submit clarifications or additional documents. This is considered “conditional approval”. The conditional approval will be documented as well as the individual designated by the IRB to review responsive materials from the investigator and determine that the conditions have been satisfied and further review by the IRB at a subsequent convened meeting would not be necessary.
- Stipulations of approval: Post approval requirements of the research, including but not limited to: post approval reporting requirements, monitoring requirements, IRB approval limitations of the submitted research proposal.
- Summary of the discussion of controverted issues and resolution;
- The rationale for significant risk/non-significant risk device determinations;
- Voting results, including number for, against, abstained and reused, and total number present. Each vote also records the names of the members present at the meeting but who did not vote because they were not in attendance for the entire discussion of the protocol, or from whom a completed ballot was not received.;
- The names of IRB members who left the meeting because of a conflicting interest along with the fact that a conflicting interest was the reason for the refusal.
- The approval period. When the IRB determines that research requires IRB review more frequently than annually, the meeting minutes must document the IRB’s basis for establishing such review interval.;
- Determinations required by the federal regulations and protocol-specific findings justifying those determinations:
  - Waiver or alteration of the consent process,
  - Research involving pregnant women, fetuses, and neonates.;
  - Research involving prisoners.;
  - Research involving children.;

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- When the IRB approves a research study that is sponsored and financially supported by the NIH, the meeting minutes must reflect that any changes to the sample NIH approved informed consent or NIH-approved research study protocol approved by the IRB were justified in writing by the investigator to the satisfaction of the IRB; and
- HIPAA determination as outlined in Policy HI 1201 regarding compliance with the privacy standards set forth under federal and state law.

1.5.2. Approval: Draft minutes will be distributed to members at a subsequent IRB meeting for review and approval.

- Corrections requested by the IRB will be made by the RSPP manager or designee and the minutes will be printed in final form and made available to members at the following meeting. The IRB Chair and the person preparing the minutes shall sign and date final, approved minutes.
- The IRB Coordinator will maintain copies of the minutes, as well as the agenda and pertinent materials on file (see Policy FO 305).

### 1.5.3. Approved Minutes

A copy of the approved minutes is sent to the Institutional Official, as well as the Vice President of Research and Academic Relations, who in turn, sends them to all appropriate Site Administrators based on where the research is to be conducted.

## 1.6. Telephone and Video Conferencing Use

### 1.6.1. Convened meeting using telephone conferencing/video conferencing

Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using telephone conferencing or video conferencing. The member who is not physically present will be connected to the rest of the members via speaker phone or video conferencing technology. In this manner, all members will be able to discuss the protocol even though the member(s) is not physically present.

Members participating by technology may vote, provided they have had an opportunity to review all materials the other members have reviewed prior to the meeting.

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The minutes shall denote that the voting member attended the meeting via telephone conference call or video conference call, and that he/she received all pertinent meeting materials prior to the meeting. The minutes shall also denote that the member attending via telephone conference call actively and equally participated in the discussion of all protocols.

#### 1.6.2. Meetings Conducted Via Telephone Conference or Video Conference Calls

On rare occasion, a meeting may be convened via telephone conference call or video conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

#### 1.7. **Voting**

Members not present at the convened meeting, nor participating via telephone conference call or video conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

For a member's vote to count toward the final decision on a study, the member must be present or connected for the entire discussion.

Voting will occur by coded ballot at a convened IRB meeting. The ballots are coded so that the RSPP staff can ensure that no member with a known conflict of interest voted inadvertently. Members of the IRB vote upon discussion of the recommendations made by the Primary Reviewer, and according to the criteria for approval (see Policies RR 402 and RR 404). The votes are tallied and reflected in the minutes. The voting ballot is not retained.

## 2. **SCOPE**

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

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

45 CFR 46.103, 46.108

45 CFR parts 160 and 164

21 CFR 56.108, 56.109

FDA Information Sheets, 1998

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OHRP Guidance on IRB Meetings Convened via Telephone Conference Call (March 28, 2000)

OHRP Compliance Activities: Common Findings and Guidance, Section G (July 11, 2002).

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

AAHRPP Elements II.1.D., II.1.E., II.2.C., and II.5.B.

#### **4. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 203

SOP 402

SOP 404

SOP 501

SOP 701

SOP 702

SOP 1201