SOP: 203
Duties of IRB Members

1. POLICY

Each IRB member's primary duty shall be the protection of the rights and welfare of the individual human beings who are serving as the participants of research. The IRB member shall understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Investigator and the research participants. In order to fulfill their duties, IRB members shall be versed in regulations governing human participants' protection, biomedical and social behavioral research ethics, and the policies of the University germane to human research participant protection.

Specific Policies

1.1 Attendance

Members of the IRB shall attend IRB meetings on a regular basis. Failure to attend regularly could result in the member's removal from the IRB.

1.2 Expectations

1.2.1 Member Expectations

Nonaffiliated member(s): Nonaffiliated members shall provide input based on their knowledge about the local community and be willing to discuss issues and research from their perspective.

Non-scientific members: Nonscientific members shall provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants.

Scientific members: Scientific members shall contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members shall also be able to advise the IRB if additional expertise in a scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants.

IRB Chair: In addition to the above responsibilities, the IRB Chair shall chair meetings of the IRB. IRB Chairs shall perform or delegate to an appropriate voting IRB member expedited review when appropriate and suspend the conduct of a research project deemed to place individuals at unacceptable risk, pending IRB review. The IRB Chair shall be empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an Investigator is not following IRB requirements.

The IRB Chair, in consultation with the Director of Compliance and the respective HRPP Director, may appoint an IRB Vice Chair to assist or act on behalf of the IRB Chair in particular IRB matters and at IRB meetings, either as a general procedure or on a case-by-case basis. The IRB Chair also may delegate any of his/her responsibilities as appropriate to other qualified individuals. Such documentation shall be in writing and maintained by the respective HRPP Director.

1.2.2 IRB Expectations

The IRB shall operate as a fair and impartial Board, immune from pressure by the University's administration, the Investigators whose protocols are reviewed, or other sources.

1.3 Primary and Secondary Reviewer Model

1.3.1 Convened IRB Review

The IRB utilizes the primary and secondary reviewer model to review research projects reviewed by the convened IRB. The primary and secondary reviewer model is used for initial review, continuing review, and review of modifications to currently approved research projects. The IRB Chair is authorized to delegate the review to one primary and one secondary reviewer based upon the member's expertise and experience. The criteria used to determine whether IRB members are considered experienced to conduct reviews is in the general opinion of the IRB Chair or designee.

1.3.1.1 Primary Reviewer

The primary reviewer (one member) shall present his/her findings and provide an assessment of the soundness and safety of the protocol to the IRB. He/she shall make specific recommendations or clarifications required for approval and leads the IRB discussion of the study. The primary reviewer is required to conduct an in-depth review of all materials.

1.3.1.2 Secondary Reviewer

The secondary reviewer (one member) shall add to the discussion, as necessary. The secondary reviewer is required to conduct an in-depth review of all materials.

1.3.1.3 Other IRB Members

Other IRB members are expected to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

1.3.2 Expedited Review

The IRB Chair reviews or delegates review to an appropriate Vice Chair for protocols that are granted expedited review. In the event both the IRB Chair and Vice Chair are unavailable, the IRB Chair, HRPP Director, or IRB staff shall select a reviewer from the IRB members to conduct expedited review.

1.4. Review Requirements

1.4.1 VA Research

When the IRB reviews VA research that involves mentally disabled persons or persons with impaired decision-making capacity, the IRB membership shall include at least one member who is an expert in the area of the research. The IRB Administrator shall make certain that one or more individuals who are knowledgeable about or experienced in working with such participants will be present at the meeting.

1.4.2 Vulnerable Populations

When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Administrator shall make certain that one or more individuals who are knowledgeable about or experienced in working with such participants will be present at the meeting.

1.4.2.1 Prisoners

When the IRB reviews research that involves prisoners, the IRB Administrator shall make certain that one or more individuals who are prisoner representatives or prisoners will be present at the meeting.

When the IRB reviews research that involves prisoners**,** a majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

2. SCOPE

These policies and procedures apply to all IRB members and staff.

3. RESPONSIBILITY

The HRPP Director is responsible for clearly articulating all IRB members' duties to potential and current IRB members.

IRB members are responsible for fulfilling their duties as specified in this SOP.

IRB members are responsible for utilizing appropriate checklists for verifying and documenting the review determinations.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Guidance Document, IRB Guidebook

FDA Information Sheets, Guidance for IRBs and Clinical Investigators, Frequently Asked Questions, 1998 Update

5. REFERENCES TO OTHER APPLICABLE SOPS

None.

6. ATTACHMENTS

203-A	HSC New Study Reviewer Checklist – Full Board
203-A-1	Norman Campus New Study Reviewer Checklist – Full Board
203-B	HSC New Study Reviewer Checklist – Expedited
203-B-1	NC New Study Reviewer Checklist - Expedited
203-BB	HSC & NC Categories of Expedited Review Criteria Checklist
203-C	HSC New Study Reviewer Checklist – Exempt
203-C-1	NC New Study Reviewer Checklist - Exempt
203-CC	HSC Categories of Exemption Checklist
203-CC-1	NC Categories of Exemption Checklist
203-D	VA Research Reviewer Checklist
203-E	HSC Reviewer Checklist for Research Involving Pregnant Women, Fetuses, & Neonates
203-E-1	NC Reviewer Checklist for Research Involving Pregnant Women, Fetuses, & Neonates
203-F	HSC Reviewer Checklist for Research Involving Prisoners
203-F-1	NC Reviewer Checklist for Research Involving Prisoners
203-G	HSC Reviewer Checklist for Research Involving Children
203-G-1	NC Reviewer Checklist for Research Involving Children

203-H HSC Continuing Review Reviewer Checklist
203-H-1 NC Continuing Review Reviewer Checklist
203-I HSC Modification Reviewer Checklist
203-I-1 NC Modification Reviewer Checklist
203-J HSC Waiver of Consent Checklist
203-J-1 NC Waiver of Consent Checklist
203-L Member Responsibilities - Member
203-M Member Responsibilities - Chairperson
203-N Member Responsibilities - Alternate Member
203-O Member Responsibilities - Reviewer Duties

7. PROCESS OVERVIEW

7.1 IRB(s) are appointed as committees to serve the University. Each IRB member serves the University as a whole. IRB members act as a gatekeeper between the Investigator and the research participants by protecting the rights and welfare of human research participants.

7.2 Certain duties are expected of each member during the term served. The HRPP Director explains the duties to potential members before a member is appointed to the IRB.

7.3 The HRPP Director documents the expectations for members of the IRB. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human research participant protection, biomedical and social behavioral research ethics, and the University policies concerning human research protections.

7.3.1 The HRPP Director documents the duties and expectations of IRB members and periodically reviews members' duties.

7.3.2 The HRPP Director or designee maintains current descriptions of IRB member responsibilities and answers questions from IRB members as needed.

7.3.3 The HRPP Director meets with prospective members to discuss the expectations of IRB members.

7.3.4 The HRPP Director notifies the IRB Education Coordinator of a new member appointment. The IRB Education Coordinator schedules a New Member Orientation with the new IRB member and prepares a New member packet. The HRPP Director and IRB Education Coordinator conduct a New Member Orientation for each new member appointed to the IRB.

7.3.5 The HRPP Director or designee attends the IRB meetings and monitors IRB member performance to make certain that members are carrying out their expected duties.

7.3.6 The HRPP Director monitors the membership of the IRB, per SOP 202, Management of IRB.

7.3.7 The HRPP Director makes recommendations to the IRB Chair as needed regarding changes to member description of responsibilities, staffing, meeting scheduling, and other factors that affect members' ability to perform their duties.

7.4 At the convened IRB meetings, IRB members' responsibilities include acting as Primary and Secondary Reviewers.

7.4.1 The HRPP Director documents the duties and expectations of IRB members acting as Primary and Secondary Reviewers.

7.4.2 The HRPP Director or designee maintains current descriptions of Primary and Secondary Reviewers' responsibilities and answers questions from IRB members as needed.

7.4.3 The IRB Administrator requests the IRB Chair to assign Primary and Secondary Reviewers for the meeting before the agenda is completed.

7.4.4 The IRB Administrator includes the names of the Primary and Secondary Reviewers on the agenda for each convened Board meeting item. IRB members are responsible for acting as the Primary or Secondary Reviewers at the convened meeting.

7.5 IRB Chairs, Vice Chairs, and IRB members' responsibilities include utilizing reviewer checklists.

7.5.1 IRB Chairs, Vice Chairs, and IRB members review initial research projects, continuing reviews, and modifications to previously approved research utilizing the appropriate reviewer checklists.

7.5.2 IRB Chairs, Vice Chairs, and IRB members document and verify their review determinations utilizing the appropriate reviewer checklists.

APPROVED BY:_____ **DATE: 09/01/2009**

NEXT ESTABLISHED REVIEW DATE: May 2012