

**DUTIES OF IRB MEMBERS**

<b>SOP #:</b>	<b>203</b>	<b>VERSION #:</b>	<b>1</b>	<b>EFFECTIVE DATE:</b>	<b>5/1/09</b>	<b>SUPERSEDES DOCUMENT:</b>	<b>/ /</b>
<b>THIS POLICY PERTAINS TO:</b>			<b>THE IRB</b>				
<b>RESPONSIBILITY FOR EXECUTING POLICY:</b>		<b>VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT; ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT</b>					
<b>LAST REVIEWED ON:</b>		<b>/ /</b>		<b>RESULTS:</b>	<b>REVISED</b>		
<b>APPROVAL AUTHORITY:</b>		<b>Associate Vice President for Research and Economic Development</b>					
<b>APPROVED BY:</b>						<b>DATE:</b>	<b>/ /</b>

**1. POLICY**

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of that research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to serve as a link between the Investigator and the research subjects. In order to fulfill his or her duties, IRB members are expected to be knowledgeable of the regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of the University of North Dakota germane to human subject protection. The IRB must be, and must be perceived to be, fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional or nonprofessional sources.

**2. SPECIFIC POLICY**

**2.1 Duty to the University of North Dakota**

The IRB is a University committee. As such, IRB Members serve the University of North Dakota as a whole, rather than a particular school or department. Therefore, members must not allow their own interest or that of their department to supercede their duty to protect the rights and welfare of research subjects.

**2.2 Term of Duty**

Regular IRB members are expected to commit to a 3 year term of service and during that time, fulfill certain duties. These duties will be described prior to appointment, and each IRB member is expected to fully understand the duties of IRB members prior to accepting appointment as an IRB member.

**2.3 Specific Duties**

**2.3.1 Regular and Alternate Members:**

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

2. Nonscientific members: Nonscientific members are expected to 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 if a protocol adequately protects the rights and welfare of subjects.
3. Nonaffiliated members: Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
4. IRB Chairperson: In addition to the above responsibilities (germane to the member's capacity), the Chairperson chairs the meeting. The IRB Chairperson performs, or delegates to appropriate voting IRB members authority to perform, expedited and exempt review when appropriate. The IRB Chairperson is empowered to suspend the conduct of a research project or clinical trial deemed to place individuals at unacceptable risk, pending IRB review. The IRB Chairperson is also empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an Investigator is not following the IRB requirements.

The IRB Chairperson may delegate to the IRB Vice Chairperson or to an experienced IRB Member to assist or act on behalf of the IRB Chairperson in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis. The IRB Chairperson also may delegate any of his/her responsibilities as appropriate to other qualified individual.

2.3.2 Primary Reviewers: In addition to the duties described in section 2.3.1 above, each regular member will be expected to act as a Primary Reviewer for assigned studies at convened meetings. The Primary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. He or she leads the IRB discussion of the study. The Primary Reviewer is required to review the entire protocol submission. An IRB member may not participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB, and would therefore not be assigned as a Primary Reviewer to such a project.

2.3.3 Regular Reviewers: All members of the IRB will receive all submission materials. When a reviewer is not assigned as a Primary Reviewer, the reviewer will review the study materials thoroughly enough to be prepared for the meeting and to provide input into the discussion.

### **3. RESPONSIBILITY**

The IRB Coordinator 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.

### **4. APPLICABLE REGULATIONS AND GUIDELINES**

[OHRP IRB Guidebook](#)  
[FDA Information Sheets, FAQ's, Section II, question 17](#)

## 5. ATTACHMENTS

OR 203-A Regular Member Responsibilities  
OR 203-B Alternate Member Responsibilities  
OR 203-C IRB Chairperson Responsibilities  
OR 203-D IRB Vice Chairperson Responsibilities  
OR 203-E Reviewer Duties  
OR 203-F Subcommittee Member Responsibilities  
OR 203-G Subcommittee Chairperson Responsibilities

## 6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Chairperson, IRB Coordinator</i>	Document the expectations for members of the IRB.
<i>IRB Coordinator</i>	Meet with prospective members to discuss expectations.