COMPOSITION OF THE IRB

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THIS POLICY PERTAINS TO:			**THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT**				
LAST REVIEWED ON:			**/ /**	**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:			**Associate Vice President for Research and Economic Development**				
APPROVED BY:						**DATE:**	**3/1/14**

1. POLICY

The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The composition of the UND IRB complies with or exceeds the minimum guidelines set forth in the federal regulations. The UND IRB is composed of at least ten members and three alternate members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Qualified persons from multiple professions and of both sexes shall be considered for membership. IRB membership shall not consist entirely of men or of women. The University of North Dakota will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

Individuals who are responsible for business development are prohibited from:

- Serving as members or ex-officio members on the IRB.
- Carrying out day-to-day operations of the review process.

2. SPECFIC POLICIES

2.1 Membership Selection Criteria

The IRB members shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes, to assess the research submitted for review.

There shall be at least 1 member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be 1 member who has no

other affiliation with this institution, either self or family member. For FDA-regulated research, there shall be at least one member who is a licensed physician.

2.2 Composition of the Board

2.2.1 **Regular Members:** The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include the following:

1. Scientific member(s): The IRB shall include at least one member whose primary concerns are in scientific areas. A physician or Ph.D. level physical or biological scientist would satisfy this membership requirement. When the IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 45 CFR 46.107(f) and 21 CFR 56.107(f). However, when FDA regulated products are reviewed, the convened meeting must include a licensed physician member; therefore, at least one member of the IRB must be a physician licensed in the state of North Dakota.

2. Nonscientific member(s): The IRB shall include at least one member whose primary concerns are in nonscientific areas. Nonscientific members are individuals whose education, work, or interests are not primarily in medical or scientific areas.

3. Nonaffiliated member(s): The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The nonaffiliated member can be either scientific or nonscientific, but should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

4. IRB Chairperson: The IRB Chairperson should be a highly respected individual from within or outside the University of North Dakota, fully capable of managing the IRB and matters brought before it with fairness and impartiality. The IRB Chairperson must be an experienced member of the IRB, and can be either a scientific member or non scientific member. The Chairperson is elected annually from the membership of the IRB to serve a one-year term of office. The number of consecutive terms that a Chairperson may serve is not limited.

5. IRB Vice Chairperson: The IRB Vice Chairperson must be an experienced member of the IRB, and can be either a scientific member or non scientific member. The IRB Vice Chairperson is elected annually from the membership of the IRB to serve a one-year term of office. The number of consecutive terms that a Vice Chairperson may serve is not limited.

2.2.2 **Alternate Members:** Alternates to the IRB should be chosen for their expertise and perspective. They are qualified voting members who serve as designated alternates for regular members, but they are not required to attend each meeting. They will be asked to attend meetings when their expertise is needed and/or when they are needed to establish a quorum for the meeting in the absence of the designated regular member. Alternate members are encouraged to attend meetings regularly, but they will only vote when they are officially substituting for a designated regular member of the IRB. Alternates will receive all the materials for meetings and general

updates so they are able to actively participate in meetings. Alternates on campus may also be asked to review proposals.

2.2.3 **Vulnerable Populations:** When the IRB reviews research involving a vulnerable population, including categories of participants vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about and experienced in working with these subjects. The IRB will apply additional protections as necessary to protect potentially vulnerable research subjects. If the IRB regularly reviews such research, consideration will be given to include on the Board one or more individuals knowledgeable about our experienced in working with these participants.

2.2.4 **Special Representatives:** When certain types of research are reviewed, the IRB may secure the assistance of special representatives who are knowledgeable about the concerns of certain groups

2.2.5 **IRB Committees:** The Chairperson, with the approval of the IRB, may appoint standing committees or ad hoc committees. Each committee shall normally be composed of at least three members. The Chairperson may appoint non-IRB members to a committee. Each standing or ad hoc committee shall have those powers and that authority stipulated in the motion authorizing the committee. Each standing or ad hoc committee shall serve at the pleasure of the IRB.

1. **Clinical Medical Subcommittee:** The purpose of the Clinical Medical Subcommittee of the UND IRB is to provide preliminary review for clinically oriented medical projects that would be considered to be greater than minimal risk to participants.

   The Clinical Medical Subcommittee is composed of at least three members who represent health-related disciplines, including at least two physicians. The subcommittee composition is designed to adequately protect the interests of patients and others subjected to medical research procedures.

   a. Appointment: Members of the Clinical Medical Subcommittee are appointed to their positions by the Vice President for Research and Economic Development upon nomination by the IRB.

   b. Term of Office: The term of office is three years, and there is no limit to the number of consecutive terms that a member may serve on the Subcommittee.

   c. Removal: Members of the Clinical Medical Subcommittee may be removed from office following determination by the IRB, based on a two-thirds majority vote of the full IRB, that the member is unable or unwilling to fulfill the responsibilities of a member of the Subcommittee. Final determination is made by the Vice President for Research.

   d. Chairperson: The Chairperson of the Clinical Medical Subcommittee is appointed by the Vice President for Research and Economic Development to serve for at least one year. The Chairperson is also a full voting member of the IRB. The Chairperson is responsible for maintaining all necessary communication and correspondence between the IRB and the Subcommittee, and for presenting Subcommittee recommendations and comments to the IRB. If the Chairperson is unable to attend a meeting of the IRB, another member of the Subcommittee may be appointed to

attend, or the Chairperson may submit comments in writing to the Chairperson of the IRB or to the IRB Secretary.

e. Responsibilities: The Clinical Medical Subcommittee reviews all clinically oriented medical proposals prior to their review by the IRB. Members of the Subcommittee may confer with the project director to gain additional information. The Subcommittee may advise the IRB to approve a proposal as submitted; to approve a proposal contingent on the proposal being modified in specified ways; to defer decisions about a proposal until major questions about human subjects' concerns have been resolved; or to disapprove a proposal. In all cases, projects requiring IRB review may only be approved at a convened meeting of the IRB where a majority of the IRB members are present and approve of the proposed involvement of human subjects.

2.2.6 **Consultants/Ad hoc Reviewers:** At the time of preliminary review of a new proposal or a modification to an existing proposal, the IRB Chair, IRB Coordinator, or the primary reviewer may request further review of the proposal by an outside consultant or ad hoc reviewer if it was determined that a consultant would aid in the review of the proposed research. The IRB Coordinator, in consultation with the IRB Chair, will identify a consultant based on the particular issues to be addressed. Depending on the complexity of the issue, a short list of written questions may be submitted to the consultant, and the responses may be read or distributed to the IRB. If the proposal requires full IRB review, the consultant may be invited to attend the IRB meeting, and key information provided by the consultant would be documented in the meeting minutes. The IRB may invite scientists or non-scientists from within or outside the University of North Dakota to attend IRB meetings. These individuals would have access to all documents submitted to the IRB relevant to the specific project under review, may participate at the deliberations and make recommendations on the project, but may not vote.

2.3 IRB Roster

An IRB Roster will be maintained for the IRB. The IRB members will be queried at the time of IRB appointment and approximately each year to evaluate any changes. The IRB Roster will contain the following information:

- Name of IRB member
- Earned degrees
- Scientific Status
- Representative capacity (e.g., children, pregnant women, prisoners, Native Americans)
- Experience and Credentials
- Relationship of the member to the organization
- Affiliation status
- Office (e.g., Chair or Vice Chair)
- Membership status
- List of members for whom the alternate member can substitute.

3. RESPONSIBILITY

The Vice President for Research and Economic Development is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members and for the appointment of such members.

The IRB Chairperson and the IRB Coordinator are responsible for recruiting, installing, and evaluating new IRB members, and for the annual evaluation of IRB membership.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107
21 CFR 56.107
FDA Information Sheets, FAQ section II, questions 14, 15

5. ATTACHMENTS

OR 201-A IRB Member Roster Fields

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
Vice President for Research and Economic Development, IRB Chairperson, IRB Coordinator	Ensure the overall diversity of the IRB membership (gender, race, ethnicity, community affiliation and professional experience) through non-discriminatory selection methods.
Vice President for Research and Economic Development	Following established criteria, appoint Chair and Vice Chair, and new primary or alternate members.
IRB Secretary, IRB Coordinator	Maintain a roster of all regular and alternate members Maintain a file on all members including their curriculum vita, education, nomination letters and other evidence of professional ability. Maintain a list of available consultants who are eligible and qualified to attend meetings as invited consultants. Maintain communication with the Clinical Medical Subcommittee for the review of clinically oriented research projects.