IRB MEETING ADMINISTRATION

SOP #:	**302**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**6/1/14**	**SUPERSEDES DOCUMENT:**	**5/1/09**
THIS POLICY PERTAINS TO:			**THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB STAFF**				
LAST REVIEWED ON:		/ /		**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:			**Associate Vice President for Research and Economic Development**				
APPROVED BY:						**DATE:**	**3/1/14**

1. POLICY

Except when an expedited or exempt review procedure is used, the IRB will review proposed research at convened meetings at which a quorum and appropriate expertise is present. Parliamentary procedure is according to the Standard Code of Parliamentary Procedure by Alice F. Sturgis. The IRB will meet monthly, or at some other frequency determined by the IRB Chairperson and the Associate Vice President for Research and Economic Development.

2. SPECIFIC POLICY

2.1 Quorum

- A quorum is defined as the majority of the voting members.
- A quorum consists of regular members and/or their alternate members and includes: at least one member whose primary concerns are in scientific areas; at least one member whose primary concerns are in nonscientific areas; and at least one non-affiliated member. The non-affiliated member also represents the general perspective of participants.
- When FDA-regulated research is reviewed there shall be one member who is a physician.
- An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.
- Consultants will not be used to establish a quorum and may not vote with the IRB.
- IRB members who leave the room due to a conflict of interest cannot be counted towards quorum.
- If quorum is lost during a meeting, the IRB cannot take votes until it is restored.

2.2 Primary Reviewers

Prior to the meeting, the IRB Secretary, in consultation with the IRB Coordinator and/or IRB Chairperson, will designate Primary Reviewers for each research proposal according to their scientific or scholarly expertise, and if there are not IRB members with the appropriate expertise, an expert consultation will be arranged.

2.3 Consultants

When the need for advance expertise has been identified, the IRB Coordinator, in consultation with the IRB Chairperson, will contact an appropriate expert (consultant) and arrange for

assistance. The consultant will be given the same materials as the Primary Reviewer. The consultant will be required to sign a Financial Interests Disclosure Document, if appropriate. The consultant may attend the IRB meeting and present their review. The consultant may participate in the deliberations and make recommendations, but may not vote. If the consultant is unable to attend the IRB meeting, a written report will be provided to all IRB members prior to or at the IRB meeting. If the consultant does not provide written report, key information from the consultant's verbal report to the IRB will be recorded in the minutes.

2.4 Research Involving Vulnerable Participants

If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants are present at a convened meeting.

2.5 Meeting Materials Sent Prior to IRB Meetings

All IRB members will be sent study documentation required for review sufficiently in advance of the meeting to allow time for adequate review. These materials include:

1. Agenda: a meeting agenda will be prepared by the IRB Secretary and distributed to IRB members prior to each meeting. A copy of the agenda will be maintained on file with the meeting minutes.

   The meeting agenda will remind members to declare any potential COI they may have with research that is about to be reviewed at the outset of each meeting. The IRB Chairperson will ask for a declaration of such conflict and this will be incorporated in the minutes of the meeting. The IRB minutes should also specifically reflect such recusals as they occur during meetings.

   The Agenda will list which members are assigned to be the Primary Reviewers for each study that is to be reviewed. The Primary Reviewers will review the projects they are assigned in depth and be prepared to present the study at the meeting. All other members are expected to review the study.

   All members will receive all of the submission documents with the exception of grant applications. Only the Primary Review will receive a copy of the grant.

2. Initial Reviewer materials (including Primary Reviewers)

   - A completed Human Subjects Research Form
   - Financial Disclosure/COI Form (if applicable)
   - Full Investigator's or Sponsor's protocol (if applicable)
   - Investigator Brochure (studies involving an experimental drug or device)
   - Proposed informed consent document(s) and/or script as appropriate
   - Copies of surveys, questionnaires, etc.
   - Copies of letters of cooperation with research sites
   - Advertising intended to be seen or heard by potential subjects, including email solicitations and physician letters
   - Grant Application (if applicable)
   - Data Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board (DSMB), if applicable for more than minimal risk research.
   - The DHHS-approved sample consent document (if applicable).

- The complete DHHS-approved protocol (if applicable).

3. Continuing Review materials

   - Completed Research Project Review and Progress Report
   - Copy of the current consent document(s) with the IRB approval date stamp
   - A clean copy of the consent documents(s) without the IRB approval date stamp
   - A copy of the current HIPAA Authorization document, if applicable and if separate from the informed consent
   - Any other relevant documents provided by the Investigator
   - The protocol or materials sufficient for the IRB to determine whether research meets the regulatory criteria for approval

4. Protocol Changes or Amendments to approved research: All IRB members are provided with and are asked to review sufficient information about the proposed changes to previously approved research to determine whether the modified research continues to fulfill the criteria for approval. The reviewer materials include:

   - Completed Protocol Change Form
   - Investigator's Protocol or Sponsor's protocol (if applicable)
   - Current approved consent/assent document(s) (if applicable)
   - Any newly proposed consent/assent document(s) (if applicable)
   - Any other relevant documents provided by the Investigator

2.6 Minutes

The Federal regulations for the protection of human subjects (45 CFR 46.115(a)(2)) require that the minutes of IRB meetings "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." These requirements are minimal.

The University of North Dakota does not believe it can be assumed that all regulatory requirements for review of research have taken place at an IRB meeting unless the IRB minutes record that they were considered and discussed. Minutes should enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions.

2.6.1 Recording: The IRB Secretary will take minutes of each meeting. Minutes will be written in sufficient detail to show the following:

- Meeting attendance including status of each attendee (regular member, consultant, etc.), alternate member and who they are replacing, and members who recuse themselves due to conflicts of interest, if any.
- The minutes document the members present at the beginning of the meeting, and document between actions those who enter and leave.
- Report of Exempt and Expedited Reviews, Adverse Events and unanticipated problems received and reviewed by the IRB since the last Full IRB meeting.
- Determination of level of risk for the research reviewed;

- Justification of deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
- Actions taken by the IRB on each agenda item requiring Full IRB action, including the basis for requiring changes in or tabling of the research. For proposals approved pending receipt of the minor modifications requested by the IRB, a list of the required modifications will be included in the minutes.
- Summary of the discussion of controverted issues and resolution.
- Summary of key information from consultant's report if applicable.
- Approval Period for initial and continuing review.
- Determinations required by the regulations, and protocol specific findings justifying those determinations: for waiver of alteration of informed consent; for research involving pregnant women, human fetuses, and neonates; for research involving prisoners; for research involving children as participants; and for research involving participants with diminished capacity. The rationale for significant risk/non-significant risk device determinations.
- Voting results, including the number for, against, abstaining, and abstaining due to a conflict of interest.

A majority of members must vote in favor of an action for that category of action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest must recuse themselves from the discussion and voting and such will be noted in the minutes.

2.6.2 Approval of Minutes: Minutes must be written and available for review within 3 weeks of the meeting date.

Draft minutes will be distributed to members at or before the next regularly scheduled IRB meeting for review and approval. Corrections requested by the IRB will be made by the IRB Secretary and the minutes will be printed in final form and made available to members at the following meeting.

A copy of the approved minutes will be sent to regular and alternate IRB members, Clinical Medical Subcommittee Members, the Internal Auditor, the Associate Vice President for Research and Economic Development, and Legal Counsel. Copies of IRB meeting agendas and minutes will be maintained in the Research Development and Compliance office.

2.7 Telephone Use

2.7.1 Convened Meeting using Speaker Phone:

> When an IRB member is not physically able to be present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the materials the other members have reviewed.

2.7.2 Meetings Conducted Via Telephone Conference Calls:

On occasion, meetings may be convened via a telephone 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.

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

2.8 Voting

Members of the IRB vote upon the recommendations made by the IRB according to the criteria for approval. Members also will determine level of risk and the frequency of review for each protocol.

3. RESPONSIBILITY

The IRB Chairperson or IRB Vice Chairperson are responsible for IRB meeting procedural conduct and documentation.

The IRB Chairperson or IRB Vice Chairperson is responsible for conduct and leadership of IRB meeting convened for review. In the absence or both the IRB Chairperson and IRB Vice-Chairperson, an experienced IRB member may be designated to chair an IRB meeting.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.108
21 CFR 56.108, 56.109
FDA Information Sheets, 1998

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Secretary	Complete agenda for IRB meetings and assemble meeting materials. Assign Primary Reviewers. Attend IRB meetings and record proceedings of the meeting. Provide IRB members with list of proposals and adverse events reviewed since the last regularly convened IRB meeting. Ensure that a quorum is present.
IRB Chairperson	Chair the IRB meeting. Ensure that a quorum is met, appropriate expertise is present, and all business is addressed, that proceedings are recorded, and that any member who has a conflict of interest does not participate in the IRB's consideration of the study for determination.
IRB Secretary	Complete draft of minutes and distribute to appropriate individuals. When minutes are approved, file a copy and distribute approved minutes to appropriate individuals.