

INITIAL REVIEW – CRITERIA FOR IRB APPROVAL

SOP #:	403	Version #:	1	EFFECTIVE DATE:	6/1/14	SUPERSEDES DOCUMENT:	5/1/09
THIS POLICY PERTAINS TO:			ALL RESEARCH SUBMITTED TO THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB STAFF, IRB MEMBERS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:		3/1/14

1. POLICY

All research proposals that intend to enroll human subjects must meet certain criteria **before** study related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report, and are specified below. In addition, certain other criteria that are unique to the University of North Dakota system may apply and must be met as well.

2. SPECIFIC POLICY

2.1 Minimal Criteria for Approval of Research

In order for a research project to be approved, the IRB must find that:

- A. Risks to subjects are minimized:
 - By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
 - In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - Data Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board (DSMB)

If the research study involves more than minimal risk, the UND IRB requires that each new research application except those qualifying as exempt include a Data

and Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board Plan (DSMB). Often in externally sponsored studies, the DSMP is normally incorporated into the protocol and is called a DSMB Plan. If the proposed study has a DSMB, a copy of the plan or charter will need to be attached to the IRB application.

For an Investigator-sponsored study involving greater than minimal risk, the Principal Investigator is responsible for creating and implementing a data and safety monitoring plan. The plan will need to detail how confidentiality is protected and, to the extent possible, risks are reduced to a minimum. The plan does not have to be complicated but should be appropriate for the risks associated with it. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, phase and size of the particular study.

The DSMP needs to address:

- Items to be monitored (i.e. subject eligibility, adherence to treatment plan, documentation of dropouts, evaluation of primary and secondary endpoints, adverse events and/or problems with informed consent).
- Data Management: who is responsible for the collection and storage of data, where will it be stored (i.e. lab notebook, database) and security measures needed to protect the data from inadvertent loss or inappropriate use. Who will perform analysis on the data and how often?
- A plan to assure compliance with reporting adverse events and/or unanticipated problems involving risk to participants or others.

C. Selection of subjects is equitable. In making this assessment the IRB will take into account the purpose of the research and the setting in which the research will be conducted. The IRB will evaluate the recruitment, enrollment, and payment procedures for participants to determine that the Investigator has access to a population that would allow recruitment of the required number of participants, and ensure that undue coercion will not be used. The IRB will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

D. Informed consent:

- will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.
- will be appropriately documented as required by the regulations.

The circumstances of the consent process must provide the prospective participant or the representative sufficient opportunity to consider whether to participate, and minimize the possibility of coercion or undue influence. The individuals communicating information to the participant or the representative during the consent process (in addition to the consent document) must provide that information in language understandable to the participant or the representative.

The information being communicated to the participant or the representative during the consent process must not include any exculpatory language through which the participant or the representative was made to appear to waive the participant's legal rights, and includes no language through which the participant or the representative appeared to

release the investigator, the sponsor, the institution, or its agents from liability for negligence.

There is a statement that results of the research will be posted on clinicaltrials.gov:

- “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

E. Sponsored Research Contracts

- Sponsor contracts that are reviewed by the UND Grants & Contracts Administration:

Grants & Contracts Administration will review contracts and the IRB and the Grants & Contracts Administration will share contract and study information as necessary for each sponsored protocol to ensure that protocol, consent, and contract language are consistent.

- Sponsor contracts NOT reviewed by the UND Grants & Contracts Administration:

When a contract is not reviewed by the UND Grants & Contracts Administration, but is reviewed by another entity in which the Investigator reports, the IRB application specifies that a copy of the contract must be submitted to the IRB with the proposal to ensure that the protocol, consent, and contract are consistent.

Contracts will be reviewed for the following by both the Grants & Contracts Administration and the Associate Vice President for Research and Economic Development:

- The organization will comply with the protocol, applicable regulations, and ethical requirements.
- The contract will define who will be responsible for research related injuries.
- If the sponsor will monitor the conduct of the research, the contract will be required to state that if the study monitor uncovers information that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB’s approval to continue the study, the sponsor will make sure that the information is communicated to the IRB.
- If the sponsor discovers results that could affect the safety or medical care, the sponsor will make sure the IRB finds out.
- A description of the plans for disseminating findings from the research and the roles that the Investigator and sponsor will play in publication or disclosure of the research results.
- The contract or other funding agreement requires the sponsor to send data and safety monitoring plans and reports to the organization.
- The contract or other funding agreements specifies the time frame for providing routine and urgent data and safety and monitoring reports to the organization as indicated in the data and safety monitoring plan approved by the IRB.
- The contract or other funding agreement specifies a time frame after closure of the study during which the sponsor will communicate to the organization any findings

that may impact participant safety. This will be based on the appropriate time frame for each individual study.

- F. When the research is more than minimal risk, the research plan must include adequate provisions for monitoring the data collected to ensure the safety of subjects.
- G. Where appropriate, there are adequate provisions to protect the privacy of subjects, and to maintain the confidentiality of data.
- H. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.
- I. The necessary resources are available, including:
 - Sufficient time to conduct and complete the research.
 - Adequate numbers of qualified staff.
 - Adequate facilities.
 - A process to ensure that persons assisting with the research were adequately informed about the protocol and their research-related duties and functions.
 - Availability of medical or psychological resources that participants might require as a consequence of the research.
- J. Studies are reviewed at intervals appropriate to the degree of risk the research subjects are exposed to as participants in the study, but not less than once per year.
 - Studies may be reviewed more frequently than annually if the IRB believes that the study population is especially vulnerable.
 - Studies may be reviewed more frequently if the IRB believes that previous studies indicate high incidence of adverse events.
 - Studies may be reviewed more frequently if the IRB believes close monitoring is indicated.
 - If the IRB determines that a study that has been approved for an annual review requires closer monitoring, the IRB may make a determination to review the study on a more frequent basis. The reasons for such a determination will be included in the minutes and communicated to the Investigator.
- K. Advertisements will be reviewed using SOP Attachment RR 403-A. The IRB will need to approve final copies of printed advertisements to evaluate the relative size of type used and other visual effects. If an advertisement is recorded for broadcast, the IRB will need to review the final audio or video recording.

2.2 Other Criteria

The IRB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

2.2.1 Clinical Medical Subcommittee

The Clinical Medical Subcommittee is responsible for reviewing all greater than minimal risk proposals coming before the IRB that involve human subjects who are patients undergoing medical treatment as part of the research project, or that involve imposing physical stress or intrusive medical procedures on research volunteers.

Research involving "intrusive medical procedures" is interpreted to include any research that involves entry into the participant's body by substances, surgery, examination procedures, or procedures for obtaining samples from the participant's body.

The Clinical Medical Subcommittee is not required to review any other types of proposals submitted to the IRB, but may request to do so on its own initiative.

2.2.2 For National Institute of Justice (NIJ) funded research:

- All projects are required to have a privacy certificate approved by the NIJ Human Subjects Protection Officer.
- Under a privacy certificate, researchers and research staff do not have to report child or elder abuse unless the participant signs another consent form to allow child or elder abuse reporting.
- All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researchers.
- The confidentiality statement on the consent form must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.

3. RESPONSIBILITY

The Associate Vice President for Research and Economic Development and Grants & Contracts Administration will review contracts to ensure that the required elements are present.

The IRB Secretary is responsible for ensuring that IRB reviewers have all the tools and resources they need to complete their research reviews.

The IRB Chairperson or IRB Coordinator is responsible for providing IRB members adequate submission review training and ongoing guidance.

The IRB Chairperson, in consultation with the IRB Coordinator and/or IRB Secretary, is responsible for selecting Primary Reviewers and/or consultants with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB.

IRB Members are responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

21 CFR 56.108, 56.111

5. ATTACHMENTS

RR 403-A Direct Advertisement Guidelines

RR 403-B Payment, Reimbursement, Compensation Guidelines

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Secretary</i>	Provide Primary Reviewers with appropriate Reviewer Checklist and Primary Reviewer Guidelines.
<i>IRB Secretary, IRB Chairperson, IRB Coordinator</i>	Select reviewers with appropriate expertise for the research to be reviewed. If advanced or other expertise is needed, obtain consultant.
<i>IRB Members, Primary Reviewers</i>	Review research proposal and summarize findings using the Primary Reviewer Guidelines.
<i>IRB Members, Primary Reviewers</i>	Ascertain whether any special considerations exist that may influence the review of a proposal.
<i>IRB Members, Primary Reviewers</i>	Ascertain whether the evidence exists that third party verification of submitted information is needed.
<i>Primary Reviewers</i>	Prepare summary of findings and recommendations for presentation at the next convened IRB meeting.