IRB-REQUIRED INVESTIGATOR ACTIONS

SOP #:	**801**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**6/1/14**	**SUPERSEDES DOCUMENT:**	**8/24/12**
THIS POLICY PERTAINS TO:			**ALL RESEARCH SUBMITTED TO THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, 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

Whether conducting single site or multi-site research, it is the Investigator's responsibility to keep the IRB informed of unexpected, protocol related, non-serious and serious adverse events, and other unexpected findings that could affect the risk/benefit ratio of the research. An Investigator is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events. Investigators are also responsible for informing government and other Sponsors of any unanticipated or serious adverse events, as appropriate.

2. SPECIFC POLICIES

2.1 IRB Review of Research

All human subjects research that is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University of North Dakota in connection with his or her institutional responsibilities must be reviewed by the IRB.

2.2 Investigator Expectations

It is an expectation that the investigator will:

- Design and implement ethical research.
- Comply with Federal regulations.
- Comply with UND IRB policies and procedures.
- Disclose any conflict of interest (financial or other) that may affect the relationship with the research participant or the outcome of the research.
- Have sufficient time to conduct and complete the research.
- Ensure that all persons assisting in the research are adequately trained and informed about the protocol.
- Consider whether other procedures involving less risk are more appropriate when designing the research and will employ sound scientific design in the conduct of research.
- Design the research using procedures already being conducted on the participants for non-research reasons.
- Minimize risk to the participant.

2.3 Informed Consent

The Investigator must obtain informed consent from subjects prior to their enrollment into the research. The Investigator must use the informed consent document approved by the IRB. Approval and expiration dates will be stamped on the approved consent documents, making them valid only during the dates indicated on the form. Investigators must follow Federal guidelines for obtaining informed consent. Project description, cover letters, or implied consent rather than informed consent documents may be used for exempt research projects.

2.4 Adverse Event and Unanticipated Problems Involving Participants or Others

The IRB must be informed of any serious, unexpected, or unanticipated problems involving risks to participants or others that occur during the approval period. Investigators or Sponsors must also submit Sponsor-generated reports of adverse events occurring at other investigative sites.

2.5 Protocol Changes or Amendments in Approved Research

Changes in approved research during the period for which approval has already been given may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects. Investigators or Sponsors must submit requests for changes to the IRB in writing using a Protocol Change Form. Upon receipt of the protocol change, the IRB Chairperson or designee will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the full IRB. Minor changes involving no more than minimal risk to the subject will be reviewed by the expedited review process. Changes in exempt projects can be approved by the IRB Chairperson or designee, or the IRB Coordinator.

2.6 Continuing Reviews and Project Closures

Continuations: The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. Investigators or their designees and/or Sponsors are required to provide a periodic report regarding their investigation prior to the end of the approval period, or upon completion of the study. For renewal of approval, a Research Project Review and Progress Report will be provided to the Investigator at least 45 days from study expiration date. A second reminder will be sent about 20-30 days before the expiration date.

Project Closure: All research projects need to be closed out once data analysis is completed. A Research Project Termination Form needs to be filled out and sent to the Research Development and Compliance office.

2.7 Student-Conducted Research

Activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include: (i) All master’s theses and doctoral dissertations that involve human subjects; and (ii) Research projects that involve human subjects and for which findings may be published or otherwise disseminated. All

students applying for IRB review must obtain the signature of their faculty advisor on the Human Subjects Review Form or Exempt Certification Form.

2.8 Conflict of Interest

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. Therefore, the IRB considers financial and other conflict of interest issues in its objective deliberations on applications.

Investigators engaged in research must disclose on at least an annual basis all financial interests related to their research, and provide updated information within 30 days when new financial circumstances may pose a conflict of interest and when research proposals and grant applications are submitted. Investigators are required to submit this information for themselves and all research staff working on the project.

Investigators whose projects require Full Board or expedited review must reveal on their application to the IRB whether they have an economic interest in, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research. It is the Investigator's obligation to complete the Financial Interests Disclosure Document in order to report potential conflicts to the Research Development and Compliance office. This must be done at the time of initial review, at the time of continuing review, and when there are changes in financial circumstances. If a conflict exists, a Financial Interests Disclosure Document must be completed and submitted with the initial IRB application. Whenever there is a change in financial circumstances, an update must be provided to the IRB within ten (10) working days. Documentation as described above is required of the principal investigator and all research personnel. It is the principal investigator's responsibility to ensure that all research personnel have submitted the necessary documentation.

The following defines conflict of interest and significant financial interest.

Conflict of Interest: A conflict of interest occurs when an employee is involved in an activity, commitment, or interest that could adversely affect, compromise, or be incompatible with the obligations of the employee to the University of North Dakota. A conflict can involve commitment of time, research integrity, or financial gain.

A **conflict of time commitment** means employee involvement in and commitment to unauthorized non-university activities that interfere with obligations to students, colleagues, and the primary mission of the University.

A **conflict of research integrity** means any obligation between an employee and an external entity that is in conflict with the employee's obligations to the University, or that restricts or impairs the employee's ability to perform research or other activities at the University.

A **conflict of financial interest** means influencing the University in such a way as to lead to unauthorized direct or indirect financial gain for the employee or any member of the employee's close family (spouse and/or dependent children). Conflicts of financial interest may arise when a person who has a significant financial interest in a non-university entity a) can also influence or approve purchase of goods or services worth

more than $10,000 per year in their university role, or b) is responsible for the design, conduct, or reporting of research supported by federal agencies.

The term **significant financial interest** means anything of monetary value, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria); equity interests (e.g., stocks, stock options, patents, copyrights, other ownership interests); and non-University royalties from intellectual property rights (e.g., patents, copyrights, trade secrets, and trademarks). Any of these conflicts of interests of any PI, Consultants to the IRB, or staff, or his or her immediate family, in aggregate. (The thresholds described apply to the aggregate ownership of IRB members or staff and his or her immediate family. For example, if a PI, his/her spouse, and dependent children own together $10,000 or 5% worth of equities in the sponsor).

If a financial interest is disclosed on the Financial Interests Disclosure Document, the Associate Vice President for Research and Economic Development will review the form. If a conflict appears to exist, the Associate Vice President for Research and Economic Development, with the assistance of the IRB, will require the Investigator to manage the conflict of interest so that it does not adversely affect the participant or the credibility of the human research protection program. Management of the conflict of interest may include, but is not limited to:

- Divestment;
- Monitoring of the research;
- Monitoring of the informed consent process;
- Investigator does not obtain consent, but has a third party obtain informed consent;
- Require the Investigator to disclose conflict of interest to participants in the informed consent and during the consent process when knowing the conflict would affect the willingness of an individual to participate in the research. Disclosure cannot be used alone to mange a conflict that adversely affects the participant.
- Other limitations on the Investigator.

The research project will be tabled until the Associate Vice President for Research and Economic Development has made a written determination. The financial disclosure form, any supplementary information provided by the Investigator and if applicable, the management plan will be provided to all IRB members at a convened meeting as part of the review of that research. The IRB has final authority to approve the research or to require modifications to the research given the management plan.

2.8.1 Changes in the Conflict of Interest Status during the Course of the Study

If there is a change in the conflict of interest status of an investigator during the course of a study, the investigator is required to notify the IRB within ten (10) working days of the change. The IRB will review the change as a modification to the protocol.

2.8.2 Annual Review

At the time of continuing review, the investigator will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

2.8.3 Conflict of Interest Training

On an annual basis, a notice is sent out by the Office of Research Development & Compliance to faculty and staff via the University Letter, Research Newsletter, and faculty and staff listservs informing all employees of the need to submit Conflict of Interest forms no later than September 30. The notice includes links to the COI policy online and encourages review of the policy before completion of COI forms. For faculty and staff who do not meet the reporting deadline, follow-up is undertaken to ensure forms are submitted in a timely manner. Investigators who do not have current COI forms on file with the Office of Research Development & Compliance will not be allowed to submit funding proposals to external agencies.

Whenever there is a change in the University of North Dakota Conflict of Interest Policy, training sessions on the changes are conducted jointly by the Office of Research Development & Compliance and the Grants & Contracts Administration to inform researchers of new requirements. These sessions are scheduled multiple times throughout the academic year to ensure researchers have multiple opportunities to attend a training session.

2.8.4 Conflict of Interest Training for United States Public Health Service (PHS) Grantees

All PHS grantees or those considering submission of a proposal to PHS are required to complete a mandatory education class on COI. Training sessions are offered multiple times throughout the academic year and are conducted jointly by the Office of Research Development & Compliance and the Grants & Contracts Administration. Training is required of each individual initially and then every 4 years. Notice of the required training is sent out at the beginning of each academic semester by the Office of Research Development & Compliance to faculty and staff via the University Letter, Research Newsletter, and faculty and staff listservs. Investigators who do not complete the mandatory training will not be allowed to submit funding proposals to PHS agencies.

2.9 Finder’s Fees and Bonus Payments for Recruitment

Faculty, staff, students, and all others conducting human research under the purview of the University of North Dakota are strictly prohibited from offering or receiving any "finder’s fee" or other inducement, in cash or in kind, for the purpose of referring patients as candidates for participation in research. Likewise, no individual or organization conducting human research under the auspices of the University may receive “bonus payments” from Sponsors that are tied to the rate or timing of subject enrollment. For example; an additional payment of $5,000 to site that can recruit an additional 5 participants in a week or additional payment to sites that reach their recruitment goal.

2.10 Department of Justice Requirements

For research conducted within the Bureau of Prisons, the researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.

For National Institute of Justice-funded research, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

2.11 Education Requirement

To ensure that all Investigators and research personnel receive adequate education in human subject protection, the UND Institutional Review Board requires all researchers to complete human subject education at least once every three years. The IRB will not release the approvals for new or continuing protocols until all individuals involved with the project, including student advisers and key personnel, have completed the training. Key personnel are defined as persons in contact with human subjects or persons that have access to identifiable data.

Occasionally, Investigators may have completed human subject education at another institution. The Investigator must provide a copy of the certification indicating the type of education and the date of completion to the UND IRB for review. The Investigator will be informed if the human subject education is acceptable and meets the UND IRB requirements.

2.12 Record Keeping

It is the **responsibility** of the Investigator (and Advisor, if PI is student) to maintain records of:

- all correspondence with the IRB
- copies of forms submitted to the IRB
- original IRB stamped consent document (all versions)
- signed consent documents
- protocols and amendments (all versions)
- any other documentation requested by sponsor (for funded research)

If a student is the Principal Investigator, and if any of the study records contain personal identifiers (video recordings, signed informed consents, surveys with personal identifiers, etc.) the records must be stored on campus with the advisor. Once the study is completed and data is analyzed, the student may only take the de-identified data and IRB correspondence (approval letter, approved consent, continuations, closure forms etc.) with them when they graduate. The advisor must keep a copy of the study records for three years from when the study is closed.

3. RESPONSIBILITY

The Associate Vice President for Research and Economic Development is responsible for engaging appropriate Investigator sanctions when Investigators are not in compliance with IRB requirements.

The Associate Vice President for Research and Economic Development is responsible for responding to reports of potential conflict of interest.

The IRB Chairperson and IRB Coordinator are responsible for tracking Investigator compliance with IRB requirements stipulated during the IRB's review of the Investigator's research.

The Associate Vice President for Research and Economic Development is responsible for review of conflict of interest/financial disclosure forms and forwarding conflicts to the Vice President for Research and Economic Development.

The IRB Chairperson or IRB Vice Chairperson is responsible for facilitating Investigator compliance with IRB requirements through his/her management of IRB deliberations, and

providing Investigators clear guidelines pertaining to that compliance through IRB communications to the Investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111
21 CFR 54
45 CFR 46.109, 46.111
OHRP COI Policy Draft

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Secretary	Provide Investigators with complete information on preparing IRB submissions, securing initial and ongoing approval of research, and providing all required reports. Secure all necessary information for ongoing IRB review and approval.
IRB Chairperson, IRB Coordinator, IRB Members, Associate Vice President for Research and Economic Development	Provide Investigators with appropriate training in preparing IRB submissions and in conducting the informed consent process and other subject protection activities. Identify Investigator non-compliance as soon as possible and initiate IRB actions.
Associate Vice President for Research and Economic Development	Review potential conflict of interests and triage to Vice President for Research as appropriate. Manage potential conflicts of interest and provide written final determination to the IRB
IRB Members	Review COI determination and all supplemental materials at convened IRB meeting.
IRB Secretary	Distribute communications to and from Investigators to appropriate IRB staff and members in a timely manner.