QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM

SOP #:	**901**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**5/1/09**	**SUPERSEDES DOCUMENT:**	**/ /**
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 STAFF**				
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:			**Associate Vice President for Research and Economic Development**				
APPROVED BY:						**DATE:**	**/ /**

1. POLICY

The purpose of a quality assurance and improvement program is to heighten awareness of regulatory requirements and improve the ethical conduct of research in IRB approved research. Therefore, the QA/QI program consists of four components:

- Evaluation of the effectiveness of the human subject research protection program;
- Determination of whether Investigators implement protocols as approved by the IRB;
- Identification of issues to be addressed in HRPP education and training;
- Evaluation of the informed consent process to determine if it meets standards and can be improved.

2. SPECIFIC POLICIES

2.1 Institutional Review Board Compliance

The operations of the University of North Dakota IRB are subject to periodic assessment for purposes of the protection of human research subjects and quality improvement. Such assessments will determine the extent to which the affiliated IRB complies with Federal regulations and its own Standard Operating Procedures (SOP's), and the adequacy of its processes and documentation.

Items to be reviewed to ensure compliance with standard operating procedures and applicable regulations include IRB files, IRB minutes, and IRB SOP's.

2.1.1 File Review

The IRB Coordinator will evaluate the on-going activities of the IRB protocols, by reviewing not less than twenty (20) proposal files per year. Items to be reviewed will include:

(1) Information considered during the initial review
(2) Analysis of risks and benefits, including determination of minimal risk
(3) Privacy and confidentiality protections
(4) Use of a waiver or alteration of informed consent
(5) Use of the appropriate category for review
(6) Designation of primary reviewer
(7) Information considered while monitoring ongoing research (modifications, adverse events),
(8) Information considered at continuing review

Documentation of the University of North Dakota IRB's actions must clearly demonstrate the activities of the committee. The IRB Secretary, in conjunction with the IRB Coordinator, will review individual IRB proposal files to ensure that there is clear documentation within each file of the IRB's actions and activities for that project. The IRB Secretary will review the following IRB activities:

(1) Initial review and approval
(2) Monitoring ongoing research
(3) Continuing review and approval
(4) Study closure

2.2 Investigator Compliance: Site Visits and Third Party Verification

The Institutional Review Board has the authority to observe or have a third party observe the informed consent process of research it has approved, and to verify that the study is being conducted as approved and within the Institutional policies and procedures. The IRB Chairperson, IRB Staff or IRB members may perform site visits or use another party either affiliated or not with the institution to verify information in the study application, or in any interim or continuing review submissions. The criteria for selecting Investigators to be visited may include:

- Investigators who conduct studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Investigators who conduct studies that involve large numbers of subjects,
- Investigators selected at the discretion of the Research Development and Compliance office, and
- Investigators selected at the discretion of the IRB.

Due to the high variability in research projects, it is anticipated that modifications will be made to tailor each audit to the specific project. Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IRB requirements. The IRB members or IRB Staff may conduct surveys or interviews with screened and/or enrolled subjects as deemed necessary. Sponsors may be asked to submit copies of monitoring reports. The purpose of the audit is to ensure protection of the human subjects in the research. The information gathered during the audit is for the IRB to use to monitor the implementation of approved protocols, identify areas that need improvement, correct of target education, and to gather information for continuous improvement of the audit tool and the audit process.

3. RESPONSIBILITY

The Associate Vice President for Research and Economic Development, the IRB Chairperson, and IRB Staff are responsible for the establishment, implementation and oversight of the QA/QI program.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109 (e)
21 CFR 46.109 (f)

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Coordinator, IRB Secretary	Conduct periodic assessments of IRB proposal files
IRB Coordinator	Contact the Investigator or key site personnel to set up a day and time to conduct a site visit. Prior to the site visit, confirm the date and time.
Site Visitor	Bring a copy of the current protocol, informed consent document, and any adverse event reports submitted. Confirm that the study is being conducted in compliance with the information provided on these documents by observation if possible. Specially: the method of subject recruitment, and in particular, that there are safeguards in place for the recruitment of subjects vulnerable to coercion or undue influence, the process of obtaining informed consent, the consent form being used and the facilities available in an emergency. If appropriate, obtain information about any adverse events that may have been reported. If appropriate, obtain information about any adverse events that may not have been reported. If project is inactive, suspended, or terminated, obtain information regarding this status. Complete the Site Visit Report
IRB Secretary	Include discussion of site visit in IRB agenda (dependent upon whose study it is)
Site Visitor	Once Site Visit Report is reviewed and approved by IRB send copy of report to Investigator and Director.
IRB Chairperson or IRB Coordinator	Develop and implement quality improvements as indicated by audits