REPORTING REQUIREMENT FOR UNANTICIPATED PROBLEM, SERIOUS AND CONTINUING NON-COMPLIANCE AND/OR SUSPENSION OR TERMINATION OF IRB APPROVAL

SOP #:	**409**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**5/1/09**	**SUPERSEDES DOCUMENT:**	**/ /**
THIS POLICY PERTAINS TO:			**ALL RESEARCH CONDUCTED UNDER THE JURISDICTION OF THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB MEMBERS, INVESTIGATOR**				
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:			**Associate Vice President for Research and Economic Development**				
APPROVED BY:						**DATE:**	**04/29/09**

1. POLICY

The IRB will notify one or more of the following as appropriate

- The head or appropriate designee of the funding department or agency
- The appropriate designee of the sponsoring company or organization
- Vice President for Research and Economic Development
- FDA
- OHRP
- Local agencies as required by Institutional officials

of any serious and continuing non-compliance, unanticipated events, suspension or termination of IRB approval of a study resulting from:

1. ***Unanticipated problem involving risks to participants or others:*** A problem, which (1) is unanticipated, and (2) indicates that participants are at increased risk of harm. Examples of unanticipated problems involving risks to participants or others:

    - Any event (including on-site and off-site adverse events, injuries, side effects, deaths, or other problems, regardless of whether the event was serious), which in the opinion of the Principal Investigator (1) was unexpected, and (2) was related to the research procedures;
    - Any event that requires prompt reporting according to the sponsor;
    - Any accidental or unintentional change to the IRB-approved protocol that involved risks or has the potential to recur;
    - Any change to the protocol made without prior IRB review to eliminate apparent immediate hazard to a research participant;
    - Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research;
    - Any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff;
    - Any independent safety monitoring reports or DSMB reports;
    - Breach of privacy/confidentiality/data security/loss of study data/destruction of study data due to noncompliance; or

- Incorrect labeling/dosing of study medication or test article.

2. Any instance of serious or continuing noncompliance with FDA, HHS regulations, or the requirements or determinations of the IRB.

***Serious non-compliance*:** defined as an action or omission taken by an Investigator or study personnel that any other reasonable Investigator would have foreseen as compromising the rights and/or welfare of the participant.

Examples of serious non-compliance:

a. Failure to adhere to the federal regulations governing the use of humans in research;

   i. Failure to obtain IRB approval prior to initiation of research procedures;
   ii. Failure to notify the IRB of changes in approved procedures;
   iii. Failure to obtain informed consent;
   iv. Failure to document informed consent;
   v. Failure to maintain complete record of informed consent;
   vi. Failure to notify the IRB of changes in the scope/intent of the study; **or**

b. Failure to adhere to institutional polices where subject's well-being or rights have been impacted.

Continuing non-compliance: pattern of repeated actions or omissions taken by an Investigator or study personnel that indicates a lack of ability or willingness to comply with federal regulations, UND IRB policies and procedures, or the determinations of the UND IRB.

2. SPECIFIC POLICIES

All unanticipated problems and adverse events involving risks to participants or others will be reported to OHRP within 30 days. The IRB Chairperson and IRB Coordinator will draft a letter that outlines the nature of the event, the findings of the IRB, actions taken by the IRB, reasons for the IRB's action, and plans for continued investigation or action. The letter is sent to the Associate Vice President for Research and Economic Development for review, approval and signature.

All unanticipated problems involving risk to participants or others need to be reported to FDA by the Investigator when the research is FDA regulated. Copies of such reports must be sent to the IRB.

3. RESPONSIBILITY

The IRB Chairperson and IRB Coordinator are responsible for drafting a letter to be sent to appropriate individuals and agencies outlining the event, findings and action taken by the IRB.

The Associate Vice President for Research and Economic Development is responsible for reviewing and approving draft.

The IRB Chairperson and IRB Coordinator are responsible for distributing letter to appropriate individuals and agencies.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108(b)(1)
56.108(b)(2)
56.108(b)(3)
OHRP DRAFT Guidance on Reporting and Reviewing Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others
Guidance on Reporting Incidents to OHRP

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Chairperson and IRB Coordinator	Within 30 days of completion of investigation, draft a letter that outlines the nature of the event, the findings of the IRB, actions taken by the IRB, reasons for the IRB's action, and plans for continued investigation or action
Associate Vice President for Research and Economic Development	Review and approve letter
IRB Chairperson, IRB Coordinator	Sign letter and distribute to appropriate individuals and agencies.