

NON-COMPLIANCE WITH IRB POLICIES AND PROCEDURES

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THIS POLICY PERTAINS TO:			ALL RESEARCH CONDUCTED UNDER THE JURISDICTION OF THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		IRB CHAIRPERSON, IRB COORDINATOR, IRB MEMBERS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:		/ /

1. POLICY

Reports of noncompliance will be directed to the appropriate IRB staff and to the IRB for investigation and corrective action. Complaints about the IRB process or the conduct of research may or may not involve noncompliance with IRB policies or federal regulations and will be handled as potential unanticipated problems involving risks to participants or others. Complaints that do not have elements of noncompliance should be handled in accordance with the IRB policy for addressing complaints.

2. SPECIFIC POLICY

2.1 Definitions:

Non-compliance: Failure to comply with applicable Federal Regulations, UND IRB policies and procedures, UND policy, or the determinations of the UND IRB.

Serious non-compliance: 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:

1. Failure to adhere to the federal regulations governing the use of humans in research;
 - a. Failure to obtain IRB approval prior to initiation of research procedures;
 - b. Failure to notify the IRB of changes in approved procedures;
 - c. Failure to obtain informed consent;
 - d. Failure to document informed consent;
 - e. Failure to maintain complete record of informed consent;
 - f. Failure to notify the IRB of changes in the scope/intent of the study; **or**

2. Failure to adhere to institutional policies where subject’s well-being or rights have been impacted.

Continuing non-compliance: A 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.

2.2 Receiving Reports of Noncompliance

Reports of noncompliance may be provided to the IRB Chairperson, IRB members, IRB Staff, or the Research Development and Compliance office from anyone inside or outside of the university community who has reason to believe that the noncompliance with the IRB policies and procedures has occurred. These complaints will be accepted verbally or in writing.

2.2.1 Receipt of verbal reports.

Allegations that are presented via telephone or in person through the Research Development and Compliance office will be directed to the IRB Coordinator. The recipient of the call should take care to record all relevant information in a thorough manner and request that the caller provide a contact number for follow-up calls, unless the caller desires to remain anonymous.

The person making the allegation may choose to remain anonymous. The recipient of an anonymous call should inform the caller that the matter will be investigated to the extent possible given the information provided. The recipient of the call should ask the caller for any available evidence that the caller is willing to give that will facilitate an investigation into the matter, but should not encourage the caller to provide a name or contact information if the caller has expressed a desire to remain anonymous. It is permissible to advise the caller to provide additional information at a later date if new information becomes available or if the caller remembers details that were not presented originally.

2.2.2 IRB.

Upon receipt of an allegation of noncompliance, the IRB Coordinator and the IRB Chairperson will present an investigation report to the IRB. For studies which were previously reviewed by the IRB and given IRB approval, the IRB will review all actions relating to the alleged noncompliance, compliant or concern.

If the alleged noncompliance, complaint or concern does not have an IRB approved protocol to which it is associated, all actions relating to the alleged noncompliance, complaint or concern will be directed to the IRB.

2.2.3 Investigator.

The Investigator will be contacted via telephone or e-mail by the IRB Coordinator to discuss the allegation of non-compliance. The IRB Coordinator will begin the investigation at this time.

2.2.4 Report to IRB of Pending Investigation.

If the investigation of the allegation has not been completed prior to the next scheduled meeting of the IRB, the IRB will be notified that an allegation of noncompliance has been received and that an investigation has been initiated. This information will be presented in a manner that does not identify the Investigator, study, or facility. However, if the allegation will impact other IRB business at that or another meeting, the IRB will be informed as needed to ensure effective decision-making by the IRB relative to that Investigator, protocol, or facility.

Report of Allegation/Investigation Complete. If the allegation was received and the investigation completed prior to the next scheduled IRB meeting, the IRB will be presented with the allegation and findings.

2.2.5 Investigation.

The IRB Coordinator, and if necessary, the IRB Chairperson will investigate the allegation upon notification of the alleged non-compliance. The matter will be reported to the Full IRB at its next scheduled meeting.

2.2.6 Determinations.

After the investigation, the IRB Coordinator and the IRB Chairperson will determine whether:

- a. the allegation was false,
- b. the non-compliance is not serious and not continuing, or
- c. the non-compliance might be serious or continuing, or

False allegation: If the IRB Coordinator and the IRB Chairperson determine that the allegation of non-compliance is false, then the matter will be documented for the protocol file and no further action will be taken.

Not serious and not continuing: If it is determined by the IRB Coordinator and the IRB Chairperson that the allegation is not serious and not continuing, the Investigator will be notified by the IRB Coordinator or the IRB Chairperson. In addition, the IRB Coordinator or IRB Chairperson will discuss the issue with the Investigator and an action plan will be drafted. The final action plan will be forwarded to the Investigator via letter or e-mail and the information will be included in the IRB agenda as an information item.

Non-Compliance that may be Serious or continuing: The Investigator will be notified by the IRB Coordinator or the IRB Chairperson of the findings and/or requests for information by phone call, letter, or e-mail. The Investigator will be asked to respond in writing to the allegation and depending on the response, the Investigator may be asked by the IRB Coordinator or IRB Chairperson to attend the IRB meeting and/or a meeting with the IRB Chairperson.

The Investigator will be asked to respond in writing to the allegation and/or finding and/or request for information. The Investigator will have 14 consecutive days to respond. If the Investigator needs more time, an extension may be granted by the IRB Chairperson. The written response will be presented to the Full Board at a convened meeting for review.

2.2.7 Review by the IRB Committee (Serious or Continuing):

All incidences of non-compliance determined to be Serious or Continuing will be presented to the IRB and the IRB will vote to determine whether the non-compliance was serious or continuing (or will defer the decision to a future meeting pending receipt of additional information). The results of the vote will be documented in the minutes.

At a convened IRB meeting, the IRB Coordinator and IRB Chairperson will present the issue to the IRB. All IRB members will receive the investigation report, synopses of any communication with the Investigator, the last approved IRB application or continuation, the approved consent, protocol and any other pertinent information. All members attending the IRB meeting will review all the documents and determine whether:

1. There is no issue of serious and continuing non-compliance.
2. There is serious and continuing non-compliance.

3. More information is needed and determination is deferred to future meeting pending receipt of additional information.

If the Investigator offers a timely and satisfactory explanation for the concern and a plan to eliminate future incidents of such noncompliance, and the IRB accepts the explanation and plan, the IRB may elect to terminate the noncompliance investigation process and report that the noncompliance issue was satisfactorily resolved with no further action.

If the corrective action plan calls for any changes to the previously approved research and the change involves more than minor modifications, the modification must be reviewed by the convened IRB. If the change is only a minor modification, the change can be reviewed by expedited review.

If the Investigator does not provide a timely response, or offers an unsatisfactory explanation or corrective action plan, the IRB may ask the Investigator to meet with the IRB Chairperson or attend an IRB meeting to discuss the issue.

Meeting with the IRB Chairperson: The Investigator may be asked to attend a meeting with the IRB Chairperson and other appropriate members of the IRB or IRB Staff to discuss the allegations and/or findings and/or requests for more information.

If the Investigator has attended an informal meeting with the IRB Chairperson or provided a written response, the IRB will receive a summary of the conference or the Investigator's written response included with the other documentation relating to the allegation, investigation and findings.

Attendance at IRB Meeting: The Investigator may be asked or may choose to attend a meeting of the Full IRB. The Investigator would be scheduled to appear at the meeting only after the Full IRB had the opportunity to discuss the issues and findings.

If the Investigator initiates the request to attend the Full IRB meeting, the request must be received by the IRB office (2) weeks in advance of the IRB meeting.

If the Investigator attends the IRB meeting, the Investigator shall have an opportunity to present a response to the IRB immediately following the presentation of the allegation and investigation.

Note: During the investigation, the IRB may impose restrictions to the research study until satisfactory answers are received by the IRB.

Actions that may be taken during or after the investigation of non-compliance:

1. No action;
2. Suspension: Suspend enrollment and/or all research procedures for the specific research study in question; (in accordance of SOP on Suspension and Termination of IRB approval)
3. Termination of the research; (in accordance of SOP on Suspension and Termination of IRB approval)
4. Require a response from the Investigator with a plan for corrective action;
5. Initiate audits of all or some part of the Investigator's active protocols;
6. Modification of the research protocol;
7. Modification of the information disclosed during the consent process;
8. Additional information provided to past participants;

9. Modification of the continuing review schedule;
10. Obtain more information pending final decision;
11. Conference with other IRBs involved with the research;
12. Requirement that current participants re-consent to participation;
13. Provide information to current participants whenever such information might relate to the participant’s willingness to continue to part in the research;
14. Monitoring of the research;
15. Monitoring of the consent process;

2.2.8 Notification of Relevant Parties of Reports and Findings of Serious or Continuing Non-Compliance.

Upon determination by the IRB of whether an incident of non-compliance was either serious or continuing noncompliance, the incident will be reported according to SOP RR 409 Reporting Requirements for Unanticipated Events, Serious and Continuing Non-compliance, and/or Suspensions or Termination of IRB approval. If the identity of the person who reported the allegation, complaint, or concern is known, a summary of the findings of the investigation may be forwarded to this person as well.

3. RESPONSIBILITY

The IRB Chairperson and IRB Coordinator are responsible for the investigation of reports of non-compliance.

IRB Members are responsible for the review of reports of investigation of non-compliance and determination of actions needed to be taken by the IRB and Investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108(b)(2), 56.113
 45 CFR 46.113

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Secretary IRB Chairperson, IRB Members</i>	Upon receipt of non-compliance or discovery /admission of noncompliance, immediately notify the IRB Coordinator and IRB Chairperson.
<i>IRB Coordinator, IRB Chairperson</i>	If report of non-compliance is unbeknown to the Investigator, notify the Investigator (unless notification could jeopardize the investigation) that an investigation is being conducted.
<i>IRB Coordinator, IRB Chairperson</i>	Conduct investigation into (alleged) non-compliance. Notify the Chair requesting a written response.
<i>IRB Coordinator, IRB Chairperson</i>	Keep IRB notified as appropriate. Upon completion of the investigation, present the facts and findings to the IRB.
<i>IRB Chairperson, IRB Members</i>	Review the information at a convened meeting of the Full Board and make a determination to close investigation or assign corrective action.

*IRB Coordinator, IRB
Secretary*

Notify the Investigator of the IRBs determination and corrective action
Notify all appropriate parties of the allegation and outcome.