Bowling Green State University

Institutional Review Board
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IRB PROCEDURE STATEMENT

Procedure: Procedures for Handling Incidents of Noncompliance

Procedure ID: 2002-19

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A. Background

Non-compliance is defined as failure by a Principal Investigator (PI) to follow Federal, State, and/or University regulations which govern protections for human subjects in research. In addition, non-compliance includes failure to follow directives from or requirements of the Institutional Review Board (IRB).

Any incident of **serious non-compliance** (i.e., non-compliance that adversely affects the rights or welfare of human subjects in research) or **continuing non-compliance** (i.e., non-compliance that has been identified and required resolutions/sanctions have not been completed) should be reported immediately to the IRB Office.

Non-compliance with IRB procedures is a violation of BGSU's FWA: Federal Wide Assurance (FWA) for the Protection of Human Subjects (FWA00003853).

Researchers complete required research training that details the ethical principles and guidelines for research involving human subjects as detailed in ***The Belmont Report***: Respect for Persons, Beneficence, and Justice.

B. Procedure

1. Any reports/issues of non-compliance must be reported to the IRB Office by the PI immediately, and reported in writing within 5 business days of when the PI becomes aware of a problem, or at any time by other reporters.

    - Examples of Non-compliance:
        - Conducting research without IRB approval
        - Not reporting research problems of adverse events
        - Failure to use informed consent documents
        - Failure to conduct an approved research project according to the IRB protocol submitted by the PI and approved by the IRB

2. **To report a non-compliance incident, the PI or reporter should provide in writing via email or letter the following information to the IRB Office**:

   TITLE: Report to the IRB of a Non-Compliance Incident (include each subheading with the required information)

   - Date and Time of the non-compliance incident
   - Description of the incident non-compliance and known or possible cause(s) for the incident
   - Responsibilities or conduct of the PI, other research personnel, human subjects or any others involved in the incident
   - Responses or outcomes of the incident (e.g., any remedial actions taken; plan to inform the other human subjects in the study about this incident or safety procedures related to this incident)
   - Plan of action or measures to be taken to prevent the problem from happening in the future
   - Any other pertinent details that describe the incident

   Note. In cases of emergencies, the PI or reporter should call the IRB Office immediately to report the non-compliance incident.

3. The IRB Office is assisted by the Research Compliance Officer (RCO) in gathering information about the reported issue. The IRB Chair in consultation with the Vice President for Research and Economic Engagement (VPREE), RCO, IRB Vice-Chair, and/or IRB Administrator determines whether or not the resolution of the non-compliance incident can be completed and resolved at this level or review.

   This administrative review is to determine whether or not the reported event involved: a) an incident of non-compliance that related or possibly related to participation in the research, and/or b) placed human subjects or others at a greater risk of harm including physical, psychological, economic, or social harm than was previously known or recognized.

   - Examples of possible resolutions or corrective actions may include:
     - Additional human subjects training required for the PI or research personnel involved in the study
     - Protocol changes to correct non-compliance
     - Suspension or termination of research when non-compliance is not resolved
     - Data collected during non-compliance is destroyed

   Note. The corrective actions should ensure that the incident will not happen again with the investigator or protocol in question.

   If possible, resolution of the incident of non-compliance at this level is completed, communicated to the PI (and Advisor, if applicable) by the Chair of the IRB, and recorded in the IRB records.

4. If resolution of the report/issue cannot be made at this level of review (i.e., with the VPREE, RCO, IRB Chair, IRB Vice-Chair, and/or IRB Administrator), then the issue is referred to the Full Board of the IRB for the next meeting or on-call meeting. The IRB Chair presents the incident of non-compliance and all information from the previous levels of review.

5. The Full Board considers and discusses all information and determines if the incident was an instance of **serious non-compliance** or of **potential continuing non-compliance**, and whether the human subjects or others were/are at an increased risk of harm.

6. A vote of all members of the Full Board is taken at the meeting. Votes are tallied and the outcome(s)/action(s) for the non-compliance incident are recorded. This review of the Full Board of the IRB is the final decision.

7. The Full Board can impose sanctions on the PI, request modifications to the research study, or require other resolutions of the incident of non-compliance. In rare instances, the Full Board may discontinue approval for the study.

8. A final summary of the non-compliance incident and decisions by the IRB is written, and any sanctions are implemented and communicated in writing to the PI. The IRB Office notifies the Full Board, VPREE, RCO in writing within 5 business days of the outcome of the incident. Dependent on the nature and severity of the non-compliance incident, copies may be provided to the PI's Chair, Dean, and the Provost.

9. In rare instances, Federal Regulations require the IRB to report issues to the Office of Human Subjects Protection (OHRP) dependent on the nature and severity of the non-compliance incident. All correspondence is routed through the VPREE and RCO. Reports to OHRP should be submitted within 30 business days of the initial report of the non-compliance incident.

Note. Adapted from OHRP guidelines and IRB procedures at other academic institutions.