Bowling Green State University

Institutional Review Board
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IRB PROCEDURE STATEMENT

Procedure: Reporting of Research Problems and Adverse Events

Procedure ID: 2022-18

Effective: July 1, 2021
Revised: May 2022

A. Background

The IRB has the authority to receive, process, and adjudicate all reports/issues of:

- **Subject complaints, problems, concerns, and questions** about rights as a research subject;
- **Anticipated (Expected) Problems** (potential risks previously described to the IRB and human subjects);
- **Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO);** UPIRSOs are any information, including any incident, experience, or outcome that meets **ALL** of the following conditions:
    - unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (i.e., the IRB-approved research protocol and informed consent document) and the characteristics of the human subjects population being studied, and
    - related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), and
    - the research placed human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.
- **Adverse events** (any unfavorable medical events in one or more of the human subjects) and **serious adverse events** (unforeseen psychological and physical harm such as death, disability, or hospitalization).

B. Procedure

1. Any reports/issues of: 1) concerns communicated by research subjects, 2) anticipated or unanticipated problems, or 3) adverse events, must be reported to the IRB Office by the PI immediately when becoming aware of any problems or adverse events, and in writing within 5 business days, or at any time by other reporters.

    - Examples of Subject Issues:
        - Lack of compensation when promised

- Complaints of mistreatment
- Nondisclosure of risks in the consent form

- Examples of Unanticipated Problems may include:
  - Deviation from the IRB approved research protocol
  - Loss of confidentiality or violations of HIPAA
  - Any event that represents a risk of unforeseen psychological or physical harm

2. The IRB Office notifies the PI of the study (and Advisor, if applicable) that all research is stopped until resolution of the problem/event, and copies the Research Compliance Officer (RCO) on this communication.

3. The IRB resolves issues within its authority and procedures. Issues/reports that are deemed to involve or violate University Policies (see https://www.bgsu.edu/general-counsel/university-policies.html), are referred to the Vice-President for Research and Economic Engagement (VPREE) and the RCO for further action.

4. **To report a research problem or adverse event, 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 Research Problem or Adverse Event (include each subheading with the required information)

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

Note. In cases of emergencies or bodily harm, the PI or reporter should call the IRB Office immediately about the problem/event, and contact police and medical personnel, if appropriate.

5. The IRB is assisted by the RCO in gathering information about the reported issue. The IRB Chair in consultation with the VPREE, RCO, IRB Vice-Chair, and/or IRB Administrator determines whether or not the reported event constitutes: a) an unanticipated problem that related or possibly related to participation in the research, and/or b) places human subjects or others at a greater risk of harm including physical, psychological, economic, or social harm than was previously known or recognized.

6. If possible, resolution of the problem/event 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.

- Examples of possible resolutions may include:

  — suspension of enrollment of new subjects
  — awarding of compensation that was previously promised
  — modification(s) of the consent form
  — submission and implementation of revised research protocols
  — changes in subject screening for inclusion and/or exclusion in the study
  — surrendering and discarding of all data collected inappropriately (sent to IRB and eliminated from all data sets)
  — attendance at two Full Board meetings to understand the review process

7. If resolution of the problem/event 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 problem/event is referred to the Full Board of the IRB for the next meeting or on-call meeting. The IRB Chair presents the problem/event and all information from the previous levels of review.

8. The Full Board considers and discusses all information and determines if the problem(s)/event(s) were/constitute an unanticipated problem that is related or possibly related to the research, was/is defined as unforeseen, and/or indicates that participants or others were/are at an increased risk of harm.

9. 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 problem/event are recorded. This review of the Full Board of the IRB is the final decision.

10. The Full Board can impose sanctions on the PI, request modifications to the research study, or require other resolutions of the problem/event. In rare instances, the Full Board may discontinue approval for the study.

11. A final summary of the problem/event and decisions by the IRB is written. Any sanctions are implemented and communicated in writing to the PI. The IRB Office notifies the Full Board, RCO, VPREE in writing within 5 business days, of the outcome of the reported event. Dependent on the nature and severity of the problem/event, copies may be provided to the PI's Chair, Dean, and the Provost.

12. 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 issue. All correspondence is routed through the VPREE and RCO. Reports to OHRP should be submitted within 30 business days.

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