IRB PROCEDURE STATEMENT

Procedure: Determination of Not Research with Human Subjects

Procedure ID: 13-08-002 Effective: August 7, 2013

A. Background

Bowling Green State University (BGSU) policy requires that the Institutional Review Board (IRB) review of all research involving human subjects. If a project meets the federal definitions of “research” (45 CFR 46.102(d)) and “human subject” (45 CFR 46.102(f)) the work must be reviewed by the IRB.

Since the federal regulations are subject to institutional interpretation and federal guidance periodically changes, BGSU researchers may not know if their project requires IRB review. The IRB has allowed for an administrative review process to simplify the procedure for obtaining a formal determination as to if a researcher’s project requires IRB review and approval.

B. Definitions

Research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

A human subject is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.”

C. Procedure

1. The researcher completes the Review Determination Form and submits the form for review using IRBNet.

2. The ORC submits the submission for administrative review.

3. One ORC staff member reviews the request and determines a review outcome:
   a. Not Research with Human Subjects – IRB review and approval is not required. The project may begin.
NOT RESEARCH WITH HUMAN SUBJECTS

b. Information Required – the reviewer does not have sufficient information to make a decision. Additional information is required from the researcher before the request will be reviewed.

c. Modifications Required – IRB review and approval is required. A complete protocol application must be submitted.

4. The ORC notifies the P.I., and the research advisor (if applicable), of the review outcome via email. The official notification letter can be located in the “Board Documents” section of the relevant project in IRBNet.