Office of Research Compliance
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IRB PROCEDURE STATEMENT

Procedure: Determination of "Not Research with Human Subjects"

Procedure ID: 13-08-002 **Effective:** January 17, 2019

A. Background

BGSU policy requires review of all research involving human participants. Research, as defined by Department of Health and Human Services (DHHS) Policy for the Protection of Human Subjects at 45 CFR 46.106(l), is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." A human subject, as defined by DHHS Policy for the Protection of Human Subjects at 45 CFR 46.102(e(1)), is "a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." BGSU's IRB is responsible for the review of research projects involving human participants.

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 whether a researcher's project requires IRB review and approval.

B. Procedure

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

2. The Research Compliance Officer 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.
   b. Information Required – the Office of Research Compliance does not have sufficient information to make a decision. Addition 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 IRBNet. The official notification letter can be located in the “Board Documents” section of the relevant project in IRBNet.