

IRB PROCEDURE STATEMENT

Procedure: **Review Determination Form** for Evaluating Whether a Project is Research and/or Involves Human Subjects

Procedure ID: 2022-02

Effective: January 17, 2019

Revised: May 2022

A. Background

BGSU policy requires review of all research involving human subjects.

Research, as defined by United States Department of Health and Human Services (HHS) *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(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 HHS *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(e)(1), “means a living individual about whom an investigator (whether professional or student) conducting research: (i) 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, or analyzes, the information or biospecimens; or (ii) 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 subject or 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 will provide a review determination to ascertain whether a researcher’s project requires IRB review and approval.

B. Procedure

1. The researcher completes the **Review Determination Form**, found under Forms and Templates at IRBNet (irbnet.org), and submits the form for review using IRBNet.
2. The IRB Administrator and/or Chair of the IRB 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 Institutional Review Board 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** – **further IRB review and approval is required**. A complete IRB Application with required documents (i.e., consent form, etc.) must be submitted.
3. The IRB Administrator notifies the Principal Investigator (PI), and the research advisor (if applicable), of the review outcome via IRBNet. The official notification letter and other applicable document(s) can be found in the “Board Documents” section under the “Reviews” tab of the relevant project in IRBNet.