



# Idaho State University

## POLICIES AND PROCEDURES

### Human Subjects in Research

#### ISUPP 7050

#### *POLICY INFORMATION*

**Policy Section:** *Research*

**Policy Title:** *Human Subjects in Research*

**Responsible Executive (RE):** *Vice President for Research*

**Sponsoring Organization (SO):** *Office for Research*

**Dates: Effective Date:** *April 8, 2013 (10-20-20)*

**Revised:** *April 13, 2023*

**Review Date:** *April 2028*

## I. INTRODUCTION

As an institution dedicated to the development and dissemination of knowledge, ISU recognizes that carrying out this mission may involve research using live human beings. When such research is deemed appropriate, the University is responsible for ensuring it is done ethically, in full compliance with pertinent laws and regulations, with consideration to participant's protection, safety, and privacy, and with scientific justification.

## II. POLICY STATEMENT

This policy establishes that all research conducted at ISU involving humans will be governed by procedures and processes mandated by regulatory authorities (e.g., the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA)). To meet this responsibility, ISU has created an Institutional Review Board (IRB), which reports to the Institutional Official (IO). The Vice President for Research or their designee serves as the IO. The IRB is empowered by federal regulations to conduct general oversight, establish (and monitor compliance with) policies and procedures based on the regulations of the federal agencies mentioned above, and to fulfill other roles as required by federal regulations. The IRB is also the proper body to contact with concerns about the proper and

ethical involvement of humans in research conducted under the auspices of ISU. All researchers who conduct research that involves human subjects are responsible for complying with IRB policies.

### III. DEFINITIONS

- A. **Research:** a systemic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- B. **Human Subjects Research:** a living individual about whom an investigator is (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.

Due to the nuances involved in determining whether or not a specific situation qualifies as Human Subjects Research, questions may be directed to the IRB for clarification.

### IV. AUTHORITY AND RESPONSIBILITIES

The enforcement of this policy is the responsibility of the Vice President for Research.

### V. PROCEDURES

The institution's use of humans in research is regulated by federal law. It is the responsibility of the IRB to develop (and update as necessary) detailed policies and procedures which ensure ISU complies with federal requirements and national standards for research involving humans.

Procedures and other policies related to human subjects in research can be found on the ISU Research website.