

Version: 1

Effective Date: 05/01/2019

104: Human Subjects Research Determination

The intent of this Standard Operating Procedure (SOP) is to describe how a human subjects research determination is made at Illinois State University (ISU) and who has the authority to do so. This SOP is for use by anyone who conducts human subjects research at ISU and is approved by the Institutional Official.

Table of Contents

1. Human Subjects Research Determination	2
--	---

1. Human Subjects Research Determination

All projects meeting the definition of human subjects research (see IRB SOP 101.A Definitions) fall under the auspices of the Human Research Protection Program (HRPP). Investigators who are unsure whether their research meets the definition of human subjects research or those who need confirmation that it does not may submit a request for a determination to Research Ethics and Compliance. Determination requests may be submitted through the electronic submission system.

The Director of Research Ethics and Compliance, the Compliance Coordinator, the Human Subjects Research Specialist and the IRB Chair or designee have the authority to make the determination. In order to make the determination, the following questions are considered:

- Is there a specific research question or hypothesis?
- Is the primary intent to generate knowledge that can be applied broadly?
- Does the study involve interaction with intervention with individuals or a group of individuals? (This includes surveys, interviews, educational tests, etc.)
- If the study involves interviews or surveys, are any of the questions about personal opinion or private information?
- If there is no interaction or intervention, does the study involve access to private data or specimens, such as medical or school records?

When the determination is made that the research does not require IRB review, a formal letter may be drafted at the investigator's request. Projects that do not require IRB should not be submitted for review unless the investigators are seeking documentation that their project does not involve human subjects research.