

## **POLICY TITLE:**

**Human Research Protection** 

## **APPLIES TO:**

Faculty, staff, and students conducting human subjects research at or on behalf of Kentucky State University

# **ADMINISTRATIVE AUTHORITY:**

Office of Research and Innovation
Sponsored Programs
Office of the Provost and Vice President of Academic & Student Affairs
Division of Academic & Student Affairs

#### **APPROVED BY:**

**Kentucky State University Board of Regents** 

## **EFFECTIVE DATE:**

August 8, 2025

#### **NEXT REVIEW DATE:**

August 8, 2028

# **POLICY STATEMENT:**

Kentucky State University (KSU) is committed to the highest ethical principles in the conduct of research and to its responsibility to ensure the rights and welfare of human research subjects. While the Institutional Review Board (IRB) has the authority to approve human subjects research, the protection of those subjects is a shared responsibility involving KSU, the IRB, and all individual researchers.

### **DEFINITIONS:**

# **Human Subject**

A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

## Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

# **Institutional Review Board (IRB)**

The independent committee established by KSU to review and approve research involving human subjects to ensure the protection of their rights and welfare.

#### **PROCESS:**

# **Guiding Principles and Authority**

- KSU shall maintain a Human Research Protection Program (HRPP) to oversee all research involving human subjects.
- KSU shall maintain an Institutional Review Board (IRB) registered with the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).
- The IRB has the authority to approve, require modifications in, or disapprove all research activities involving human subjects conducted under the university's purview. Research disapproved by the IRB may not be approved by other university officials.
- All human subjects research at KSU will be guided by the ethical principles outlined in the Belmont Report and must comply with federal regulations, including 45 CFR 46.

#### **Training Requirement**

All researchers engaging in human subjects research are required to complete training related to the ethical conduct of research, as specified in the official HRPP Procedures.

#### **Official Procedures**

The specific, detailed policies and procedures governing the HRPP and the IRB—including protocol submission, review processes, committee composition, informed consent, and all other operational details—are maintained by the Office of Sponsored Programs in the official KSU Human Research Protection Program (HRPP) Policies and Procedures manual.

# **REFERENCES AND RELATED MATERIALS:**

- KSU Human Research Protection Program (HRPP) Policies and Procedures Manual
- 45 C.F.R. § 46 ("The Common Rule")
- The Belmont Report

## **CONTACTS:**

| Subject           | Office             | Telephone      | E-mail                 |
|-------------------|--------------------|----------------|------------------------|
| General Questions | Sponsored Programs | (502) 597-5837 | Dorothy.Daley@kysu.edu |

# **HISTORY:**

| Revision Type       | Date of Issuance/Revision | Drafter(s)/Editor(s) |
|---------------------|---------------------------|----------------------|
| Issued (New Policy) | June 2025                 | Zach Atwell          |