Information

Authority of the Institutional Review Boards

Effective

October 1, 2004

Number

RES-4.02

Applicability

This policy applies to University of Louisville researchers, research staff, Institutional Review Board members, or other individuals involved in human subject research activities reviewed by the University of Louisville Institutional Review Board.

Administrative Authority

Executive Vice President for Research & Innovation

Responsible Unit

Human Subjects Protection Program Office

Institutional Review Boards

University of Louisville

300 E. Market Street, Suite 380

Louisville, KY 40202

Telephone: 502-852-5188

hsppofc@louisville.edu

History

This policy was approved by the Board of Trustees on September 23, 2004 and effective October 1, 2004.

Revision Date(s): October 26, 2021 (template format); May 8, 2007

Reviewed Date(s): January 17, 2025

The University Policy and Procedure Library is updated regularly. In order to ensure a printed copy of this document is current, please access it online at http://louisville.edu/policies.

Categories

Reason for Policy:

This policy establishes the authority of the University of Louisville Institutional Review Boards (IRB).

Statement:

It is the policy of the University of Louisville that human research activities conducted under the oversight of the organization will be conducted in accordance with applicable federal law and regulations that include but are not limited to Federal Regulations 45 CFR 46, 21 CFR 50, 21 CFR 56, and 45 CFR 160 and 164, applicable Kentucky state statutes and regulations, the principles of The Belmont Report and local University Institutional Review Board (IRBs) requirements.

The University of Louisville authorizes the IRBs of the organization to review and have authority to:

1. Approve, modify (to secure approval), or disapprove all human research conducted by the organization;

2. Suspend or terminate research not conducted in accordance with the regulations, statutes and principles or IRB's requirements mentioned above or that has been associated with unexpected serious harm to subjects;
3. Observe, or to have a third party observe, the consent process;
4. Observe, or have a third party observe, the conduct of the research; and
5. Serve as the Privacy Board for the University of Louisville that approves waivers of authorization in accordance with the HIPAA Privacy Rule.

Research covered by this policy that has been approved by a University IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, as per 45 CFR 46.112 and 21 CFR 56.112, those officials may not approve the research if a University of Louisville IRB has disapproved it.

Any IRB member or staff who believes that they have been subject to inappropriate influence should report this immediately to the IRB chair or the Director, Human Subjects Protection Program, who will report the attempt to influence to the Executive Vice President for Research and Innovation (EVPRI). The EVPRI will investigate, or have investigated, the attempt to influence and determine an appropriate response to the attempt based on penalties similar to those outlined in the University's Administrative Sanctions for Violations of University of Louisville Research Policies.

Related Information:

Human Subjects Protection Program Website: https://louisville.edu/research/researchers/compliance/irb.

Procedures:

Procedures for conducting the business of the University of Louisville IRBs may be found in the Human Subjects Protection Program Office (HSPPO) Policy Manual.