HUMAN SUBJECTS RESEARCH BASICS

What to know about obtaining approval at KU for research involving human subjects

ARE YOU PLANNING TO CONDUCT HUMAN SUBJECTS RESEARCH?

Research involving human subjects must be approved by the HRPP.



A **human subject** is a living individual about whom an investigator obtains data through intervention or identifiable data/records.



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



Examples of activities that require HRPP review: biological specimen collection | educational interventions | interviews | physical data collection | pilot studies | secondary research on previously collected human data | surveys



HRPP REVIEW PROCESS

Submit applications electronically through <u>eCompliance</u>.

Upload all necessary documents:

- KU human subjects research protocol form
- Recruitment materials (emails, flyers, etc.)
- Consent forms
- Study measures (e.g., survey questions)

When will I receive a response from HRPP? Expect an initial review response in 5-7 business days. Minimal risk studies are typically approved in 12-15 business days.

EDUCATION + TRAINING

Required human subjects training

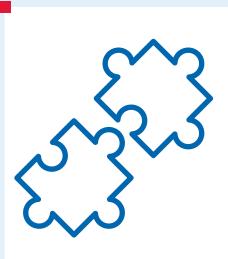
- All study personnel must complete <u>online ethics training</u> prior to engaging in human research.
- Training, provided by <u>CITI Program</u>, is valid for 3 years.



Join us on Zoom at 11:30 a.m. on the final Friday of each month.

- HRPP's monthly informal educational sessions on current topics of interest are open to all KU-Lawrence human subjects researchers.
- See <u>HRPP calendar</u> for upcoming topics.





COLLABORATIVE RESEARCH

Does your human subjects research project involve study personnel outside of KU?

- If your study team includes members from another institutuion with an HRPP, your project may require an institutional agreement to document the IRB responsible for overseeing the research.
- If you will have study team members outside of KU who are not subject to oversight of an HRPP, they will be asked to sign an Individual Investigator Agreement to abide by the KU-Lawrence human subjects program.

NOTE: Another institution's HRPP approval, alone, **does not** provide documentation of HRPP oversight for KU researchers.



CONTACT US

irb@ku.edu 785-864-7385 research.ku.edu

HRPP STAFF

Alyssa Haase Jennifer Dumpert Tessa Maclean

