Are you conducting research with human subjects?

Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. The following activities are deemed NOT to be research:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and sue of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

Human subjects are defined as a living individual about whom an investigator conducting research obtains

1. Data through intervention (*physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes*) or interaction (*communication or interpersonal contact between investigator and subject*) with the individual, OR
2. Identifiable private information (*information about behavior that occurs in a context in which an individual can reasonably expect that no recording/observation is taking place and that the information will not be made public*).

YES

Complete a protocol in Kuali and submit for IRB Review.

NO

Continue with your project. It is not research

Protocol is reviewed by IRB Staff and Determined to be Exempt, Expedited, or Full Board.

EXEMPT

Project is exempt from IRB Committee Review and does not require continued monitoring by the IRB. An IRB Administrator will review the protocol and provide an exemption category number. Research may not begin until IRB Administrator Review is complete.

Exempt process takes ~ 1-3 weeks from submission.

EXPEDITED

Project is non-exempt research involving minimal risk. Review will be carried out by the IRB Chair and at least one other member of the IRB. Research cannot begin until the review is complete. Most expedited projects will not require continued monitoring by the IRB.

Expedited process takes ~ 2-4 weeks from submission.

FULL BOARD

Project is non-exempt research involving risk. Review will be carried out by a convened meeting of the full IRB Board. Research cannot begin until the review is complete. Most full board projects will require annual continuing review by the IRB.

Full Board process takes ~ 2-8 weeks from submission.