**Is an Activity Human Subject Research Requiring IRB Review and Approval?**

Start here.

Is the activity a systematic (methodical in procedure or plan; marked by thoroughness and regularity; consistency on data points being collected) investigation designed to develop or contribute to generalizable knowledge (i.e., designed to draw general conclusions or to infer beyond a smaller collection of facts/data)?

- **Yes**
  - Activity is research. Does the research involve obtaining private information about *living* individuals?
    - **Yes**
      - Activity is research involving human subjects. IRB approval is required.
    - **No**
      - Does the research involve intervention or interaction with the individuals?
        - **Yes**
          - Activity is research involving human subjects. IRB approval is required.
        - **No**
          - This research does not involve human subjects, so no IRB approval is needed.

- **No**
  - Activity is not research, so no IRB approval is needed.

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?

- **Yes**
  - Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public).
    - **Yes**
      - Activity is research involving human subjects. IRB approval is required.
    - **No**
      - This research does not involve human subjects, so no IRB approval is needed.

***Although a study may not require IRB approval, other federal, state and local laws and/or regulations may apply to the activity. Please contact the Office of Research Integrity and Compliance (ORIC) at 252-744-2914 or umcirm@ecu.edu if there are any questions or for further guidance.***