Chart 1: Is an Activity Research Involving Human Subjects Covered?

- Start Here
- Is the activity a **systematic** investigation designed to develop or contribute to **generalizable** knowledge?
  - Yes
  - Activity is research. Does the research involve obtaining information about living individuals?
    - Yes
    - Does the research involve **intervention or interaction** with the individuals?
      - Yes
        - Can be physical procedures, manipulation of the subject or alterations of the subject’s environment
        - Can be any form of communication or interpersonal contact
        - Activity is research involving human subjects
          - Yes
          - Even if exempt under 46.101(b) 4
            - But
            - FSU reviews and approves all research including exempt
            - Go to Chart 2
          - No
        - No
    - No
  - No
  - Activity is not research
- No
  - The research is not research involving human subjects and 45 CFR 46 does not apply.
    - No
    - 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 which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purpose by an individual and which the individual can reasonably expect will not be made public.)
          - Yes
            - Other Federal, State and local Laws and or regulations may apply to the activity
          - No
            - BUT
            - Go to Chart 2
        - BUT
      - No
    - BUT
  - BUT