WHAT NEEDS SUBMISSION TO THE JHSPH IRB?

Does your study involve data or specimens from or about individual living people?

- YES
  - Are you or your team doing any of the following:
    - Interacting with or obtaining consent from participants, or
    - Accessing or analyzing identifiable* data or specimens, or
    - Receiving federal funding as the primary recipient?
      - YES
        - SUBMIT TO IRB
        - Including:
          - Publicly available data
          - HIPAA limited data sets
          - Public health surveillance
          - Key informant research
          - Data Coordinating Centers and biorepositories
      - NO
        - STOP: Do Not submit to IRB
          - Not HSR**
  - NO
    - Does the research involve only deceased individuals, and originate from a “covered entity” governed by HIPAA?
      - YES
        - SUBMIT TO IRB
      - NO
        - STOP: Do Not submit to IRB
          - Not HSR**.

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*Data are Identifiable if:
- They include “private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.” (45 CFR 46.102(e)(5)). Data are also considered identifiable if the identity of the participant is coded, but you or your team has access to the codes.
- Under HIPAA, one or more of 18 listed identifiers (Protected Health Information) are included.

**Not HSR means that it does not meet the definition of humans subjects research
There is some risk in making this determination yourself if you are ever challenged by a journal or other source. You are welcome to submit any study to the IRB for a determination; contact the IRB for clarification. You should submit for a determination to protect yourself if the topic is particularly socially or politically sensitive.

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