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

Are you or your team doing any of the following:
- Formative/pilot work collecting private information* from individuals
- Formative/pilot work involving vulnerable populations (JHU students or employees, minors, adults lacking capacity, sex workers, etc.)
- Interacting with or obtaining consent from participants, or
- Accessing or analyzing identifiable** data or specimens, or
- Receiving federal funding as the primary recipient?

Does the research involve only deceased individuals with data originating from a “covered entity” governed by HIPAA?

Yes
- STOP: Do Not Submit to IRB
- Not HSR***

No
- GO SUBMIT TO IRB
- Not HSR**.

Does your study involve de-identified clinical data from Johns Hopkins Medicine?

Yes
- STOP: Do Not submit to IRB
- Not HSR**.

No
- GO SUBMIT TO IRB
- Including:
  - Publicly available data
  - HIPAA limited data sets
  - Public health surveillance
  - Key informant research
  - Data Coordinating Centers and biorepositories

***Not HSR means that it does not meet the definition of humans subjects research

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

If unsure, you should submit to your JHU IRB for a determination as to whether or not your project is HSR.

---

**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 identifiers.
- Under HIPAA, includes one or more of 18 listed identifiers (Protected Health Information).

*Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).