

WHAT MUST INVESTIGATORS SUBMIT TO THE JHU IRBs?

(Faculty; students follow divisional requirements)

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

YES

NO

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

NO

 **SUBMIT TO IRB**

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


YES


NO

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

YES

NO

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

 **SUBMIT TO IRB**
Including:
Publicly available data
HIPAA limited data sets
Public health surveillance
Key informant research
Data Coordinating Centers and biorepositories

***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).

**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 identify 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).

***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.