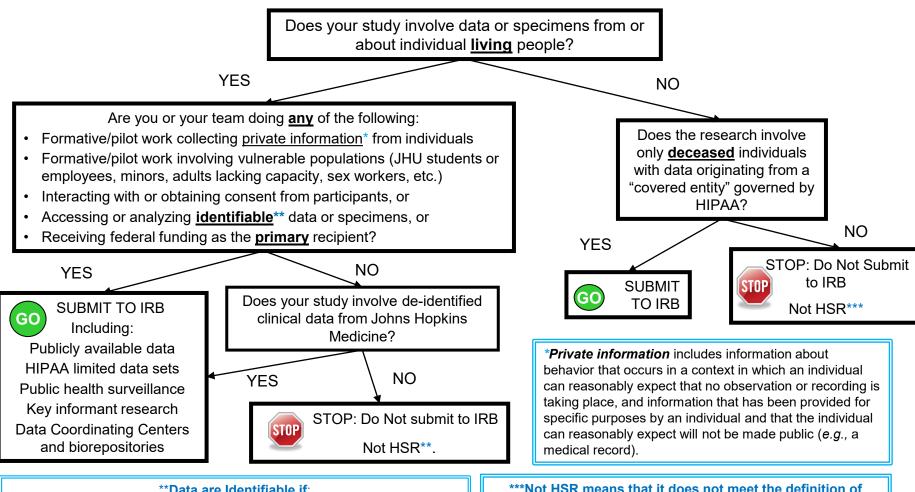
## WHAT MUST INVESTIGATORS SUBMIT TO THE JHU IRBs?

(Faculty; students follow divisional requirements)



## \*\*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.