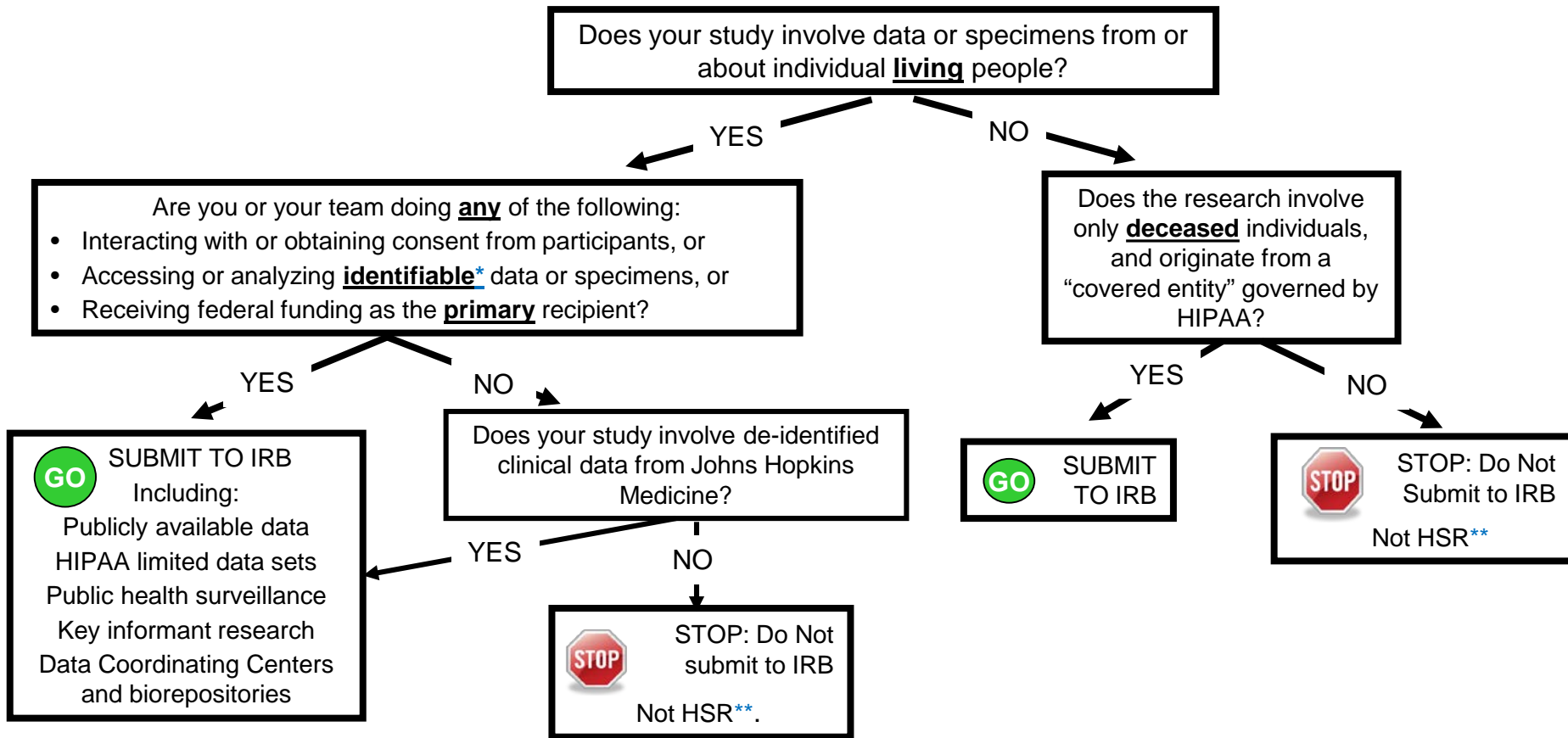


WHAT NEEDS SUBMISSION TO THE JHSPH IRB?



*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 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.