IRBs in the Academic Setting

Joan B. Cobb Pettit, JD, MA
Exec. Director, JHSPH IRB

Disclaimer

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Requirements for an Academic Research Institution

- FWA is a promise by an Institution to the DHHS/OHRP to comply with human subjects research (HSR) protections regulations.
- Required of institutions (Universities) that receive federal dollars for HSR
- Reviewing IRBs (internal and external) must be registered

What is Required for the FWA?

- Institutional Official overseeing HSR
- All HSR must have IRB oversight
- All investigators must have HSR training
- Must have written policies and procedures governing IRB operations and HSR activities

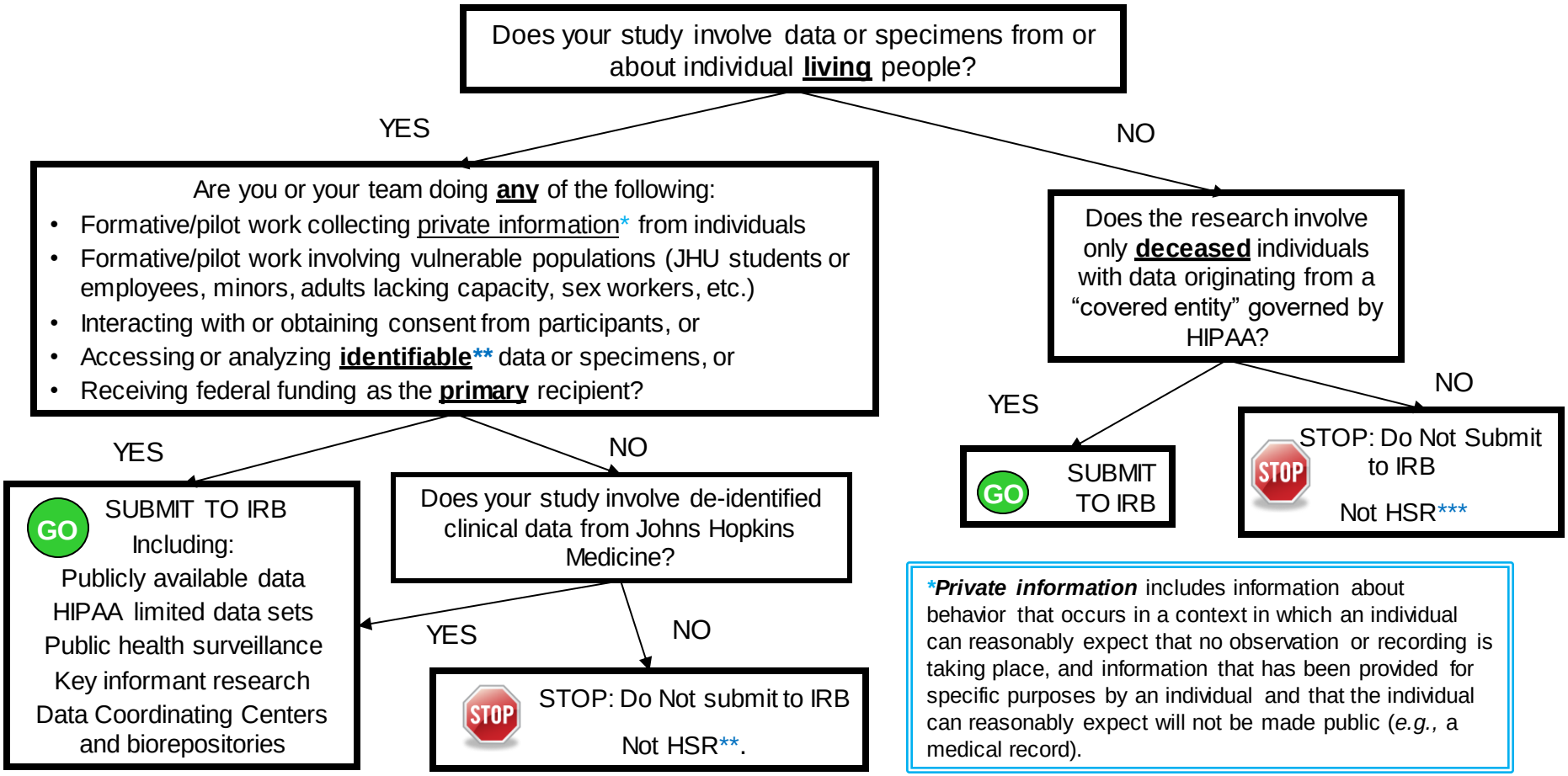
IRB (Office) Role

- Determine if the activity is Human Subjects Research
- Determine if the University is "engaged" (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)
- If HSR, and employee/agent is "engaged", must submit to IRB
- IRB will triage to Exempt, Expedited, or Convened Review

But it's a little more complicated….

WHAT MUST INVESTIGATORS SUBMIT TO THE JHU IRBs?

(Faculty; students follow divisional requirements)



***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.

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Collaborators?

- The Single IRB Policy
- International studies and local IRB approval
- Clinical Trial Complexities (data coordinating centers, safety monitoring, clinicaltrial.gov posting, consent form postings, etc.)

Ancillary Reviews

- Pharmacy & Therapeutics (P&T)
- Biosafety
- Conflict of Interest
- Radiation
- Permissions from Data Sources
- Data Use Agreements

Questions?

- *Contact me at jpettit@jhu.edu*