Does your study involve data **about** individual living people? [see Note #1]

— YES →

Does the **entire** dataset already exist?

— NO →

Are you collecting data from key informants?

Does the entire dataset already exist?

— YES ↓

Are all the data **publicly** available? [see Note #2]

— NO →

GO Submit to IRB

Are all the data publicly available?

— YES ↓

STOP: Do Not submit to IRB

Not HSR! [see Note #4]

— NO ↓

Does the dataset as used in your study contain **identifiers** or **links to identifiers**? [see Note #3]

Are you collecting data from key informants?

— YES ↓

Could being part of the study put the informants at any risk?

— NO →

STOP: Do Not submit to IRB

Not HSR! [see Note #4]

Could being part of the study put the informants at any risk?

— NO → (to STOP: Do Not submit to IRB / Not HSR!)

— YES ↓

GO Submit to IRB

Does the dataset as used in your study contain identifiers or links to identifiers?

— YES ↓

GO Submit to IRB

— NO →

Did you or a co-investigator originally collect the data AND does the original dataset now contain identifiers or links to identifiers?

Did you or a co-investigator originally collect the data AND does the original dataset now contain identifiers or links to identifiers?

— YES ↓

GO Submit to IRB

— NO →

STOP: Do Not submit to IRB

Not HSR! [see Note #4]

! Not HSR (Human Subjects Research) also means that you can answer "No" on grant applications to the question "are human subjects involved?"
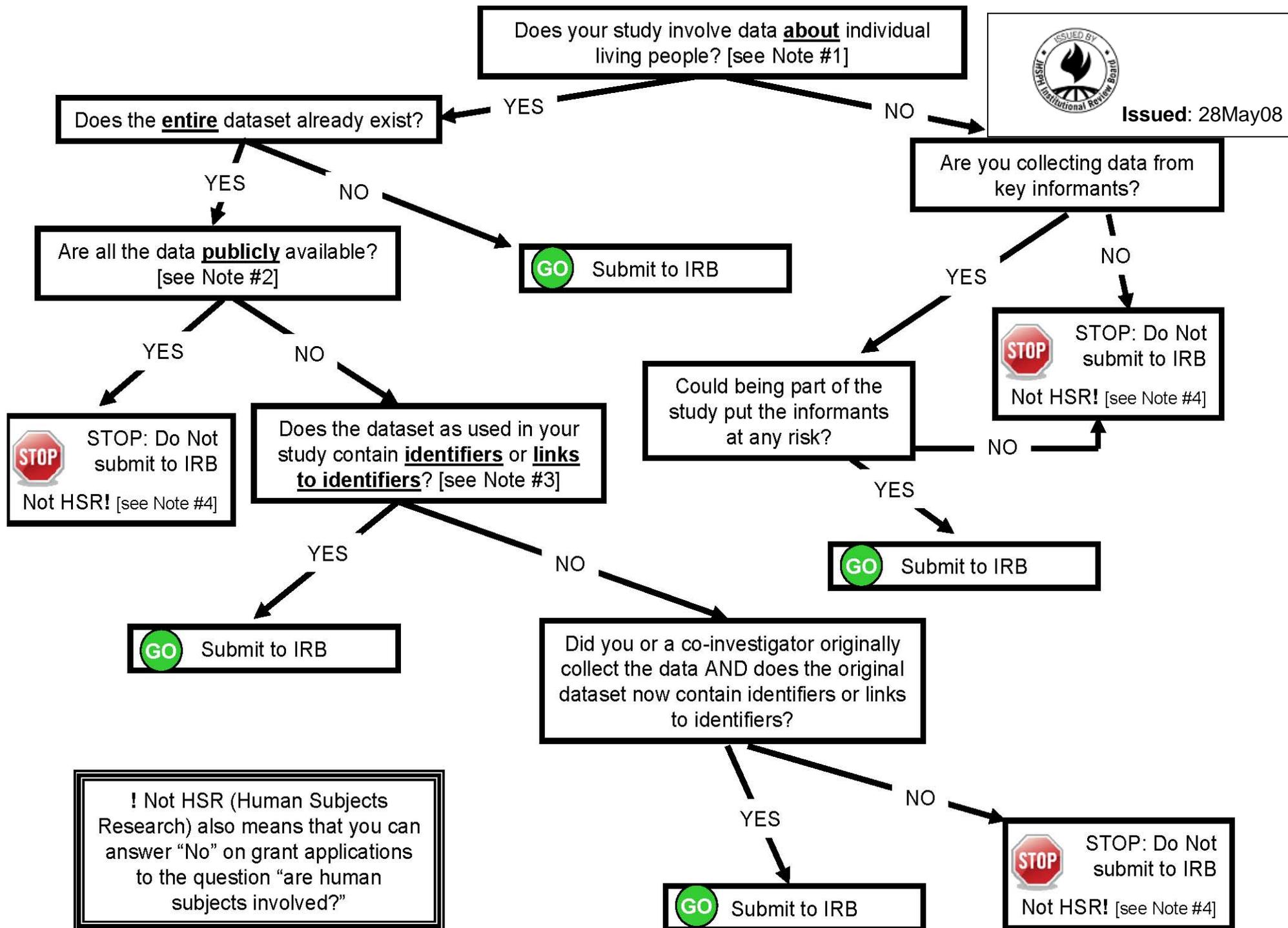
Notes: Is it human subjects?

1. "About" means the data provide information about individual living people, not simply collected from individual living people. Key informant data about agencies or other entities (e.g., asking a hospital administrator about wait times in the ER, asking a drug manufacturer about dispensing patterns) or from experts or opinion leaders about their areas of expertise does not constitute data about individual living people.

2. "Publicly available" means the information is available to anyone, without prior clearance or qualification. Examples of publicly available data include census data, state court records, openly available national household surveys, or data available on the web. If you need a Data Use Agreement, it is not publicly available.

3. Identifiers provide the possibility of linkage to specific individuals. Examples include names, social security numbers, addresses, hospital IDs, or any HIPAA-defined identifiers. Identifiable can also mean that you can reasonably link to a specific individual based on an ensemble of variables. If you retain records that link an individual to a study ID, even if those records are kept in a separate location, then those individuals remain identifiable as long as you keep those records.

WHEN IN DOUBT, CALL THE IRB OFFICE FOR HELP: 410.955.3193

4. Can I still submit something I think is NHSR to the IRB for review?

• Yes! There is some element of risk in making this determination yourself, should you ever be challenged on the decision not to submit by a journal editor or other source. You are welcome to submit any research protocol to the IRB and you will receive a statement with a determination following review. We urge you to do so to protect yourself if the topic is particularly socially or politically sensitive.

• If you elect to use the flow chart with attached clarifications, then we recommend printing it out, with notations regarding how you made you ultimate decision, and retain it in your files.