

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 your ultimate decision, and retain it in your files.