



## Guidance on Use of Secondary Data for Research (e.g., datasets\* or medical records)

### 1. What is the difference between a retrospective and prospective data analysis?

A **Retrospective Data Analysis** evaluates data that is in existence at the time the project is submitted to the IRB for initial review.

A **Prospective Data Analysis** evaluates data that does not yet exist at the time the project is submitted to the IRB for initial review.

### 2. What level of IRB review should I request?

- **Not Human Subjects Research (NHSR):** If the data already exists in a de-identified state and only needs to be shared “as is” with the requesting researcher. *Many public use datasets fall into this category.*
- **Exempt:** Exempt review applies if the information to be collected already exists and is publicly available OR data is identifiable but will be recorded in such a manner that subjects cannot be identified, either directly or indirectly. Since data must exist at the time the project is submitted to the IRB, this limits exempt review to retrospective dataset reviews.

\*Note: If a code needs to be recorded with the data then the study **cannot** be exempt. The researcher should apply for expedited review instead.

- **Expedited:** Expedited review can occur for retrospective and prospective data analyses.
- **Full Board:** While rare, full board (“committee”) review may be required for some retrospective and prospective data analyses. (for instance, if the investigator plans to collect sensitive data, or if the review results in a change in care for the patients whose data is being collected)

**Note:** Increasingly, repositories that store datasets that are rich in detail about its participants, or contain sensitive topics, may require expedited or full committee review. The rationale is that the potential exists that a participant could be harmed if confidentiality is breached, even if the dataset is technically de-identified when provided to the researcher. These are often referred to as “restricted use” data sets and may be accompanied by Data Use Agreements (DUAs) which put stipulations on how data may be used and how it must be secured.

For more information on DUAs please visit [Data Use Agreement Guidance pdf](#).

### 3. What type of consent should I include in my proposal?

In general, the level of consent required increases depending on how identifiable and sensitive the data to be collected/used, and whether the data is being collected prospectively or retrospectively. **Prospective data collection and analysis** usually involve an informed consent process and an Authorization to use Protected Health Information. For **retrospective data**



**analyses**, it is common to request waiver of consent and/or waiver of authorization with appropriate justification. To request a waiver, submit a request to the IRB for Waiver of Consent and/or Waiver of Authorization forms.

#### **4. Do HIPAA privacy regulations apply to secondary data analyses?**

HIPAA regulations are *supplemental* regulations to the basic “Common Rule” that governs human subjects research. HIPAA applies to use of protected health information (PHI) in research that is collected or disclosed by “covered entities.”

Only certain administrative units at FAU are “covered entities.” However, if FAU researchers receive PHI from covered entities outside of FAU, they may have to follow that institution’s procedures for accessing PHI. Complete the worksheets: **Am I Using Protected Health Information?** or **Does HIPAA Apply to My Research** to assess whether HIPAA regulations apply to your study. The worksheets are located **here**.

The following scenarios may apply:

- Data is fully **de-identified** and not subject to HIPAA Privacy Rule regulations, **OR**
- Data is considered to be a **limited data set (LDS)**, an exception to the Privacy Rule requirement to obtain an authorization from a person for research use of their protected health information.

The limited data set option is a less restrictive option than complete de-identification. It allows the inclusion of health information with certain identifiers. (e.g., certain dates and geographic data). However, a researcher who receives an LDS from a covered entity must sign a data use agreement (DUA) which requires the researcher receiving the limited data set to observe certain security safeguards, **OR**

- Data is **identifiable** and must adhere to HIPAA regulations. A signed consent and HIPAA authorization are required from the research participant or the PI must request a waiver or alteration of consent or authorization.