Data Registries (HRPP 7.3)

Description:

This policy describes UNMC's requirements for creation and operation of a data registry, and for research use of data from a registry.

Definitions:

Internal Data Registry: a collection of data that is stored and managed within the organization under the oversight of the UNMC IBR. This data may include:

- **Personal health information (PHI)** like medical records,
- **Identifiable private information (IPI)** such as names or contact details,
- Or **de-identified data,** which means personal details have been removed

External Data Registry: a collection of data that is stored and managed outside the organization, normally under the oversight of an external IRB. The data may include PHI, IPI, or be limited to de-identified data.

Private Information: refers to any details that people expect to remain private. This includes:

- Behaviors in places where a person would expect privacy (like in their home), and
- Information given for a specific reason, such as health records, that people wouldn't expect to be shared publicly

Identifiable Private Information (IPI): private information that can be linked back to a specific person. If a researcher can figure out who the information belongs to (either directly or indirectly), it is considered identifiable.

Investigator Responsibilities:

- The creation of a registry utilized for human subject research is subject to IRB review
    - The investigator who develops and/or maintains the registry must **submit a Data Registry Application through RSS**
    - **NOTE**: if your registry also includes human biological materials (like blood or tissue samples), a Tissue Bank Application must be completed instead
- The investigator must obtain appropriate agreements prior to collecting data into the registry. These include:
    - A **Data Use Agreement** (DUA) *(how the data can be used),* or
    - A **Data Transfer Agreement** (DTA) *(rules for sharing data between institutions)*
- The investigator must obtain informed consent of subjects whose data will go into the registry OR obtain a waiver from the IRB

Research USE of Data from a Registry:

- **Submit a Medical Records application in RSS** for IRB review and approval
- The use of PHI or IPI stored in a data registry requires informed consent of the donor unless:
    - Consent obtained at the time the data was placed into the registry was sufficiently detailed regarding the future use of the data, or
    - The IRB waives consent and, if PHI is involved, HIPAA authorization is waived