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:

Data Registry: repository of clinical or other patient data under oversight of the UNMC IRB (internal) or an external IRB (external).

The data is banked with no specific research aim, but may eventually be used for:

- Human subject research
- Assessment of patient outcomes
- Improve healthcare delivery
- Other non-research purposes

IRB Review and Consent Requirements:

INTERNAL Data Registry

- Submit an application:
  - Data Registry- if creating a registry
  - Human Biological Materials (HBM) – if creating a registry that will include the collection of HBM a Tissue Bank application should be submitted
- The IRB must find that:
  - The purpose and goals of the registry are clearly justified.
  - The minimum amount of PHI necessary to accomplish the purpose and goals is entered into the registry.
  - There is acceptable security to safeguard the confidentiality and integrity of the data.
  - There are procedures in place for the release of PHI from the registry.
  - As necessary, a DUA, DTA, or BAA is in place before the data is released.
- The collection of identifiable private information into the registry utilized for human subject research requires informed consent of the person for whom the data is obtained:

- If data will be collected as an addendum to another protocol, separate informed consent must be obtained. If the other protocol states the registry is for future unspecific research, then consent does not need to be negotiated a second time.
- Collection of data cannot be a requirement for participation in another study for which there is potential for direct benefit.

EXTERNAL Data Registry

- Submission of clinical data with or without identifiers that was ***collected solely for clinical purposes*** to an external data registry (utilized for human subject research) does not constitute human subject research and is not subject to UNMC IRB approval, ***provided the healthcare professional*** submitting the data:
  (1) is not involved with the research aside from submitting the data and
  (2) will not, in the future, use data in the registry for research in which they're participating.
  - Healthcare professionals who submit clinical data to external registries must submit the Data Registry Application to be entered for tracking purposes.
  - If the clinical data contains PHI, authorization for disclosure of PHI to the External Data Registry must be obtained or waived.
- If the healthcare professional submitting the data IS involved with the research, then this constitutes human subject research and is subject to IRB approval.

Use of Data from a Registry for Research:

- A Data Registry application must be submitted.
- Use of identifiable private information previously stored in a data registry requires informed consent of the donor, unless:
  - Consent can be waived, and, if PHI is involved, authorization is waived. Consent may be waived if the study is retrospective in nature. If PHI is involved, appropriate ethical access is required but may be waived since the study is minimal risk.
  - All prospective data collection requires consent to be obtained prior to the data being collected in the registry. Consent may be waived in future studies if the registry is sufficiently detailed regarding future use.
  - Consent obtained at the time the data was placed into the registry was sufficiently detailed regarding future use.