Using PHI in Research (HRPP 3.4)

Description:

This policy describes UNMC's requirements for ensuring the appropriate protections for use of PHI in research.

Definitions:

Protected Health Information (PHI): individually identifiable health information that:

1) Is created or received by the organization, and
2) Relates to the past, present, or future physical or mental health or condition of an individual, the provisions of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Honest Broker: a person designated by the Organization certified to collect specified health information from the tissue or data bank, remove all identifiers, and provide **de-identified** health information or tissue to research teams or healthcare workers.

Use or Disclosure of PHI:

The Privacy Rule permits the Organization to use or disclose PHI for research only under certain circumstances/conditions:

- The subject of the PHI must grant written permission. The subject may revoke this at any time, but the investigator may continue to use/disclose the PHI obtained prior to the revoked authorization.
- The PHI will be used for reviews preparatory to research and the investigator must have ethical access (HRPP Policy 3.12).
- The IRB or Privacy Board has granted a waiver of Authorization (HRPP Policy 5.2).
- The PHI was de-identified.
- The PHI is released in the form of a Limited Data Set with a Data Use Agreement (DUA) between the researcher and the Organization.

Procedures:

Research Involving the Use of PHI:

1) The investigator submits an IRB application.
2) The application is reviewed by the IRB and is determined as full board, expedited, or exempt.
3) The minimum amount of PHI is recorded and, when possible, data without PHI should be preferred.
4) Individuals without ethical access must obtain data from the “honest broker”.
5) If PHI is being sent to an external entity, a DUA or sponsored agreement must be finalized by Sponsored Programs Administration (SPA) prior to final IRB approval.

Research Utilizing Decedent PHI:

- It’s not considered human subject research BUT HIPAA still applies for individuals deceased 50 years or less, so the IRB (in its capacity as the HIPAA Privacy Board) still must review the use of such PHI.
- To approve the use of this PHI, the researcher must obtain and deliver the following to the IRB:
    - Oral or written assurance that the use or disclosure is sought solely for research.
    - Oral or written assurance that use or disclosure is necessary for purpose of research.
    - Documentation, at the request of the organization, of the death of the individual whose PHI is sought.
- The investigator is not required to obtain authorization from the personal representative or next of kin, however permission may be required by State Law.
- None of this applies to subjects deceased more than 50 years.