# 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):*** any information, created or received by the Organization, that can identify an individual and relates to their past, present or future health, healthcare services, or payment for such services

***Honest Broker:*** a person designated by the Organization certified to collect specific 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:

Under HIPAA, PHI may be used/disclosed for research only under certain circumstances/conditions:

- **With Written Authorization from the Subject**
  - Authorization must comply with 45 CFR 164.508(c)
  - Typically merged into the Informed Consent Form (ICF)
  - **Required core elements:**
    - Description of the PHI to be used or disclosed
    - Persons authorized to make the requested use or disclosure
    - Persons who may use the PHI or to whom the covered entity may make the requested disclosure
    - Purpose of the requested use or disclosure
    - Expiration date or event *(e.g. "end of research study", or "none")*
    - Signature and date

- **Required statements:**
  - Right to revoke authorization
  - Conditions of treatment
  - Risk of re-disclosure
- Subjects may revoke, but PHI collected up to that point may still be used to preserve research integrity

- **For Preparatory Activities to Research**
  - Allowed uses:
    - Preparing research protocols
    - Developing hypotheses
    - Recruiting subjects
  - Restrictions:
    - Investigator must have ethical access to the PHI in accordance with HRPP Policy 3.12
    - PHI may not be used for research purposes other than those described
    - PHI may not be removed from the Organization during the course of review
    - Still may qualify as human subjects research under 45 CFR 46 and therefore may require informed consent, even though HIPAA requirements are met
- **With a Waiver of Authorization**
  - Granted by an IRB or Privacy Board
  - Must follow HRPP Policy 5.2
- **If the PHI Has Been De-Identified**
  - PHI is considered de-identified if either of the following applies:
    - **Expert determination:** a qualified expert applies accepted methods, determines that the risk of re-identification is very low, and documents the methods and results that justify the determination
    - *Ex. A biostatistician applies statistical models to ensure anonymity*
    - **Safe harbor method:** all 18 HIPAA identifiers of the individuals or of relatives, employers, or household members of the individuals are removed, and the Organization has no knowledge that the remaining information could still identify someone
  - De-identification must be performed by a certified Honest Broker

- **Through a Limited Data Set (LDS)**
    - Must be governed by a Data Use Agreement (DUA), which includes:
        - Permitted uses and disclosures of the information
        - Who is permitted to use or receive the data set, and
        - Specifies that the recipient of the limited data set will:
            - Not use or further disclose the information outside what's permitted by the DUA/DTA
            - Use appropriate safeguards to prevent use or disclosure
            - Report to the Organization any use or disclosure of the information not provided for by its DUA
            - Ensure any agents to whom it provides the limited data set agrees to the same restrictions and conditions
            - No attempt to identify or contact the individuals
    - DUA negotiated through Sponsored Programs Administration (SPA)
    - The investigator must have ethical access to the PHI
    - The limited data set will be prepared by the "honest broker"

## Procedures:

### Research Involving PHI:

- Submit appropriate IRB Application
- Data minimization is required (only collect PHI as necessary)
- Use of PHI by individuals who do not have ethical access must go through:
    - The Honest Broker, or
    - Data coded with a non-identifiable key (one-way code)
- If PHI is shared externally, a DUA or sponsored agreement must be in place

### Research Using Decedent PHI:

- Not considered human subjects research, but HIPAA still applies if the person has been **deceased 50 years or less**
- IRB/Privacy Board must receive:
    - Assurance that the PHI is only for research purposes
    - Justification for why PHI is necessary for the purposes of the research
    - Proof of death, if requested
- No authorization from next of kin is required under HIPAA, but state law or institutional policy may apply