Ethical Access (HRPP 3.12)

Description:

This policy defines ethical access and describes UNMC's requirements to protect the privacy of patients in the context of recruitment for participation in research, or for identification of subjects for review of medical records.

Definitions:

Ethical Access: structured to minimize the risk of loss of privacy by restricting access to a prospective subject's private information; specifically, by limiting the flow of information.

Based on the principle that violation of a potential subject's privacy represents a harm; either an actual harm due to release of information that the potential subject considers "private", or a moral harm due to violation of autonomy.
*Access to patient information for recruitment or screening for research must not violate a patient's privacy.

Ethical Access Applies to:

1) Obtainment of information about the patient which leads the investigator to believe or conclude that the patient is eligible for the research (i.e. determine eligibility); and
2) Subsequent approach to the patient to explain the research and obtain consent to participate (i.e. initial contact)

Obtaining Information About a Patient:

Ethical access may occur in 1 of 3 ways:

1) **Legitimate access for clinical reasons through**:
    a. An existing clinical relationship.
    b. A potential clinical relationship (working directly with a provider who has an existing clinical relationship and could reasonably be called upon to care for the patient in a clinical setting).
    c. Professional responsibilities require interaction (or knowledge of) a potential subject independent of their role as a researcher (ex. Hospital epidemiologist, operating room nurse, etc.).

2) **The patient gave express consent for investigators to search medical records or databases (i.e. Opt-in)**
3) **The ORA/IRB grants a waiver of the requirement of ethical access provided the following 3 conditions are met:**
    - **a.** Minimal risk to the patient's privacy
    - **b.** It won't affect the patient's rights and welfare (i.e. a reasonable person would not object to sharing the information being asked)
    - *c.* It is impracticable to identify or recruit potential subjects without the waiver (*Note: time consuming, expensive, and inconvenient do NOT necessarily mean "impracticable")*.

Approaching Patient to Explain Research:

- **Physical approach**- allowed if one of the following applies:
    - The investigator has an existing clinical relationship, and the patient is aware of it.
    - Someone WITH an existing clinical relationship (1) explains the research study and (2) asks permission for study personnel to approach the subject and discuss the research.
        - Study personnel may not approach the potential subject without introduction by a care provider and the express permission of the subject.
- **Verbal contact**
    - Allowed if it's as a result of identification through an existing clinical relationship.
    - If it's initiated based on the "opt-in" designation, following HRPP Policy 3.6.
- **Written contact:** follow HRPP Policy 3.6.

Ethical Access for Review of Medical Records:

For research involving review of existing or prospective medical records, and where consent of the subject was waived, the requirement for ethical access still applies to identify potential subjects still applies.