# 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 person which leads the investigator to believe or conclude that the person is eligible for the research ***(i.e. recruitment/determining eligibility);*** and
2) Approach to the person to explain the research and obtain consent to participate ***(i.e. initial contact)***

## Obtaining Information (*recruitment/determining eligibility*):

**Ethical access may occur in 1 of 3 ways:**

1) **Legitimate access for clinical reasons:**
    a. Investigators have legitimate clinical access through:
        i. Existing clinical relationship *(e.g. treating provider, pharmacist, NP on care team)*

ii. Collaboration with a provider in the same clinical group *(e.g. covering call)*
iii. Professional duties requiring access *(e.g. hospital epidemiologist)*

2) **Subject Consent to Records Review:**
   a. The subject has opted in *(e.g. via Nebraska Medicine Conditions of Treatment Form)*
   b. The subject consented to be contacted for future research while participating in another study
3) **IRB Waiver of Ethical Access Requirement:**
   a. Allowed only when:
      i. Minimal risk to privacy
      ii. No adverse impact on rights/welfare
      iii. Impracticable to recruit without waiver *(e.g. no one with ethical access is available)*
   b. **NOTE**: this waiver only applies to reviewing records for eligibility, not for participation consent

## Approaching Potential Subjects to Explain Research *(initial contact)*:

- **Physical Approach (In-Person Contact)**: permitted only if
  - Investigator has a known, existing clinical relationship with the subject, or
  - Someone with an existing clinical relationship introduces the study and obtains subject's permission for the research team to approach them and discuss the research
- **Verbal Contact** ***(e.g. phone/video call)***
  - Must follow same rules as physical approach
  - If based on opt-in consent, must comply with **HRPP Policy 3.6**
- **Written Contact** ***(e.g. email, letter)***
  - Must also follow **HRPP Policy 3.6** which governs:
    - Content
    - Format
    - Identification of sender/recipient
    - Contact methods and frequency

## Ethical Access for Medical Record Review:

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

## Investigator Responsibilities:

- Investigators must describe in their application how they have ethical access or justification for a waiver of the requirement
- If the investigator does NOT have ethical access for the purposes of recruitment, they may add a co-investigator with appropriate access
- If the investigator wishes to use a research coordinator acting on their behalf, justification must be provided in the application
- If the investigator does not have ethical access for the purposes of review of medical records, they may:
    - Add a co-investigator with appropriate access or an honest broker (see HRPP Policy 3.4), or
    - request a waiver of ethical access with proper justification