# 3.12 Ethical Access

## 1.0 Purpose

The purpose of this policy is to define ethical access and to describe the Organization'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.

## 2.0 Policy

It is the policy of the Organization that obtainment of information about a potential subject, and approach to the potential subject, must occur in a manner that respects the privacy of that person.

## 3.0 Ethical Access for Recruitment of Subjects

For the purposes of this policy, the recruitment of subjects requires two distinct activities, each of which must respect the privacy of patients: (1) obtainment of information about the patient which leads the investigator to believe or conclude that the patient is eligible for the research, and (2) subsequent approach to the patient to explain the research and obtain his/her consent to participate.

- **3.1.** The obtainment of information about the patient which leads the investigator to believe or conclude that the patient is eligible for the research must occur in a manner that does not represent an invasion of his/her privacy. That is, the investigator must have ethical access to clinical information about the patient.
  - **3.1.1.** Ethical access, in this context, may occur in one of three ways:
    - **3.1.1.1.** The researcher has legitimate access to a patient's information for clinical purposes, and therefore has legitimate access to that patient's information for identifying potential research subjects
      Specifically an investigator may have ethical access to this information in this context in one or more of the following manners:
      - **3.1.1.1.1.** The investigator has an ***existing clinical relationship*** with the patient; that is the information has been shared with the clinician for the primary purpose of care of the individual. The patient may or may not know this relationship exists; for example, a specialist consulted informally by the primary provider to assist in the care of the patient may never have met the patient, but the clinical relationship, and hence ethical access exists. Similarly, members of a "care team" (e.g., a hospital

pharmacist, or nurse practitioner that rounds with the primary physician provider) have a clinical relationship and therefore ethical access.
*Note that the "care team" does not usually include a research coordinator acting on behalf of the investigator. However, the IRB or expedited reviewer, or the IRB Chair or Executive Chair may extend "ethical access" to that person under limited circumstances (for example, when the risks associated with loss of confidentiality are low and the information sought is not sensitive). In general, these circumstances would be similar to the conditions of 45 CFR 46.116(d) (or rev 45 CFR 46.116(f)).*
        - **3.1.1.1.2.** The investigator ***works with a provider who has an existing clinical relationship*** with the patient, and the relationship between the investigator and the provider is such that the investigator could reasonably be called upon to care for the patient in a clinical setting. For example, a physician partner of the investigator within the same specialty and clinical group might have the responsibility to care for the patient while on hospital service, or while taking night phone calls. Under these circumstances, for the purpose of this policy, the investigator has ethical access to information about the patient he/she would reasonably need to know to care for that patient.
        - **3.1.1.1.3.** The investigator's ***professional responsibilities*** (independent of her role as a researcher) require that she has this information. For example, a hospital epidemiologist would have access to a list of inpatients with positive blood cultures, as part of her duties; an Operating Room Nursing supervisor would have a list of names and diagnoses of patients scheduled for surgical procedures on a given day.
    - **3.1.1.2.** The patient has given express consent for investigators to search medical records or other databases to determine potential eligibility (for example, Nebraska Medicine Conditions of Treatment Opt-in for Clinical Research utilizing the Electronic Health Record (EHR) Core).
    - **3.1.1.3.** The IRB has waived the requirement for the patient's consent by finding that the conditions of 45 CFR 46.116(d) (or rev 45 CFR 46.116(f)) are met. Note that waiver of the requirement to obtain the patient's consent to have access to the patient's information to determine eligibility does not imply that, or require that, the requirement for consent to participate in the research is also waived.
- **3.2.** Subsequent approach to the patient to explain the research and obtain his/her consent to participate must also occur in a manner that respects the patient's privacy, and that minimizes the perception of dissemination of private information outside the clinical context (despite "ethical access" as described above.)
  "Approach to the patient" may refer to physical approach to the potential subject (that is, a face-to-face contact), verbal contact (via telephone) or written contact (by letter or email addressed personally to the potential subject).
    - **3.2.1.** Physical approach: Potential subject may be approached by the investigator if one of two conditions applies:
        - **3.2.1.1.** The investigator has an existing clinical relationship with the patient. In contrast to section 2.1.1 above, the patient must be aware of this existing relationship; that is, the patient must already know the investigator in his clinical role; or
        - **3.2.1.2.** Someone with an existing clinical relationship has approached the patient, introduced the existence of the research study in question, and asked

permission for the investigator (or her representative) to approach the subject to discuss the research.
Other personnel who may have access as described above (investigator with existing clinical relationship but who has never met the potential subject, or persons who have other professional access to identifiable information) may not directly approach the potential subject without introduction by a care provider and the express permission of the subject. Under limited circumstances, the IRB may approve approach by such persons without prior introduction.

- **3.2.2.** Verbal Contact
  - **3.2.2.1.** Verbal contact initiated as a result of identification through existing clinical relationship will follow the same pattern as for physical approach described in 2.1.1 above.
  - **3.2.2.2.** Verbal contact initiated based on the Conditions of Treatment Form designation ("opt-in" designation) must follow procedures described in HRPP policy 3.6 (Subject Recruitment Through Direct Invitation) (which specifies the content and format of communication and frequency and timing of messages.
- **3.2.3.** Written contact: Written contact must follow procedures described in HRPP policy 3.6 (Subject Recruitment Through Direct Invitation) (which specifies the content and format of communication, identification of recipient and sender, return contact information, and frequency and timing of messages).

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## 4.0 Ethical Access for Review of Medical Records

- **4.1.** For research that involves review of existing or prospective records, and where consent of the subject has been waived under HHS or FDA regulations, the requirement for ethical access will still apply to identification of potential subjects, as per section 3.1 above.

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## 5.0 IRB Procedure

- **5.1.** Investigators must describe how they have ethical access in the subject identification and recruitment section of the IRB application, or the appropriate section of the Medical Records Application.
- **5.2.** The IRB (or the expedited reviewer) will evaluate ethical access as part of its determination whether or not the research satisfies the criteria for approval (45 CFR 46.111(a)(7); "When appropriate, there are adequate provisions to protect the privacy of subjects …")
- **5.3.** If the investigator does not have ethical access for the purposes of recruitment, the investigator may consider adding a co-investigator with the appropriate access, whose role would be to introduce the potential subject to the investigator (as per section 3.2.1.2).
- **5.4.** If the investigator wishes to use a research coordinator acting on her behalf, the IRB or expedited reviewer, or IRB Chair or Executive Chair will determine whether ethical access can be extended to include that coordinator as per section 3.1.1.1.1.

- **5.5.** If the investigator does not have ethical access for the purposes of review of medical records, the investigator may consider adding a co-investigator with the appropriate access, whose role would be to identify potential subjects and gather de-identified data for the investigator. This role can also be taken by an “honest broker” (per HRPP policy 3.4; Use of Protected Health Information in Research)
- **5.6.** Review of medical records must also satisfy requirements of the HIPAA Privacy Rule per HRPP policy 3.4 (Use of Protected Health Information in Research).

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