OHSU Research Integrity Office	Human Research Protection Program Policies & Procedures	
Title: HIPAA Activities Preparatory to Research	Date Effective 2/26/2008	Supercedes P&P dated:
	Identification	Page 1 of 3

Background

For activities involved in preparing for research, covered entities may use Protected Health Information (PHI) or disclose PHI to a researcher without an individual's Authorization, a waiver or alteration of Authorization, or a data use agreement. However, the covered entity must obtain from the researcher representations that: (1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research; (2) the PHI will not be removed from the covered entity in the course of review; and (3) the PHI for which use or access is requested is necessary for the research.

SCOPE

This applies to HIPAA requirements for research activities the are performed in preparation of a research activity, including some recruitment practices.

AUTHORITY

45 CFR 164.512(i)(1)(ii) regarding uses and disclosures where authorization or opportunity to are or object are not required.

I. Policy

1. Activities preparatory to research are activities conducted for the purpose of:
    - **a.** preparing a research protocol;
    - **b.** developing a hypothesis;
    - **c.** writing a grant application; or
    - **d.** identifying subjects or records of subjects who may be recruited for the research.
2. All activities preparatory to research must be submitted for review to the OHSU IRB using the "Investigator's Certification for Reviews Preparatory to Research." This form certifies that:
    - **a.** the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
    - **b.** the PHI will not be removed from OHSU in the course of review; and
    - **c.** the PHI for which use or access is requested is necessary for the research.

3. When PHI will remain within OHSU, activities preparatory to research are allowed without an individual's Authorization, a waiver or an alteration of Authorization, or a data use agreement.
    a. OHSU workforce members are permitted, with IRB approval, to use PHI for all purposes preparatory to research.
    b. Individuals from outside the OHSU covered entity may conduct limited activities preparatory to research. Such activity is limited to review of PHI and is considered a disclosure of PHI.
4. Under the "preparatory to research" provision, no PHI may leave the covered entity. Anyone within OHSU sharing PHI with an outside researcher for the purpose of preparing a protocol must obtain documented proof that the OHSU IRB has approved the Waiver of Authorization or a Business Associates Agreement.
5. In situations where activities are preparatory to research, prospective IRB review is still required for all human subject research.

II. Procedures

1. Application and Approval

a If a researcher is proposing to engage in "activities preparatory to research," he/she must submit a completed Investigator's Certification for Reviews Preparatory to Research to the IRB prior to initiating any research activities. This should be submitted through the eIRB.

b Once approved by the IRB, the researcher may proceed with the preparatory to research activities, but must not remove any PHI from OHSU. If a non-OHSU researcher is accessing PHI, accounting for disclosures requirements must be followed. See information on Policy on Accounting for Disclosures.

c Any plans to conduct activities beyond the scope of preparatory to research must be submitted to the IRB for prior approval.

2. Recruitment and Contacting Participants

a Within the Covered Entity - OHSU Workforce:

- As part of OHSU's health care operations, the research team may contact a potential study participant for recruitment purposes in order to seek Authorization to further use PHI and to obtain Consent for Research. In addition, an OHSU provider may discuss treatment alternatives, which may include participating in a clinical trial, with the patient as part of the patient's treatment or the covered entity's health care operations. No waiver of authorization or accounting for disclosures is required.
- IRB requirements for contacting subjects must still be followed and may include collaboration with the potential participant's treating physician.

b Outside the Covered Entity - Non-OHSU Collaborators and Researchers

- OHSU researchers may have OHSU contract with a business associate—who may also be a researcher—to assist in contacting individuals on behalf of OHSU, the covered entity, to obtain their Authorizations. [Link to BAA policy] This does not require accounting for disclosures because the business associate is performing a health care operation on behalf of OHSU.
- When collaborating with an outside researcher who is not a business associate, the OHSU IRB can approve a partial waiver of the Authorization for recruitment

purposes or a full waiver of Authorization, if the conditions for waiver are all met. (Link to Policy). This requires accounting for disclosures.

III. Definitions

A. Activities Preparatory to Research - activities involved in preparing for research such as identify prospective research participants, reviewing records to determine whether there is a sufficient number or type of records to conduct the research, or under certain circumstances contacting potential participants for recruitment.

B. Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

C. Health Information - Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

D. Individually Identifiable Health Information – Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

E. Protected Health Information - individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.

IV. References

HHS Website "HIPAA Privacy Rule: Information for Researchers"
http://privacyruleandresearch.nih.gov

See Specifically:

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule http://privacyruleandresearch.nih.gov/pr_02.asp

Clinical Research and the HIPAA Privacy Rule
http://privacyruleandresearch.nih.gov/clin_research.asp