Oklahoma State University

Title: Uses and Disclosures for Research Purposes-Permitted Uses and Disclosures	**Policy #: PRV-06.08**
Category: HIPAA Compliance	**Authority: 45 CFR § HIPAA SECTION: 164.512(i)**
Standard: Uses and disclosures for research purposes	**Responsibility: Health Care Components**
Effective Date: 4/14/2003	**Page 1 of 4**
Approved By: OSU Legal Counsel	**Revised: 7/1/2013**

PURPOSE:

To set forth Uses and Disclosures for Research Purposes.

POLICY:

OSU may use or disclose protected health information for research, regardless of the source of funding of the research, provided that: *§164.512(i)(1)*

1. **Board Approval of a Waiver of Authorization** – OSU obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 *Uses and Disclosures for Which an Authorization is Required* for use or disclosure of protected health information has been approved by either: *§164.512(i)(1)(i)*
    a. An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or *§164.512(i)(1)(i)(A)*
    b. A privacy board that: *§164.512(i)(1)(i)(B)*
        i. Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests; *§164.512(i)(1)(i)(B)(1)*
        ii. Includes at least one member who is not affiliated with OSU, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and *§164.512(i)(1)(i)(B)(2)*
        iii. Does not have any member participating in a review of any project in which the member has a conflict of interest. *§164.512(i)(1)(i)(B)(3)*
2. **Reviews Preparatory to Research** – OSU obtains from the researcher representations that: *§164.512(i)(1)(ii)*
    a. Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research; *§164.512(i)(1)(ii)(A)*

b. No protected health information is to be removed from OSU by the researcher in the course of the review; and *§164.512(i)(1)(ii)(B)*
c. The protected health information for which use or access is sought is necessary for the research purposes. *§164.512(i)(1)(ii)(C)*

3. **Research on Decedents Information** – OSU obtains from the researcher: *§164.512(i)(1)(iii)*
   a. Representation that the use or disclosure sought is solely for research on the protected health information of decedents; *§164.512(i)(1)(iii)(A)*
   b. Documentation, at the request of OSU, of the death of such individuals; and *§164.512(i)(1)(iii)(B)*
   c. Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes. *§164.512(i)(1)(iii)(C)*
4. **Documentation of Waiver Approval** - For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph 1 of this policy, the documentation must include all of the following: *§164.512(i)(2)*
   a. *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved; *§164.512(i)(2)(i)*
   b. *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria: *§164.512(i)(2)(ii)*
      i. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements; *§164.512(i)(2)(ii)(A)*
         1. An adequate plan to protect the identifiers from improper use and disclosure; *§164.512(i)(2)(ii)(A)(1)*
         2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and *§164.512(i)(2)(ii)(A)(2)*
         3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule; *§164.512(i)(2)(ii)(A)(3)*

ii. The research could not practicably be conducted without the waiver or alteration; and *§164.512(i)(2)(ii)(B)*

iii. The research could not practicably be conducted without access to and use of the protected health information. *§164.512(i)(2)(ii)(C)*

5. **Protected Health Information Needed** - A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph 2c of this policy; *§164.512(i)(2)(iii)*
6. **Review and Approval Procedures** - A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows: *§164.512(i)(2)(iv)*
   a. An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110); *§164.512(i)(2)(iv)(A)*
   b. A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (1)(b)(2) of this policy, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with the immediate following paragraph of this policy; *§164.512(i)(2)(iv)(B)*
   c. A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and *§164.512(i)(2)(iv)(C)*

7. **Required Signature** - The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable. *§164.512(i)(2)(v)*

PROCEDURE:

The procedure for this policy will defer to the OSU-CHS Institutional Review Board Protection of Human Subjects Research Policy and Procedure Manual, maintained by the Research Department as long as those policies and procedures are updated on a regular basis.

REFERENCE:

IRB – Protection of Human Subjects Research Policy and Procedures Manual.