

# Disclosing Protected Health Information for Research Release

## Where Is The Policy in the Privacy Rule (Title 45, Part 164)?

### 45 C.F.R. §164.512(i)

(i) Standard: uses and disclosures for research purposes. (1) Permitted uses and disclosures. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) Board approval of a waiver of authorization. The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 C.F.R. 1c.107, 10 C.F.R. 745.107, 14 C.F.R. 1230.107, 15 C.F.R. 27.107, 16 C.F.R. 1028.107, 21 C.F.R. 56.107, 22 C.F.R. 225.107, 24 C.F.R. 60.107, 28 C.F.R. 46.107, 32 C.F.R. 219.107, 34 C.F.R. 97.107, 38 C.F.R. 16.107, 40 C.F.R. 26.107, 45 C.F.R. 46.107, 45 C.F.R. 690.107, or 49 C.F.R. 11.107; or

(B) A privacy board that:

(1) 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;

(2) Includes at least one member who is not affiliated with the covered entity, 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

(3) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) Reviews preparatory to research. The covered entity obtains from the researcher representations that:

(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;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) Research on decedent's information. The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) Documentation of waiver approval. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) 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;

(ii) 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:

(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(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

(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 this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information;

(iii) 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 IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) 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:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 C.F.R. 1c.108(b), 10 C.F.R. 745.108(b), 14 C.F.R. 1230.108(b), 15 C.F.R. 27.108(b), 16 C.F.R. 1028.108(b), 21 C.F.R. 56.108(b), 22 C.F.R. 225.108(b), 24 C.F.R. 60.108(b), 28 C.F.R. 46.108(b), 32 C.F.R. 219.108(b), 34 C.F.R. 97.108(b), 38 C.F.R. 16.108(b), 40 C.F.R. 26.108(b), 45 C.F.R. 46.108(b), 45 C.F.R. 690.108(b), or 49 C.F.R. 11.108(b)) or the expedited review procedures (7 C.F.R. 1c.110, 10 C.F.R. 745.110, 14 C.F.R. 1230.110, 15 C.F.R. 27.110, 16 C.F.R. 1028.110, 21 C.F.R. 56.110, 22 C.F.R. 225.110, 24 C.F.R. 60.110, 28 C.F.R. 46.110, 32 C.F.R. 219.110, 34 C.F.R. 97.110, 38 C.F.R. 16.110, 40 C.F.R. 26.110, 45 C.F.R. 46.110, 45 C.F.R. 690.110, or 49 C.F.R. 11.110);

(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 (i)(1)(i)(B)(2) of this section, 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 paragraph (i)(2)(iv)(C) of this section;

(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

(v) 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.

**Department:**

**Title:** Disclosing Protected Health Information for Research Release

**No.**

**Effective Date:** April 14, 2003

**Authorized By:** \_\_\_\_\_

***Disclosing Protected Health Information for Research Release***  
**45 C.F.R. §164.512(i)**

## **Why Do We Need This Policy?**

The Privacy Rule establishes the conditions under which Protected Health Information (PHI) may be used or disclosed by Covered Entities for research purposes. A Covered Entity may always use or disclose health information which has been de-identified (in accordance with §§164.502(d), 164.514(a)-(c) of the rule) for research purposes. Under the Privacy rule, Covered Entities are also permitted to use and disclose PHI for research with individual authorizations, or without individual authorization under limited circumstances.

Where research is concerned, the Privacy rule protects the privacy of Individually Identifiable Health Information, while ensuring that researchers are able to access medical information necessary to conduct research. In the course of conducting research, researchers may create, use, and/or disclose Individually Identifiable Health Information for the purposes of the research. Furthermore, the Privacy rule does not intend to prevent researchers' peers from reviewing such research. However, the regulation does provide that the researcher should have adequate plans to protect the identifiers of PHI from improper use and disclosure, as well as to destroy the identifiers at the earliest opportunity unless there is a justification not to do so.

To use or disclose PHI without authorization by the research participant, a Covered Entity must obtain one of the following:

- 1) Documentation that an alteration or waiver of research participants' authorization for use/disclosure of PHI has been approved by an Institutional Review Board (IRB) or a Privacy Board. This provision of the rule might be used for example, to conduct records research, when researchers are unable to use de-identified information.

- 2) Representations from the researcher that the use or disclosure of the PHI is only for purposes of preparing a research protocol or similar uses preparatory to research. The researcher must also represent that he/she will not remove any PHI from the Covered Entity and that the PHI is necessary for the research purpose.
- 3) Representations from the researcher that the use or disclosure of PHI is solely for research on the PHI of decedents, necessary for the research, and, at the request of the Covered Entity documentation of the death of the individuals about whom PHI is sought.

If a Covered Entity uses or discloses PHI for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board documentation of the following must be obtained:

- 1) A statement that the alteration or waiver of authorization was approved by an IRB or Privacy Board that was composed as required by the rule;
- 2) A statement identifying the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
- 3) A statement that the IRB or Privacy Board determined that the alteration or waiver of authorization, in whole or in part, satisfies the criteria required by the rule;
- 4) A brief description of the PHI for which use or access has been determined to be necessary by the IRB or Privacy Board;
- 5) A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- 6) The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

## **Purpose**

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A Covered Entity may use or disclose Protected Health Information for research as provided under 45 C.F.R. §164.512(i). Department is committed to ensuring the privacy and security of individual Protected Health Information. To support this commitment, Department will ensure any use or disclosure of Protected Health Information for research purposes is in compliance with all applicable laws and regulations.

## **Policy**

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1. Department may use or disclose Protected Health Information for research, regardless of the source of funding for the research, except as otherwise stated in this policy.
2. Documentation shall be obtained indicating that an alteration to or waiver of the individual authorization required by 45 C.F.R. §164.508 for use or disclosure of Protected Health Information, has been approved by the Department Institutional Review Board (IRB), established in accordance with 7 C.F.R. 1c.107, 10 C.F.R. 745.107, 14 C.F.R. 1230.107, 15 C.F.R. 27.107, 16 C.F.R. 1028.107, 21 C.F.R. 56.107, 22 C.F.R. 225.107, 24 C.F.R. 60.107, 28 C.F.R. 46.107, 32 C.F.R. 219.107, 34 C.F.R. 97.107, 38 C.F.R. 16.107, 40 C.F.R. 26.107, 45 C.F.R. 46.107, 45 C.F.R. 690.107, or 49 C.F.R. 11.107 or the Department privacy board.
3. Department will obtain from the researcher representations required by law as described in the following procedures, and consistent with 45 C.F.R. §164.512(i)(1)(ii) and (iii).
4. Department will obtain from the researcher representations required by law as described in the following procedures, and consistent with 45 C.F.R. §164.512(i)(1)(ii) and (iii).

## Procedures

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1. Documentation will be obtained indicating that an alteration to or waiver, in whole or in part, of the individual authorization required by 45 C.F.R. §164.508 for use or disclosure of Protected Health Information has been approved by the Department Institutional Review Board (IRB), or the Department Privacy Board.
  2. Documentation of approval of an alteration or waiver must include the following information:
    - (a) a statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;
    - (b) a brief description of the Protected Health Information for which use or access has been determined to be necessary by the IRB or privacy board;
    - (c) a statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures following the requirements of the Common Rule, including the normal review procedures.
    - (d) a statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures by a privacy board which reviews the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who is not affiliated with the Covered Entity, 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 the alteration or waiver of authorization is approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure.
    - (e) a statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization indicating:
      - 1) the use or disclosure of Protected Health Information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:-
        - (i) an adequate plan to protect the identifiers from improper use and disclosure;
        - (ii) 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
        - (iii) adequate written assurances that the Protected Health Information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of Protected Health Information would be permitted by the Privacy rule; and
      - 2) the research could not practicably be conducted without the waiver or alteration; and
      - 3) the research could not practicably be conducted without access to and use of the protected health information.
3. 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.

4. Prior to a review preparatory to research, Department will obtain from the researcher representations that:
  - (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;
  - (b) no Protected Health Information is to be removed from the covered entity by the researcher in the course of the review; and
  - (c) the Protected Health Information for which use or access is sought is necessary for the research purposes.
- . Prior to research using information relating to decedent(s), Department will obtain from the researcher:
  - a) representations that the use or disclosure sought is solely for research on the Protected Health Information of decedents;
  - b) documentation, at the request of Department, of the death of such individuals; and
  - c) representation that the Protected Health Information for which use or disclosure is sought is necessary for the research purposes.
5. Personnel receiving a request from an individual or entity for use or disclosure of Protected Health Information will utilize [FILE/SYSTEMS] to determine whether the requesting individual is a person with whom Department has a knowing relationship.
6. Personnel will follow appropriate policies and procedures for verifying the identity and authority of individuals requesting Protected Health Information [SEE POLICY, VERIFICATION OF ENTITIES REQUESTING USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION].
7. Once it is determined that use or disclosure is appropriate, [MEDICAL RECORDS] personnel with appropriate access clearance will access the Protected Health Information using proper access and authorization procedures.
8. The requested Protected Health Information will be delivered to the requesting individual in a secure and confidential manner, such that the information cannot be accessed by employees or other persons who do not have appropriate access clearance to that information.
9. [MEDICAL RECORDS] personnel will appropriately document the request and delivery of the [MEDICAL RECORDS] personnel will appropriately document the request and delivery of the Protected Health Information.
10. In the event that the identity and legal authority of an individual or entity requesting Protected Health Information cannot be verified, personnel will refrain from disclosing the requested information and report the case to the [PRIVACY OFFICER] in a timely manner.
11. Knowledge of a violation or potential violation of this policy must be reported directly to the [PRIVACY OFFICER] or [COMPLIANCE OFFICER], or to the employee compliance hotline. Protected Health Information