

**Research Related Excerpts of the  
Health Insurance Portability and Accountability Act of 1996, 45 CFR 164**

The following are the key sections and paragraphs related to research under the Health Insurance Portability and Accountability Act of 1996. Researchers should consult the full text of the [HIPAA Privacy Rule](#) for additional provisions and definitions.

**§164.501 Definitions**

*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**§164.508 Uses and disclosures for which an authorization is required.**

(1) *Authorization required: general rule.*

Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows: (i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except: (i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion. (ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure. (iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure. (iv) A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose. (v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository. (vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided. (2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following: (i) The individual's right to revoke the authorization in writing, and either: (A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or (B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice. (ii) The ability or inability to condition treatment, payment,

enrollment or eligibility for benefits on the authorization, by stating either: (A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or (B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization. (iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart. (3) *Plain language requirement.* The authorization must be written in plain language. (4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

#### **§164.512 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 Sec. 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 CFR 1c.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 (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 is 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 individuals;

(B) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

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

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

(E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

(F) There is an adequate plan to protect the identifiers from improper use and disclosure;

(G) There is 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

(H) There are 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 project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

(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)(D) 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 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);

(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.

#### **§ 164.524 Access of individuals to protected health information.**

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research. (iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. § 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law. (v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

#### **§ 164.528 Accounting of disclosures of protected health information.**

(a) *Standard: right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the

accounting is requested...

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with § 164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide: (A) The name of the protocol or other research activity; (B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records; (C) A brief description of the type of protected health information that was disclosed; (D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period; (E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and (F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity. (ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

**§ 164.532 Transition provisions.**

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either: (1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research; (2) The informed consent of the individual to participate in the research; or (3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research.