

# **Using Protected Health Information (PHI) for Research Purposes**

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Under the final Health Insurance Portability and Accountability Act (HIPAA) privacy standards, the use of identifiable health information for research will require several consents or authorizations from the individual whose information is to be used.

**I. For research that involves treatment or other active medical intervention<sup>1</sup> these consents or authorizations will include:**

- A written *authorization*<sup>2</sup> for uses/disclosures of the individual's Protected Health Information (PHI) by a covered entity<sup>3</sup> (in the research context, this is an "informed consent"); and
- A *consent*<sup>4</sup> signed by the individual for any uses/disclosures made by a covered health care provider for purposes of any "treatment, payment or health care operations".<sup>5</sup>

Specifically, the HIPAA law notes that "Except as otherwise permitted by Part 164.512 (i)<sup>6</sup>, a covered entity that creates protected health information for the purpose, in whole or in part, of research that includes treatment of individuals must obtain an authorization for the use or disclosure of such information."<sup>7</sup> This *authorization* must include:

- A description of the individual's PHI will be used or disclosed for treatment, payment, or health care operations;
- A description of any PHI that will be used for research under this authorization and will be held confidential by the covered entity<sup>8</sup> that otherwise could be used without authorization under Part 164.512<sup>9</sup> or without the individual's agreement under Part 164.510<sup>10</sup> except that the covered entity cannot limit any use/disclosure which is required by law; and
- A reference to the statements made in its Notice of Privacy Practices<sup>11</sup> and in its standard Consent<sup>12</sup>.

The authorization must also include certain *core elements*<sup>13</sup> required whenever a covered entity asks the individual for permission to use his/her PHI for its own purposes. These include:

- A description of the information to be used or disclosed that identifies the information "in a specific and meaningful fashion";
- The name or other specific identification of the persons or class of persons (e.g., local study coordinators) authorized to make the requested use or disclosure of PHI;
- The name or other specific identification of the persons or class of persons (e.g., sponsor's study monitors) to whom the covered entity may make the requested use or disclosure;
- An expiration date or event that relates to the individual or to the purpose of the use/disclosure;
- A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke (including as a condition of continuing participation in a study), and a description of how the individual may revoke the authorization;
- A description of each purpose of the requested use or disclosure;
- A statement that the individual may inspect or copy PHI to be used or disclosed, (except that in agreeing to participate in a clinical trial the individual may forego any access to specified parts of his/her clinical record, though they must be informed that this right will be reinstated when the research is complete);

- If use or disclosure of the PHI will result in direct or indirect remuneration to the covered entity from a third party, a statement that such remuneration will result; and
- A statement that protected health information used or disclosed pursuant to the individual's authorization may be subject to re-disclosure by a recipient and no longer protected by the rule.
- The authorization must be signed and dated by the individual, or by a legal representative with authority to act for the individual, unless altered specifications by an IRB or PB.

Unlike the general category of "treatment, payment and health care operations" in which treatment or eligibility for insurance may not be conditioned on an individual's willingness to provide an *authorization* for other uses/disclosures of PHI, the provision of such an authorization may be a condition of the individual's opportunity to participate in a research study.

The research protocol for review by the IRB or PB must include the case finding approach if the PHI of individuals will be reviewed to determine eligibility for a study.

For research that includes treatment, a covered entity that is a direct provider of health care, such as a physician or a hospital, will also obtain the general *consent* for uses/disclosures of the individual's PHI for treatment, payment and health care operations. This general *consent may be combined with the research authorization* described above; the additional authorization for the use/disclosure of PHI can also be in the same document as the informed consent the individual signs to participate in research; or the authorization for research uses/disclosures of PHI may be combined with the covered entity's notice of privacy practices required under Part 164.520.

## **II. Research using PHI when authorization can be waived or altered.**

For research using PHI when authorization can be waived or altered, the requirements are different [Part 164.512(i)]. To be considered for waiver or alteration, the research must be approved by an IRB or PB and satisfy 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.

The first 5 (A-E) are identical to those from the Common Rule (45 CFR 46 for DHHS) that governs the IRB already. Requirements (F) and (H) are included in IRB protocols under guidance from the Office of Human Research Protections (OHRP). Requirement (G) is new.

The definition of the PB that is included in the regulations is similar to that of an IRB from the Common rule. Of note, the PB does not need to be a part of the Covered Entity, similar to the "commercial" IRBs that exist today. Similarly, a covered entity does not need to have both an IRB and a PB.

Research on decedents PHI is covered here and requires 'notification' of the IRB or PB that the data are necessary only to the research and that the individual(s) are actually deceased.

### III. Reviews preparatory to research [Part 164.512(i)(ii)].

Under the HIPAA privacy regulations, "reviews preparatory to research" are considered uses or disclosures. These reviews include

- 1) pilot studies for developing research proposals.
- 2) case finding for research involving treatment.

These reviews require notification of the IRB or PB. Under the Common rule, the pilot studies themselves may be considered research and would generally require expedited or full review by the IRB. The case finding approach used for I (research involving treatment) should be included in the IRB or PB research protocol.

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<sup>1</sup> § 164.508 (f),

<sup>2</sup> "An authorization is a more customized document that gives covered entities permission to use specified PHI for specified purposes, which are generally other than TPO, or to disclose PHI to a third party specified by the individual. Covered entities may not condition treatment or coverage on the individual providing an authorization. An authorization is more detailed and specific than a consent. It covers only the uses and disclosures and only the PHI stipulated in the authorization; it has an expiration date; and, in some cases, it also states the purpose for which the information may be used or disclosed."

<http://aspe.hhs.gov/admsimp/final/pvcguide1.htm>

<sup>3</sup> Under HIPAA, a "Covered Entity" is "... a health plan, a health care clearinghouse, [or] a health care provider who transmits any health information in electronic form in connection with a covered transaction." (45 CFR 160.103)

<sup>4</sup> "A consent is a general document that gives health care providers, which have a direct treatment relationship with a patient, permission to use and disclose all PHI for TPO. It gives permission only to that provider, not to any other person. Health care providers may condition the provision of treatment on the individual providing this consent. One consent may cover all uses and disclosures for TPO by that provider, indefinitely. A consent need not specify the particular information to be used or disclosed, nor the recipients of disclosed information." <http://aspe.hhs.gov/admsimp/final/pvcguide1.htm>

<sup>5</sup> See Part 1064.506

<sup>6</sup> This allows for a waiver of individual authorization by an IRB or privacy board for the use of PHI in non-interventional, e.g., record review research.

<sup>7</sup> See Part 164.505 (f)

<sup>8</sup> The physician/researcher, for instance

<sup>9</sup> Such as certain health oversight activities

<sup>10</sup> Such as for inclusion in a hospital's directory information

<sup>11</sup> Required by Part 164.520

<sup>12</sup> See Part 164.506

<sup>13</sup> Specified in Part 164.508 (c) and Part 164.508 (d)