Research

**Question 1:** What constitutes "research" under HIPAA?

**Answer 1:** “Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. For more information see Section 164.501 Definitions: Research.

**Question 2:** Under what circumstances can PHI be used or disclosed for research?

**Answer 2:** Uses and disclosures for research can be made with or without authorization, depending on the type of research being undertaken and the type of information being used or disclosed. The three main research categories are:

- Use or disclosure of de-identified information or a limited data set;
- Use or disclosure of information with an authorization by the research participant; and/or
- Use or disclosure of information without the participant’s authorization. (i.e., pursuant to an institutional review board or privacy board)

For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 3:** What are the benefits of research involving de-identified information?

**Answer 3:** PHI can be used or disclosed for research purposes, without authorization or consent, if it is de-identified. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 4:** What is de-identified information?

**Answer 4:** “De-identified Information” is considered de-identified if it meets either of two tests: (a) a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and documents the methods and results of the analysis that justify such determination; or (b) the information is stripped of all patient identifying information. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes and Section 164.514(b) Requirements for De-Identification of Protected Health Information.

**Question 5:** What are the patient identifiers that must be removed for PHI to become de-identified?

**Answer 5:** Patient information will be considered "de-identified" and thus, not subject to the HIPAA privacy requirements if the following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if.
according to the current publicly available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code.

For more information see Section 164.512(i) Uses and Disclosures for Research Purposes and Section 164.514(b) Requirements for De-Identification of Protected Health Information.

**Question 6:** What is a limited data set?

**Answer 6:** A “limited data set” is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- Names;
- Postal address information, other than town or city, State, and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.

For more information see Section 164.514(e) Limited Data Set.

**Question 7:** Can a limited data set be used or disclosed for research without authorization?

**Answer 7:** A covered entity may use or disclose a limited data set without authorization only for the purposes of research, public health, or health care operations and only if the covered entity enters into a data use agreement with the limited data set recipient. For more information see Section 164.514(e) Limited Data Set.

**Question 8:** What is the "data use agreement"?
**Answer 8:** A data use agreement between the covered entity and the limited data set recipient must:

- Establish the permitted uses and disclosures of such information by the limited data set recipient. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;
- Establish who is permitted to use or receive the limited data set; and
- Provide that the limited data set recipient will: a) not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law; b) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement; c) report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware; d) ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and e) not identify the information or contact the individuals.

For more information see Section 164.514(e) Limited Data Set.

**Question 9:** Are we always required to obtain an authorization for research when the information is not de-identified or in a limited data set?

**Answer 9:** No, but obtaining an authorization is one way by which a covered entity can use and disclose protected health information for research purposes. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 10:** Can the authorization form for research uses and disclosures be combined with any other document?

**Answer 10:** Yes. 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. For more information see Section 164.508(b) General Requirements for Authorization.

**Question 11:** What are our requirements before using or disclosing protected health information for research without an authorization, assuming the information is not de-identified or in a limited data set?

**Answer 11:** Unless the information is de-identified or in a limited data set, patient information only can be used or disclosed without authorization by the research participant in the following three situations:

- An alteration to or waiver, in whole or in part, of the research participants' authorization for the use or disclosure of information about them for research purposes has been approved by an Institutional Review Board or a Privacy Board;
- When the use or disclosure of the information is solely to prepare a research protocol; or
- When the use or disclosure of information being sought is solely for research on decedents.

For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.
**Question 12:** What is involved in a waiver of authorization by an Institutional Review Board or a Privacy Board?

**Answer 12:** In order to use or disclose protected health information with a waiver of authorization, the IRB or privacy board must provide extensive documentation of required findings. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 13:** What documentation is required by the IRB or privacy board for a valid waiver of authorization?

**Answer 13:** The documentation must include:

- A statement identifying the IRB or privacy board and the date on which the waiver (or alteration) of authorization was approved;
- A statement that the IRB or privacy board has determined that the waiver (or alteration) satisfies certain required criteria;
- A brief description of the protected health information for which use or access has been determined to be necessary; and
- A statement that the waiver (or alteration) has been reviewed and approved under either normal or expedited review procedures.

This documentation must be signed by the chair, or other member as designated by the chair, of the IRB or privacy board. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 14:** What are the required criteria that the IRB or privacy board must find are satisfied?

**Answer 14:** In order for a covered entity to use or disclose information without authorization for research, an IRB or privacy board must find:

- 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 criteria: (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 under the regulations;
- The research could not practicably be conducted without the alteration or waiver; and
- The research could not practicably be conducted without access to and use of the protected health information.

For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 15:** Are we as a covered entity required to retain the documentation of approval of a waiver of authorization by an IRB or privacy board?

**Answer 15:** Yes. The IRB’s or privacy board documentation must be retained by the covered entity for at least six years from when the waiver is obtained. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes and Section 164.530(j) Documentation.
Question 16: What is required when the information is sought by a researcher and the information will be used preparatory to research?

Answer 16: The covered entity must obtain from the researcher representations that:
- The 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;
- No protected health information is to be removed from the covered entity by the researcher in the course of the review; and
- The protected health information for which use or access is sought is necessary for the research purposes.

For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

Question 17: What is an example of a review preparatory to research?

Answer 17: The HHS commentary notes that this provision will permit covered entities to use and disclose protected health information to assist in the development of a research hypothesis and aid in the recruitment of research participants. According to HHS, researchers sometimes require access to protected health information to develop a research protocol, and to determine whether a specific covered entity has protected health information of prospective research participants that would meet the eligibility criteria for enrollment into a research study. Therefore, this provision permits covered entities to use and disclose protected health information for these preliminary research activities without individual authorization and without documentation that an IRB or privacy board has altered or waived individual authorization, so long as the proper representations are made by the researcher. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

Question 18: What is required if the research request for information deals only with research on decedents?

Answer 18: The covered entity must obtain from the researcher:
- Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
- Documentation, at the request of the covered entity, of the death of such individuals; and
- Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

Question 19: Must these researcher representations for preparation and for decedents be in writing?

Answer 19: The regulations do not specify whether these researcher representations can be oral or must be written. A covered entity, however, would be prudent to require them in writing. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

Question 20: When an individual requests access to his/her protected health information in our designated record set, are we required to include information on research about that individual?

Answer 20: 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. For more information see Section 164.524(a) Access to Protected Health Information.

**Question 21:** What are our duties when we are requested to provide an accounting of disclosures when some of the disclosures are for research?

**Answer 21:** Unless the disclosure was made pursuant to an authorization, or involved de-identified or limited data set information, the accounting must include disclosures made for research, even if the disclosure is made pursuant to a waiver of authorization by an IRB or privacy board. Note, however, that if the covered entity has made disclosures of protected health information for a particular research purpose for 50 or more individuals, the accounting may provide:

- The name of the protocol or other research activity;
- A description of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
- A brief description of the type of protected health information that was disclosed;
- 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;
- The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
- 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.

For more information see Section 164.528(a) Right to an Accounting of Disclosures of Protected Health Information.

**Question 22:** Are we required to include a statement in our Notice of Privacy Practices about research?

**Answer 22:** If a covered entity believes that it may use or disclose protected health information without authorization (i.e., with an IRB or privacy board waiver of authorization) for research purposes, individuals must be informed of this through the covered entity’s Notice of Privacy Practices. For more information see Section 164.512(i) Uses and Disclosures for Research Purposes.

**Question 23:** Do we need a business associate agreement with a researcher prior to releasing protected health information for research purposes?

**Answer 23:** No. The HHS commentary in the revisions to the regulations states that disclosures from a covered entity to a researcher for research purposes do not require a business associate contract. This remains true even in those instances where the covered entity has hired the researcher to perform research on the covered entity’s own behalf. HHS also notes that the regulations, however, also do not prohibit a covered entity from entering into a business associate relationship with a researcher, if desired. For more information see Section 160.103 Definition: Business Associate.