Human Research

Obtaining PHI for Research without an Authorization

Q: Can researcher use PHI without authorization? (Funding source irrelevant).

Code: IRB = internal review board; PB = privacy board

Citation: 45 CFR 164.512(i).

Has the CE obtained documentation that an IRB/PB approved an alteration to individual authorization (164.508) for use/disclosure of PHI?

Yes

Does the documentation include a statement identifying the IRB/PB and the date the alteration or waiver was approved?

Yes

Does the documentation include a statement that the IRB/PB determined that the alteration/waiver, in whole or in part, satisfies the following criteria: A. The use/disclosure 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; 3. Adequate written assurances that the PHI 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 any other research for which the use/disclosure of PHI would be permitted by this subpart. B. The research could not practicably be conducted without the alteration or waiver; and C. The research could not practicably be conducted without access to and use of the PHI.

No

CE may not disclose/use PHI for research without patient authorization.

Is the PHI sought preparatory to research, with the following representations from the CE:

A. Use/disclosure is sought solely to review PHI as necessary to prepare for a research protocol or for similar purposes preparatory to research;
B. No PHI is to be removed by the researcher from the CE in the course of review;
C. The PHI sought for use/disclosure is necessary for research purposes?

Yes

The CE may use/disclose PHI for research; authorization not required; minimum necessary applies.

No

Does the documentation include a brief description of the PHI for which use or access the IRB/PB determined to be necessary?

Yes

Does the documentation include a statement that the alteration/waiver of authorization was reviewed and approved under normal or expedited review (IRB must follow the Common Rule; PB must follow Section 164.512(i)(2)(iv)(B, C))? 

No

CE may not disclose/use PHI for research without authorization.

No

Does the documentation include a statement that the alteration/waiver of authorization was reviewed and approved under normal or expedited review (IRB must follow the Common Rule; PB must follow Section 164.512(i)(2)(iv)(B, C))? 

Yes

Is the documentation of the alteration or waiver of authorization signed by the chair/designee of the IRB/PB?

Yes

The CE may use/disclose PHI for research, without authorization; disclose minimum necessary described in the documentation.

No

CE may not disclose/use PHI for research without authorization.

Has the CE obtained documentation that the IRB approved a waiver of individual authorization for use/disclosure of PHI?

Yes

CE may not disclose/use PHI for research without patient authorization.

No

Is the PHI sought preparatory to research, with the following representations from the CE:

A. Use/disclosure is sought solely to review PHI as necessary to prepare for a research protocol or for similar purposes preparatory to research;
B. No PHI is to be removed by the researcher from the CE in the course of review;
C. The PHI sought for use/disclosure is necessary for research purposes?

Yes

The CE may use/disclose PHI for research; authorization not required; minimum necessary applies.

No

Has the CE received from the researcher: A. Representation that the use/disclosure sought is solely for research on the PHI of decedents; B. Documentation, at the CE’s request, of the individuals’ deaths; and C. Representations that the PHI sought for use/disclosure is necessary for research purposes?

Yes

The CE may use/disclose PHI for research; authorization not required; minimum necessary applies.

No

Is the CE using or disclosing a limited data set?

Yes

The CE may use/disclose PHI for research; authorization not required; minimum necessary applies.

No

CE may not disclose/use PHI for research without authorization.

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Human Research
Use/Disclosure of De-Identified PHI

Q: Health information ("HI") that is de-identified and with respect to which there is no reasonable basis to believe it can be used to identify an individual is not individually identifiable HI and may be used or disclosed by a CE. At what point is PHI de-identified?

Cite: 45 CFR 164.514(a), (b), (c).

Does CU have actual knowledge that the information could be used (alone or with other info) to identify an individual?

No

Yes

Is de-identified HI. May use the HI without authorization; minimum necessary does not apply.

Has a statistician completed a de-identification certificate under 164.514(b)(1)?

No

Yes

Is de-identified HI. May use or disclose the HI without authorization; minimum necessary does not apply.

De-identification certificate:
1. Created by person with appropriate knowledge and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;
2. Person applies such principles and methods, determines risk 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 is very small; and
3. Person documents the methods and results of the analysis that justify such determination.

Has all of the following information been removed?
* Names
* Geocodes smaller than state, including street address, county, precinct, city, and zip except for last 3 digits if area population over 20,000 (the initial 3 digits are turned to 000 for areas of less than 20,000 people)
* All dates (DOB, admit date, discharge date, DOD) except the year and those over 89 must be aggregated into 90+ category
* Phone numbers
* Fax numbers
* Email addresses
* Social Security number
* Medical record number
* Health plan beneficiary #
* Acct #
* License/certification #
* VIN, vehicle identifiers, and license plate #
* Device ID, serial #
* URLs
* IP address #
* Biometric identifiers (finger, voice, other)
* Full-face photo and comparable images
* All other unique identifiers (#s, characteristic, code, except re-identification code allowed under 164.514(c); see box "Code")

Does CU have actual knowledge that the information could be used (alone or with other info) to identify an individual?

No

Yes

Is de-identified HI. May use or disclose the HI without authorization; minimum necessary does not apply.

Code Did the CE assign a code or record ID to allow re-identification by the CE?

No

Yes

Is de-identified HI. May use or disclose the HI without authorization; minimum necessary does not apply.

Is the code/record ID derived from or related to information about the individual and is otherwise capable of being translated to identify the individual? And will the CE use/discard the code/record ID for any other purpose? And will the CE disclose the mechanism for re-identification?

No

Yes

Is de-identified HI. May use or disclose the HI without authorization; minimum necessary does not apply.

(Code is derived, CE uses or CE will disclose the code, or CE discloses mechanism for re-identification. This HI is PHI. Need authorization to use/discard or another exception must apply.)
Human Research
Use/Disclosure of Limited Data Sets
Q: A limited data set may be used or disclosed by a CE. What is a limited data set and when can the CE use/disclose it?
Cite: 45 CFR 164.514(e).
LDS = Limited Data Set

(A limited data set is PHI with the following removed):
Have the following direct identifiers of the individual and the individual’s relatives, employers, and household members been removed?
* Names
* Postal address info, other than town or city, state, and zip
* Phone numbers
* Fax numbers
* Email addresses
* Social Security number

Is the purpose of the use or disclosure research or public health or health care operations?
Yes
No

Is the purpose of the use or disclosure to create an LDS for purposes of research, public health, or health care operations?
Yes
No

Does the CE have satisfactory written assurances, in the form of a data use agreement, that the LDS recipient will only use/disclose the PHI for limited purposes?
Yes
No

Does the data use agreement:
A. Establish the permitted uses and disclosures (research, public health, or health care operations) of such information by the LDS recipient?
B. Not authorize the LDS recipient to use or disclose the information in a manner that would violate HIPAA, if done by the CE?
C. Establish who is permitted to use or receive the LDS?
D. Provide that the LDS Recipient will: 1. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law; 2. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement; 3. Report to the CE any use or disclosure of the information not provided for by its data use agreement of which it becomes aware; 4. Ensure that its agents and/or subcontractors to whom it provides the limited data set agree to the restrictions and conditions that apply to the LDS recipient with respect to such information; and 5. Not identify the information or contact the individuals?

Compliance Note:
A CE is not in compliance with the HIPAA regulations if the CE knew of a pattern of activity or practice of the LDS recipient that constituted a material breach/violation of the data use agreement, unless the CE:
1. Took reasonable steps to cure the breach or end the violation; and
2. If unsuccessful, the CE (a) discontinued disclosure of the LDS to the Recipient; and (b) Reported the problem to the Sec of HHS.
A CE who is an LDS recipient and violates a data use agreement will be in noncompliance with the HIPAA regulations.

May not use or disclose the data as a limited data set.

May use or disclose the data as a limited data set. See Compliance Note.