POLICY INFORMATION

Document # **113**	Title: **Use & Disclosure of PHI for Research**	Print Date: **8/15/2016**
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Safeguard: **HIPAA**	Approved by: **Dean Beth E. Foley** DocuSigned by: Beth Foley 7ABCB867410B5481...	Date Approved: 9/2/2016

I. POLICY STATEMENT

To provide guidance to CEHS Health Care Components (HCCs) on the use and disclosure of PHI for research purposes in accordance with 45 CFR §164.501, 164.508 and 164.512.

II. DEFINITIONS

See HIPAA Privacy Policy 100

III. AUTHORITY AND RESPONSIBILITIES

CEHS has component units that are listed as a hybrid entity in accordance with USU's HIPAA Hybrid Covered Entity Declaration. Only the health care component (i.e., covered functions) of CEHS must comply with this policy. All references in this policy to "CEHS" shall be construed to refer only to the health care component of CEHS.

IV. PROCEDURES TO IMPLEMENT

The HIPAA Privacy Rule establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. CEHS has established guidance for investigators to clarify the conditions under which PHI may be used and disclosed for research purposes. The requirements are not intended to impede research, but to add additional guidelines and protections with respect to how health information may be used as part of an approved research protocol and what the requirements are for use of this information.

Circumstances in Which PHI May Be Used and Disclosed for Research Purposes

1. With the written permission of the individual (or the individual's personal representative) in the form of an Authorization; or
2. When the health information is de-identified; or
3. When the IRB waives the requirement for Authorization; or
4. When the information is collected as preparatory to research; or
5. When the information is from decedents; or
6. When the information is part of a limited data set and CEHS has entered into a data use agreement with a second party for the sharing of information.

The clinical HIPAA Authorization **DOES NOT** cover the use or disclosure of PHI for research purposes. Research HIPAA Authorization language must be approved prior to its use by the

IRB. In addition, determination of waivers of HIPAA Authorization and the determination of whether the research involves PHI can only be made by the IRB. An investigator cannot make these determinations by him/herself.

Processing of Research Requests:

1. Requests for use of the patient's PHI in research projects must be submitted in writing to the IRB. The research request must describe with sufficient specificity the PHI necessary for the research.
2. The IRB will evaluate the request and determine whether the covered entity will grant access to the patient's PHI and determine the necessity for authorizations, or waivers.
3. The IRB will notify the requestor of the denial or approval of the request and under what circumstances the approval is made.
4. HCCs with a need to know of the approval of the research project must be notified of the decision of the IRB. The notification shall include, but is not limited to:
    a) Name of researcher(s)
    b) Scope of project such as:
        i. Timeframes;
        ii. Types of patient and records included;
        iii. Indication of whether patient authorization is required;
        iv. Whether fees may be charged by the HCC; and
        v. Method of identifying research staff.

Research Disclosure of Accounting

In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of PHI made by a HCC. This accounting must include disclosures of PHI that occurred during the six years prior to the individual's request for an accounting (see **Attachment A - Accounting for Disclosures Response Form**.) The HCC is responsible for compliance with applicable requirements concerning an accounting of disclosures for research purposes. The researcher is responsible for documenting all uses and disclosures of an individual's PHI (including decedents) for research. **Attachment B - Accounting of Disclosures of Protected Health Information Log** should be completed by the researcher and forwarded to the HCC Privacy Officer who will ensure that the information is properly retained.

In addition, for disclosures of PHI for research purposes without the individual's authorization pursuant to 45 CFR §164.512(i), and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by HCCs. Under this simplified accounting provision, a HCC may provide individuals with a list of all protocols for which the patient's PHI may have been disclosed, as well as the researcher's name and contact information.

Requests That Do Not Require Authorization or Documentation of an IRB

1. The HCC may use or disclose PHI for research purposes without the patient's authorization as follows:
    a) Activities Preparatory to Research - An investigator may review PHI in medical records or elsewhere to prepare a research protocol. This review may be used, for

example, to allow the investigator to design a research study; or to assess the feasibility of conducting a study (e.g., whether a sufficient number or type of records exists to conduct the research). The investigator shall **NOT** remove any PHI from the HCC. When an investigator wishes to conduct a review of PHI as preparatory to research he/she must provide a discussion of each of the following points in the protocol submitted to the IRB for review:

i. The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes;
ii. No PHI will be removed from the HCC during the review; **and**
iii. The PHI that the researcher seeks to use or disclose is solely necessary for the research purpose.

b) Research on PHI of Decedents - An investigator may use or disclose PHI of deceased individuals for research purposes, under limited circumstances (see 45 CFR §164.512(i)(1)(iii)). The researcher must submit to the IRB for review and approval a written request describing the research and containing:

i. Written representations that the use or disclosure is sought solely for research on the PHI of decedents;
ii. That the PHI for which use and disclosure is sought is necessary for the research purposes; **and**
iii. Documentation, at the request of the HCC, of the death of such individuals about whom PHI is being sought.

c) Waiver or alteration of an Individual's Authorization - Under the Privacy Rule, the IRB may waive or alter, in whole or in part, the Privacy Rule's written Authorization requirements for the use and disclosure of PHI in connection with a particular research project.

Full Waiver - A principal investigator may seek a complete (full) waiver of the authorization requirements for some types of research (see section 45 CFR §164.512(i)). For example, if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, and it would be impracticable to conduct the research if Authorization were required. Research conducted on existing databases or repositories where no contact information is available, may qualify for such a waiver.

Partial Waiver - Researchers may request a partial waiver of the Authorization requirements of the Privacy Rule. This may be permitted to allow a researcher to obtain PHI as necessary to recruit potential research subjects. Even though the IRB may not waive the Authorization requirement for the entire research study, they may partially waive the Authorization requirement to permit the use and disclosure of the PHI for the purposes of contacting and recruiting the individuals into the study.

Alteration of Waiver - The IRB may also approve a request that removes some, but not all, required elements of a written Authorization (i.e., an alteration). For example, removing the element that describes the purpose of the requested use/disclosure of the PHI in cases where identification of the specific research study may affect the results of the study. Any subsequent use or disclosure of the PHI obtained for a research study different from the one in which the IRB granted approval to alter HIPAA requirements must have an additional Authorization. Certain exceptions may apply and can be found in sections 45 CFR §164. 512(i), or 45 CFR §164.514(e). Only the IRB can make the determination that exceptions apply.

Waiver Process - In order to approve a request for waiver or alteration, the IRB must determine and document that the use meets the following three criteria:

i. The use or disclosure of PHI involves no more than a minimal risk to the privacy of the individuals, based on, at least, the presence of the following elements:
    - An adequate plan to protect PHI identifiers from improper use and disclosure;
    - An adequate plan to destroy the identifiers at the earliest opportunity, consistent with the 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
    - 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 other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

ii. The research could not practicably be conducted without the waiver or alteration; **and**

iii. The research could not practicably be conducted without access to and use of the PHI.

Researchers remain accountable and have responsibility for any PHI released under a waiver of authorization, and are responsible to provide documentation to the HCC of any approved waivers or alterations. The documentation should include:

i. A statement identifying the IRB and the date on which the alteration or waiver of authorization was approved.

ii. A statement that the IRB has determined that the alteration or waiver of authorization satisfies the following criteria:
    - There is an adequate plan to protect the identifiers from improper use and disclosure;

- 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;
- There are adequate written assurances that the PHI will not be reused or disclosed to any person or entity, except as required by law, for authorized oversight of the research, or for other research for which the use or disclosure of PHI is permitted.

d) De-Identified Health Information - De-identified health information is not considered PHI; therefore, the Privacy Rule permits covered entities to use and disclose de-identified data without obtaining an Authorization and without further restrictions on use or disclosure. See **HIPAA Privacy Policy 102 - De-identification of PHI**.

e) Limited Data Sets and Data-Use Agreements - The use of Limited Data Sets should be considered when requests for PHI are submitted for research purposes.

2. Requests for Use and Disclosure of PHI with Individual Written Authorization - An investigator is required to obtain written authorization from each research participant prior to the use or disclosure of the participant's individual PHI for research purposes. The purpose of the authorization is to inform an individual how their medical and research information (collected or created) is to be used; who the information will be shared with; and to inform the individual of the right to access information about them that is held by CEHS. The IRB at Utah State University provides an authorization template that should be used by researchers (See **USU IRB HIPAA Authorization Template**).
    a) The authorization must be reviewed and approved by the IRB.
    b) If the HCC creates PHI for the purpose of research that includes treatment of individuals, the HCC must obtain written authorization for the use or disclosure of such information.
    c) An HCC may condition the provision of research-related treatment on provision of an authorization for the use and disclosure of PHI for such research
    d) An authorization for use and disclosure can be submitted as a separate document, or combined with the informed consent to participate form (see **USU IRB Informed Consent Template**).
    e) The authorization must be written in plain language.
    f) The authorization must contain the following core elements and required statements:
        i. A description of the information to be used or disclosed that identifies the information in a specific manner;
        ii. The name of the person(s) authorized to make the requested use or disclosure;
        iii. A description of each research purpose of the requested use and disclosure;

iv. A statement that the HCC may condition research-related treatment on the individual's authorization and, in the event condition is required, make a further specification of the consequences to the individual of a refusal to sign the authorization;
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 use or disclosure of PHI for research in which the end date is not known, uncertain, or not applicable.
vi. A statement that information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and no longer protected by the HIPAA regulations;
vii. The individual's signature and date, (and if the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual).

g) A copy of the signed authorization must be provided to the patient or personal representative if the HCC sought the authorization from the patient. See **HIPAA Privacy Policy 111 - Use and Disclosure of PHI with Authorization**.

3. Other Considerations
   a) The HCC may use or disclose PHI for retrospective research studies involving data re-analysis only if such use or disclosure is made either with patient authorization or a waiver of patient authorization subject to IRB review.
   b) The HCC must rely on a requested disclosure as the minimum necessary for the stated purpose when documentation or representations that comply with the applicable standards for use and disclosure of PHI are provided by the researcher requesting the information.
      i. The HCC may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure or request.
      ii. The documentation required as representation of the minimum necessary PHI required for research may be satisfied by one or more written statements, provided that each is appropriately dated and signed as required by this policy. See **HIPAA Privacy Policy 117 - Minimum Necessary Standard for Use and Disclosure of PHI.**
      iii. If the HCC has knowledge that the documentation of IRB approval was fraudulent with respect to the PHI needed for research, the HCC cannot rely on the IRB documentation as fulfilling the minimum necessary standard.

V. ATTACHMENTS

Attachment A - Accounting for Disclosures Response Form

Attachment B - Accounting of Disclosures of Protected Health Information Log

VI. REFERENCES

45 CFR §164.501

45 CFR §164.508

45 CFR §164.512
HIPAA Privacy Policy 102 - De-identification of PHI
HIPAA Privacy Policy 111 - Use and Disclosure of PHI with Authorization
HIPAA Privacy Policy117 - Minimum Necessary Standard for Use and Disclosure of PHI

Attachment A

Accounting for Disclosures Response

Clinic Name_____
Name of Patient_____
Date of Patient Request_____
Disclosure Date Range From: _____ **To:** _____

- ☐ There were no applicable disclosures made of your health information for the period you specified.
- ☐ An extension is required to process your request
  Reason: _____
- ☐ Disclosures of your health information were made by this office to:
  _____

Date of Disclosure	Name & Address to Whom Disclosure Made	Description of Information Disclosed	Purpose of Disclosure

If you have questions concerning this accounting for disclosures, please contact:
{Clinic Privacy Officer Name HERE}
{Clinic Privacy Officer Address HERE}
{Clinic Privacy Officer Phone HERE}

Printed Name of Privacy Officer_____

Signed: _____ Date: _____

For Office Use:

Type of Request	Processed Date	Fee Collected	Initials
Initial		N/A	
2nd in 12 Months			
3rd in 12 Months			

Attachment B

Accounting of Disclosures of Protected Health Information Log

Clinic Name: _____

Patient Name: _____

Date of Birth: _____ MRN: _____ Phone#_____

Address: _____

Use this log to record any disclosure of the patient's Protected Health Information that is not for the treatment, payment, or health care operations, or pursuant to the patient's Authorization or otherwise excepted from the patient's right to receive an accounting.

Date of Disclosure	Name and Address to whom Disclosed	Description of information Disclosed	Purpose of Disclosure