UCONN

Administrative Policy
Policy #2003-28

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES
(Privacy & Security of Protected Health Information (PHI))

Title	USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES (Privacy & Security of Protected Health Information (PHI))
Policy Owner and Contact Information	Privacy Office privacyoffice@uchc.edu
Campus Applicability	UConn Health
Applies to	
Effective Date	12/10/2013

PURPOSE:
The purpose of this policy is to comply with HIPAA by protecting the confidentiality and integrity of Protected Health Information used and disclosed for research purposes.

SCOPE:
Applies to all UConn Health workforce:

Employees (including faculty and staff)
Volunteers
Students and residents
Temporary staff
Agency and contracted staff
Credentialed staff
Members of the Board of Directors

POLICY STATEMENT:
Research is defined as a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.
The IRB of UConn Health will act as the Privacy Board to review and approve the use and disclosure of PHI for research purposes. The UConn Health IRB will comply with federal guidelines established in accordance with 7 CFR lc.l07, 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 CFR16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107.

1. Permitted Uses and Disclosures: UConn Health may use or disclose PHI in any form[1] for the purpose of research regardless of the source of funding provided that the policies outlined below are adhered to:

[1] For use and disclosure of PHI via e-mail, fax or telephone, staff is required to follow the UConn Health policies: E-mail: Use & Disclosure of PHI Faxing of PHI Telephone/Voicemail/Answering Machine Disclosure of PHI

A. Research Authorizations:
PHI may be used or disclosed for research purposes pursuant to a valid authorization from the individual;

OR

B. IRB Waiver or Alteration:
PHI may be used or disclosed for research purposes if the IRB determines that a waiver or alteration of authorization, in whole or in part, is appropriate.

C. In addition, the following requirements must be met:
1. For Reviews preparatory to Research PHI may be used or disclosed in preparation for research provided that the UConn Health IRB obtains from the researcher representations that:
a. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
b. No PHI is to be removed from UConn Health by the researcher in the course of the review;
c. The PHI for which use or access is sought is necessary for the research purposes.

2. For Research on Decedent's Information PHI may be used or disclosed for research on decedent's information provided that the CHC IRB obtains from the researcher:
a. Representation that the use or disclosure sought is solely for research on the PHI
b. Documentation, at the request of the UConn Health IRB, of the death of such individuals; and
c. Representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

2. Research Authorization:

A. To participate in research and receive research-related treatment, the participants are required to sign an authorization for use and disclosure of PHI for research.
B. While HIPAA allows the Authorization Form for use or disclosure of PHI for research purposes to be contained in the Informed Consent Form, UConn Health has decided that unless an exception is granted by the IRB, the Authorization Form is required to be separate from the Informed Consent Form for the main study component. If there is a sub-study component, consent and the HIPAA Research Authorization may be combined

for the sub-study.

If the authorization is not contained within the research consent form, the principal investigator (PI; person responsible for the research conducted at UConn Health) must obtain a separate HIPAA Research authorization from the participant unless the requirements for an authorization is waived by the IRB.

Required Elements for Authorizations: the authorization must be written in plain language and requires:

1. Description of information to be used or disclosed that identifies the information in a specific and meaningful fashion;
2. Identification of persons or group of persons authorized to make the requested disclosure;
3. Identification of persons or group of persons to whom UConn Health is authorized to make the requested disclosure;
4. Description of the purpose of each use or disclosure of research PHI;
5. Expiration date that relates to the individual or the purpose of the use or disclosure. The statement "end of research study", "none" or similar language is sufficient if PHI is used or disclosed for research or to create and maintain a research database or research repository;
6. Participant's signature and date or legally authorized representative's signature and date with description of authority to act;
7. Statement that the participant has the right to revoke the authorization in writing. Exceptions to the right to revoke and instructions on how to revoke the authorization must be contained in the authorization;
8. Statement that research-related treatment and payment may be conditioned on obtaining authorization. The consequences of refusal to sign must be contained in the authorization; and
9. Statement that PHI used or disclosed may be subject to redisclosure by the recipient and no longer protected.

C. The individual must be provided a copy of the signed authorization.

3. Documentation of waiver approval: For a use or disclosure to be permitted based on documentation of approval of an alteration or a waiver, the documentation must include all of the following:

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

B. Waiver criteria: A statement that the IRB has determined that the alteration or waiver in whole or in part, satisfies the following criteria:

1. Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   a. an adequate plan to protect the identifiers from improper use and disclosure;
   b. 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

c. 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 project, or for other research for which the use or disclosure of PHI would be permitted;

2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the PHI.

C. PHI needed: A brief description of the PHI the IRB has determined is necessary for the researcher to use or access;

D. 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:

1. 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);

2. The IRB must review the proposed research at convened meetings at which a majority of the board members are present, including at least one member who is not affiliated with UConn Health, not affiliated with any entity conducting or sponsoring the research and not related to any person who is affiliated with any such entities, and the waiver or alteration of authorization must be approved by the majority of the board members present at the meeting, unless the board chair or designated IRB member elects to use an expedited review procedure in accordance with UConn Health IRB policies;

3. The IRB 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 PHI for which use or disclosure is being sought. If the 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 board, or by one or more members of the board as designated by the chair; and

E. Required signature: The documentation of the alteration or waiver of authorization must be signed and dated by the chair or other member, as designated by the chair, of the IRB, as applicable.

DEFINITIONS:

Designated Record Set:

PROCEDURES/FORMS:

REFERENCES:
§ 164.512 (i) Health Insurance Portability and Accountability Act of 1996 as amended byHITECH on 1/25/13

Human Subjects Protection Office HIPAA Forms: http://research.uchc.edu/rcs/hspp/

UConn Health HIPAA Privacy Policy 2003-18 – Accounting of Disclosures of Protected Health Information to Patients Upon Their Request.

RELATED POLICIES:

ENFORCEMENT:
Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

APPROVAL:

Richard Simon (Signed) 1/17/14

Director of Human Subjects Protection Office **Date**
Richard Simon, MD

Iris Mauriello (Signed) 1/9/14

Iris Mauriello **Date**
Compliance Integrity/Privacy Officer

Frank M. Torti (Signed) 3/3/14

Frank M. Torti, M.D., M.P.H. **Date**
Executive Vice President for Health Affairs

POLICY HISTORY:
New Policy Approved: 4/14/03
Reviewed Without Changes:
Revised: 11/1/05, 12/10/13

Retired Policies and Procedures

The policy listed on the attached is no longer applicable to UConn Health.

The Administrative Policy Committee reviewed the attached and voted to retire Policy 2003-28 effective September 21, 2022.

FINAL APPROVAL:

1. Bruce Liang (Signature) 9/21/2022
Bruce T. Liang, MD Date
Interim Chief Executive Officer & EVP for Health Affairs

2. Kiki Nissen (Signature) 9/21/2022
Kiki Nissen, MD Date
Administrative Policy Committee Vice Chair

3. Janel Simpson (Signature) 9/21/2022
Janel Simpson, MBA Date
Administrative Policy Committee Chair