

<b>UTAH STATE DEVELOPMENTAL CENTER POLICY AND PROCEDURE MANUAL</b>		
<b>HIPAA USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH</b>		PAGE 1 OF 3
DIRECTIVE: 70.03	EFFECTIVE DATE: April 14, 2003	REVISION DATE: 9/20/2010
REVIEWING ENTITY: HIPAA COMMITTEE		
PURPOSE: The Utah State Developmental Center (“USDC”) may access, acquire, use or disclose protected health information about individuals for research purposes, subject to certain limitations.		
AUTHORITY REFERENCE: HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT OF 1996, 45 C.F.R. § 164.512 and “Health Information Technology for Economic for Clinical Health Act” (HITECH). See American Recovery and Reinvestment Act of 2009, § 13400 (P.L. 111-115); 45 CFR § 164.400 -164.414.		

**Policy:**

1. **Access, acquisition, uses and disclosures for research purposes.**
  - a. USDC may access, acquire, use, or disclose protected health information for research purposes with the individual’s specific written authorization.
    - i. An authorization must meet all the requirements described in the “Uses and Disclosures of Protected Health Information” policy, and may indicate as an expiration date such terms as “end of research study,” or similar language.
    - ii. An authorization for access, use and disclosure for a research study may be combined with any other type of written permission for the same research study, including consent to participate in the research study.
    - iii. The researcher may condition research-related treatment on the receipt of an authorization for access, use and disclosure of protected health information.
  - b. USDC may access, acquire, use or disclose protected health information for research purposes **without** the individual’s written authorization provided that:
    - i. USDC obtains documentation that a waiver of an individual’s authorization for release of protected health information has been approved by either:
      - A. The Utah Department of Human Services IRB, or if the DHS IRB declines, in writing, to review the research proposal then by a non- DHS IRB; or
      - B. A Privacy Board that:
        - I. Has members with varying backgrounds and appropriate professional competency as needed to review the effect of the research protocol on the individual’s privacy rights and related interests;
        - II. Includes at least one member who is not affiliated with USDC, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any such entity; and
        - III. Does not have any member participating in a review of any project in which the member has a conflict of interest.
    - ii. Documentation required of the IRB or privacy board when granting approval of a waiver of authorization must include:
      - A. A statement identifying the IRB or privacy board that approved the waiver of authorization, and the date of such approval;
      - B. A statement that the IRB or privacy board has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:

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- I. The access, acquisition, use or disclosure of an individual's protected health information involves no more than a minimal risk to the privacy of individuals, based on at least the following elements:
    - (i) An adequate plan to protect an individual's identifying information from improper access, acquisition, use or disclosure;
    - (ii) An adequate plan to destroy an individual's identifying information at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the information or such retention is otherwise required by law; and
    - (iii) 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 access, acquisition, use or disclosure of the protected health information would be permitted under this policy;
  - II. The research could not practicably be conducted without the waiver; and
  - III. The research could not practicably be conducted without access to and use of the individual's protected health information.
- C. A brief description of the protected health information for which access, acquisition, use or disclosure has been determined to be necessary by the IRB or privacy board;
- D. A statement that the waiver of an individual's authorization has been reviewed and approved under either normal or expedited review procedures, by either an IRB or a privacy board, pursuant to 45 CFR 164.512(i)(2)(iv); and
- E. A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who is not affiliated with USDC, not affiliated with the entity conducting or sponsoring the research, and not related to any person affiliated with USDC, or the entity conducting or sponsoring the research. The waiver of authorization must be approved by the majority of the privacy board members present at the meeting.
- F. The privacy board may elect to use an expedited review procedure if the research involves no more than minimal risk to the privacy of individuals. The review and approval of the waiver of authorization may be carried out by the chair of the privacy board or by a member designated by the chair.
- G. The documentation of the waiver must be signed by the chair of the IRB or privacy board or by a member designated by the chair.
- iii. A researcher may request access to individual protected health information maintained by USDC in preparation for research. USDC will only provide such access if it obtains, from the researcher, written representations that:
- A. Use or disclosure is sought solely to review an individual's protected health information to prepare a research protocol or for similar purposes to prepare for the research project;
  - B. No protected health information will be removed from USDC by the researcher in the course of the review; and

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- C. The protected health information for which use or access is sought is necessary for the research purposes.
  
- iv. USDC may provide access if it obtains the following from the researcher:
  - A. Representation that the access, acquisition, use or disclosure is sought solely for research on the protected health information of deceased persons;
  - B. Documentation, if USDC requests, of the death of such persons; and
  - C. Representation that the individual's protected health information, for which use or disclosure is sought, is necessary for the research purposes.

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Karen A. Clarke, Superintendent