



Health Care Finance & Administration Policy Manual

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| Policy Number: PRIV 16-018 |
| Policy Subject: Use of Enrollee Records in Research |
| Approved by: <i>[Signature]</i> Date: 6/3/16 |

PURPOSE OF POLICY

This policy addresses how Health Care Finance and Administration (HCFA) will permit the use of enrollee personally identifiable information (PII) or protected health information (PHI) for research purposes as permitted by the Privacy Act of 1974, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), or other federal and state laws or regulations.

POLICY

HCFA may use or disclose enrollee PII or PHI for research purposes, in strict compliance with privacy rules and regulations. HCFA will provide enrollees with all the privacy rights granted by HIPAA and by federal and state laws and regulations.

DISCUSSION & LEGAL BASIS

HCFA may use or disclose PII or PHI for research purposes, regardless of the source of funding of the research, in keeping with the statutory provisions of the Privacy Act, HIPAA, and other federal or state regulations and relevant HCFA policies.

PROCEDURE

1. The HCFA Privacy and Public Records Office is responsible for obtaining documentation from the proposed researcher regarding an alteration to or waiver, in whole or in part, of the enrollee authorization required by the Privacy Act or HIPAA for use or disclosure of PII or PHI. The review and approval shall be made by an Institutional Review Board or in the alternative, a HCFA Research Privacy Board.
2. The HCFA Privacy and Public Records Office shall ensure all documentation is complete and shall maintain such documentation for the time periods required under applicable law.

3. An Institutional Review Board (IRB) instituted in accordance with applicable privacy regulations shall evaluate research proposals as applicable. In the alternative, HCFA may constitute a Research Privacy Board which:
 - a. Shall consist of the HCFA Privacy Officer as an *ex officio* member, the Bureau Chief Medical Officer as chair, and members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the enrollee's privacy rights and related interests;
 - b. Shall include at least one member who is not affiliated with HCFA, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and,
 - c. Does not have any member participating in a review of any project in which the member has a conflict of interest.
4. For disclosures absent board review and approval of a waiver or modification of authorization, HCFA must obtain from the researcher representations relative to the PII or PHI sought that:
 - a. Use or disclosure is solely to review PII or PHI to prepare a research protocol;
 - b. PII or PHI shall not be removed from HCFA by the researcher in the course of the review; and
 - c. The use or access is necessary for the research purposes.
5. For disclosures absent board review and approval of a waiver or modification of authorization for purposes of research of a decedent enrollee's information, HCFA must obtain from the researcher representations relative to the PII or PHI sought that:
 - a. Use or disclosure is solely for research on PII or PHI of decedents;
 - b. Documentation, at HCFA's request, of the death of such enrollees; and
 - c. The use or access is necessary for the research purposes.
6. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver of authorization, the documentation must include all of the following:
 - a. Statement identifying the privacy board and the date on which the alteration or waiver of authorization was approved;
 - b. Statement that the privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the statutory criteria;
 - c. Brief description of the PII or PHI for which use or access has been determined to be necessary by the privacy board;

- d. Statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures according to the Common rule, including normal review procedures;
- e. Statement that the privacy board convened and reviewed the proposed research project in accordance with applicable federal and state laws and regulations.
- g. Documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the privacy board.

DEFINITIONS

Enrollee: a person currently enrolled in any category of TennCare Medicaid and TennCare Standard, including an individual eligible for and enrolled in the TennCare Program or in any Tennessee federal Medicaid waiver program pursuant to Sections 1115 or 1915 of the Social Security Act; and, for purposes of HCFA Privacy policies, the term may also be used to reference one who was previously an enrollee during a period for which there is a privacy request or compliance inquiry.

HIPAA: Health Insurance Portability and Accountability Act of 1996, for which administrative simplification, privacy and security regulations are codified at 45 CFR §§ 160-164.

Personally Identifiable Information (PII): Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

The Privacy Act of 1974: A United States federal law, enacted December 31, 1974, and codified at 5 U.S.C. 552a which establishes a Code of Fair Information Practice that governs the collection, maintenance, use, and dissemination of personally identifiable information.

Protected Health Information (PHI): information that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium, including demographic information that identifies or may be used to identify an individual and that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- (2) Relates to the physical or mental health or condition of an individual.

OFFICE OF PRIMARY RESPONSIBILITY

HCFA Privacy and Public Records Office, Office of General Counsel

RELATED FORMS

Health Care Finance and Administration Research Application

REFERENCES

5 U.S.C. 552a

45 CFR § 164.512

OMB Circular A-130