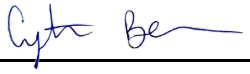
Department of Health Care Finance & Administration
Division of TennCare

Policy Number: PRIV 018	
Policy Subject: Use of Enrollee Records in Research	
Approved by: Cynthia Beeler	**Effective Date: 4/12/2024**
Position: Chief Privacy and Compliance Officer	
Signature: 	

I. PURPOSE OF POLICY

This policy addresses how the Division of TennCare (TennCare) 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.

II. POLICY

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

III. DEFINITIONS

Enrollee: An individual applying for or currently enrolled in any of the programs administered by the Division of TennCare, including TennCare Medicaid, CoverKids, Medicare Savings Program, and Long-Term Services and Supports. For purposes of TennCare Privacy policies, the term "enrollee" may also be used to reference an individual 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 C.F.R. §§ 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 past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Electronic Protected Health Information (ePHI): Electronic health information (ePHI) is any PHI that is created, stored, transmitted, or received electronically.

De-Identification: De-identification refers to the process of removing or obscuring any personal identifiers in a data set to protect the privacy of the individuals to whom the data belongs. TennCare follows the two specifications provided by HIPAA for the implementation of de-identification of health information:

1. Removal of all identifiers specified in 45 C.F.R. § 165.514(b)(2), such as identifiers of the individual, relatives, employers, or household members of the individual (otherwise known as the Safe Harbor method); or
2. rendering health information no longer be individually identifiable by applying generally accepted statistical and scientific principles and methods, leaving a very slight risk that the information could be used alone or in combination with other information to identify an individual.

Institutional Review Board: An Institutional Review Board (IRB) is a committee set up by an institution to review, approve, and monitor biomedical and behavioral research involving human subjects. The primary goal of an IRB is to protect the rights and welfare of human research subjects. An IRB can review and approve a waiver or an alteration of the individual authorization

requirement for use or disclosure of protected health information for research purposes, based on a proper application of the criteria set forth in the Privacy Rule.

IV. DISCUSSION & LEGAL BASIS

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

TennCare may disclose Protected Health Information (PHI) for research purposes if an enrollee acting as a research subject has provided authorization to the agency to release their records. TennCare may also disclose enrollee information with a waiver or modification of authorization in accordance with HIPAA, if done so in one of the following ways:

i. **After Obtaining Institutional Review Board or Privacy Board Approval**. If obtaining individual authorization is not practicable, TennCare may disclose PHI based on an alteration or waiver of individual authorization approved by an Institutional Review Board (IRB) or Privacy Board. This authorization includes reasonable assurances that the risk to the privacy of enrollees is minimal and may require de-identification of PHI using either the Safe Harbor method, or by expert determination using generally accepted statistical or scientific methods (See PRIV 014 – Records De-Identification Policy for more information).

ii. **In Preparation of a Research Protocol**. TennCare may disclose PHI for purposes of developing a research protocol, but such disclosures must be done on-premises at TennCare, and researchers may not remove PHI from TennCare for this purpose.

iii. **For Research on PHI of Decedents**. TennCare may disclose PHI of individuals who are deceased for research purposes. This process requires assurances from the researcher about the decedent status of the individual, and the necessity of PHI for research purposes.

V. PROCEDURES

Prior to Initiating a Request for the Release Enrollee Information for Research Purposes

1. Potential applicants should contact the TennCare Privacy Office to declare their intent to request the release of PHI for research purposes, using the following information:

Division of TennCare
Attention: Privacy Office
310 Great Circle Road
Nashville, TN 37243

The TennCare Privacy Office may also be contacted by email at Privacy.TennCare@tn.gov

2. After declaring their intent to solicit enrollee information for research purposes, applicants must provide a completed Application to Conduct Research Involving TennCare Member Protected Health Information, including Supplemental Assurances, to the TennCare Privacy Office.
   - If applicable, applicants must also provide Individual Authorizations for the release of PHI; or
   - documentation on the decedent status of individuals included in the research protocol, at TennCare's request.

Obtaining Institutional Review Board or Privacy Board Approval.

1. The TennCare Privacy 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 (IRB) or, alternatively, a TennCare Research Privacy Board.
2. The TennCare Privacy Office shall ensure all documentation is complete and shall maintain such documentation for the time periods required under applicable law.
3. An IRB instituted in accordance with applicable privacy regulations shall evaluate research proposals as applicable. Alternatively, TennCare may constitute a Research Privacy Board which:

   a. Shall consist of the TennCare Privacy Officer as an *ex officio* member, the TennCare 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 TennCare, 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 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 IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

b. statement that the IRB or 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 IRB or 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 IRB or privacy board convened and reviewed the proposed research project, including any de-identification procedures deemed necessary for the disclosure of enrollee PHI, in accordance with applicable federal and state laws and regulations; and
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 IRB or privacy board.

*If you feel that the research being proposed may qualify for the expedited review procedures, please contact the Privacy Office for more information.

Use of Enrollee Information in Preparation of a Research Protocol.

1. For disclosures for purposes of preparing a research protocol and without review and approval under the above section, TennCare 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 TennCare by the researcher during the review; and
c. the use or access is necessary for the research purposes.

Disclosure of Enrollee Information for Research on PHI of Decedents.

1. For disclosures for purposes of research of a decedent enrollee's information and absent review and approval under the above section, TennCare 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 TennCare's request, of the death of such enrollees; and
c. the use or access is necessary for the research purposes.

OFFICE OF PRIMARY RESPONSIBILITY

TennCare Privacy and Office, Office of General Counsel (OGC)

RELATED FORMS

Application to Conduct Research Involving TennCare Member Protected Health Information
PRIV-014 Records De-identification Policy
PRIV-007 Use and Disclosure of Personal Information

REFERENCES

5 U.S.C. § 552a
45 C.F.R. § 164.512
OMB Circular A-130
45 C.F.R. § 160.103
Privacy Act of 1974
Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 C.F.R. §§ 160-164)
Sections 1115 and 1915 of the Social Security Act