

Subject: Uses & Disclosures for Research Purposes

Page 1 of 7

Objective:

To specify when Tuality Health Alliance (THA) may use or disclose information about individuals for research purposes.

Policy:

I. General

When THA uses or discloses an individual's protected health information (PHI) for research purposes, they must consider the following:

- A. THA may use or disclose an individual's information for research purposes as specified in this policy. "Research" means "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to general knowledge."
- B. All such research disclosures are subject to applicable requirements of state and federal laws and regulations and to the specific requirements of this policy. **Note:** This policy is intended to supplement existing research requirements of the Common Rule, 45 CFR Part 46. The Common Rule is the rule for the protection of human subjects in research promulgated by the U.S. Department of Health and Human Services, and adopted by other federal governmental agencies, including the National Institutes for Health, for research funded by those agencies. In addition, some agencies have requirements that supplement the Common Rule that are applicable to a particular research contract or grant.
- C. De-identified information may be used or disclosed for purposes of research, consistent with THA Policy II-9, "De-identification of Member Information and Use of Limited Data Sets."
- D. A limited data set may be used or disclosed for purposes of research, consistent with the policies related to Limited Data Sets in THA Policy II-9 "De-identification of Member Information and Use of Limited Data Sets."
- E. THA may also conduct public health studies, studies that are required by law, and studies or analysis related to its health care operations. Such studies will be discussed in Sections IV and V of this Policy.

Subject: Uses & Disclosures for Research Purposes

Page 2 of 7

- II. Privacy Board established by THA
THA may use a Privacy Board established in accordance with 45 CFR Part 46 that has been established by THA pursuant to this policy, to perform the duties and functions specified in this policy regarding a research project being conducted, in whole or in part, by THA or by a THA office or program.

- III. Uses and disclosures for research purposes – specific requirements
 - A. THA may use or disclose member information for research purposes with the member's specific written authorization.
 - 1. Such authorization must meet all the requirements described in THA Policy II-3, "Uses and Disclosures of Member Information," and may indicate as an expiration date such terms as "end of research study," or similar language.
 - 2. An authorization for use and disclosure for a research study may be combined with any other type of written permission for the same research study.

 - B. THA may use or disclose member information for research purposes without the member's written authorization provided that:
 - 1. THA obtains documentation that a waiver of an individual's authorization for release of information requirements has been approved by a Privacy Board that:
 - a. 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 concerns;
 - b. Does not have any member participating in a review of any project in which the member has a conflict of interest.
 - 2. Documentation required of a privacy board when granting approval of a waiver of an individual's authorization for release of information must include:
 - a. A statement identifying the privacy board that approved the waiver of an individual's authorization, and the date of such approval;
 - b. A statement that the privacy board has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:
 - 1). The use or disclosure of an individual's protected information involves no more than minimal risk to

Subject: Uses & Disclosures for Research Purposes

Page 3 of 7

the privacy of individuals, based on at least the following elements:

- a). An adequate plan to protect an individual's identifying information from improper use or disclosure;
 - b). 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 identifiers or such retention is otherwise required by law; and
 - c). 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 use or disclosure of the protected information would be permitted under this policy;
- 2). The research could not practicably be conducted without the waiver; and
 - 3). The research could not practicably be conducted without access to and use of the Individual's protected information
- c. A brief description of the protected health information for which use or disclosure has been determined to be necessary by the privacy board
 - d. A statement that the waiver of an individual's authorization has been reviewed and approved under a privacy board, pursuant to federal regulations at 45 CFR 164.512(2); and
 - e. The THA Plan Director must sign documentation of the waiver of an individual's authorization, or other member as designated by the Chair of the Privacy Board, as applicable.
3. In some cases, a researcher may request access to individual information maintained by THA in preparation for research or to facilitate the development of a research protocol in anticipation of research. Before agreeing to provide such access to

Subject: Uses & Disclosures for Research Purposes

Page 4 of 7

individual information, THA should determine whether federal or state law otherwise permits such use or disclosure without individual authorization or use of a privacy board. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by a privacy board and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, THA will only provide such access if THA obtains, from the researcher, written representations that:

- a. Use or disclosure is sought solely to review an individual's protected information needed to prepare a research protocol or for similar purposes to prepare for the research project;
 - b. No member information will be removed from THA by the researcher in the course of the review; the member information for which use or access is sought is necessary for the research purposes;
 - c. Researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;
 - d. Researcher and his or her agents agree not to publicly identify the information or contact the individual whose data is being disclosed; and
 - e. Applicable federal or state law may require such other terms or conditions.
4. In some cases, a researcher may request access to individual information maintained by THA about individuals who are deceased. THA should determine whether federal or state law otherwise permits such use or disclosure of information about decedents without individual authorization. There may be instances where it would be inappropriate to disclose information, even where the individual subject of the information is dead – for example, individuals who died of AIDS may not have wanted such information to be disclosed after their deaths. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by the privacy board and formal waiver of authorization is

Subject: Uses & Disclosures for Research Purposes

Page 5 of 7

required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, THA will only provide such access if THA obtains the following written representations from the researcher:

- a. Representation that the use or disclosure is sought solely for research on the protected information of deceased persons;
- b. Documentation, if THA so requests, of the death of such persons; and
- c. Representation that the individual's protected information for which use or disclosure is sought is necessary for the research purposes.
- d. Researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;
- e. Researcher and his or her agents agree not to publicly identify the information or contact the personal representative or family members of the decedent; and
- f. Applicable federal or state law may require such other terms or conditions.

IV. THA Public Health Studies and Studies Required by Law

When THA is operating as a Public Health entity, THA is authorized to obtain and use individual information without authorization for the purpose of preventing injury or controlling disease and for the conduct of public health surveillance, investigations and interventions. In addition to these responsibilities, THA may collect, use or disclose information, without individual authorization, to the extent that law requires such collection, use or disclosure. When THA uses information to conduct studies pursuant to such authority, no additional individual authorization is required nor does this policy require a privacy board waiver of authorization based on the HIPAA Privacy rules. Other applicable laws and protocols continue to apply to such studies.

V. THA Studies Related to Health Care Operations

Studies and data analyses conducted for THA's own quality improvement purposes and to comply with reporting requirements applicable to federal or state funding requirements fall within the uses and disclosures that may be made without individual authorization as THA health care operations. Neither

Subject: Uses & Disclosures for Research Purposes

Page 6 of 7

individual authorization nor privacy board waiver of authorization is required for studies or data analyses conducted by or on behalf of THA for purposes of health care operations, including any studies or analyses conducted to comply with reporting requirements applicable to federal or state funding requirements. "Health care operations" as defined in 45 CFR 164.512 include:

- A. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of general knowledge is not the primary purpose of any studies resulting from such activities;
- B. Conducting population-based activities relating to improving health care or reducing health care costs, protocol development, case management and care coordination, contacting health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;
- C. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, and conducting training programs, and accreditation, certification, licensing or credentialing activities;
- D. Underwriting, premium rating, and other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits;
- E. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
- F. Business planning and development, such as conducting cost-management and planning related analyses related to managing and operating THA, including improvement of administration or development or improvement of methods of payment or coverage policies; and
- G. Business management and general administrative activities of THA, including management activities related to HIPAA implementation and compliance; customer services, including the provision of data

Subject: Uses & Disclosures for Research Purposes

Page 7 of 7

analyses for policy holders, plan sponsors, or other customers;
resolution of internal grievances; and

- H. Creating de-identified information or a limited data set consistent with the THA Policy II-9, "De-identification of Member Information and Use of Limited Data Sets." **Exception:** HIV-AIDS information may not be disclosed to anyone without the specific written authorization of the individual. Re-disclosure of HIV test information is prohibited, except in compliance with law or with written permission from the individual.

Reference(s): 45 CFR Part 64
45 CFR 164.512
DMAP Policy AS-001-06 Uses and Disclosures for Research
Purposes & Waivers

Formulated: March 13, 2003

Revised: January 2008

THA Plan Director

THA Medical Director