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**Human Resources Operating Procedure No. 124**

**HIPAA Privacy and Security**

**Trinity Health Corporation Welfare Benefit Plan**

**Trinity Health Corporation Retiree Benefit Plan (Grandfathered)**

**Integrity & Compliance Policy No. 01 Integrity & Compliance Program**

EFFECTIVE DATE: January 1, 2017

Original Effective Date: April 14, 2003

PROCEDURE TITLE:

***Limited Data Sets and De-Identified Data***

***To be reviewed every three years by:***

***Trinity Health Corporation Welfare Benefit Plan Privacy Official***

**REVIEW BY: January 1, 2020**

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This Procedure is in furtherance of the Trinity Health Corporation Integrity & Compliance Program as set forth in Trinity Health Corporation Integrity & Compliance Policy No. 01.

**PURPOSE**

The purpose of this Procedure is to ensure the Plan complies with the standards for De-identification and Re-identification of PHI and for the creation of a Limited Data Set (“LDS”) in accordance with HIPAA. If the regulations under HIPAA are changed by HHS the Plan will follow the revised regulations.

**PROCEDURES**

1. ***Limited Data Set***
2. The Plan will ensure there is a process regarding the creation of a Limited Data Sets (“LDS”) for research, public health and Healthcare Operations purposes. The Plan will Use or Disclose an LDS only for the purposes of research, public health or Health Care Operations.
3. The Plan will be responsible for reviewing and approving requests for an LDS.
4. An LDS will exclude the direct and indirect identifiers of the Individual, and his or her relatives, employers, or household members indicated in Section 2.d.ii. of this Procedure; however, the postal information regarding the town or city, state and zip code is permitted (excluding the postal street address) and an LDS is not required to exclude any other unique identifying number, characteristic, or code.
5. The Plan may Use PHI to create an LDS or it may Disclose PHI to a business associate to create an LDS on the Plan’s behalf.
6. The Plan will enter into a Data Use Agreement with the recipient of a LDS prior to providing the LDS to the recipient.
7. The Data Use Agreement must prohibit the recipient of the LDS from any Use or Disclosure of the PHI for a purpose beyond the one(s) set forth in the Data Use Agreement and in a manner that would violate the requirements of the Data Use Agreement.
8. If the LDS will include a Re-Identification code, the Privacy Official must approve the same.
9. In instances where the Privacy Official becomes aware of a pattern of activity or a practice of the LDS recipient that constitutes a material breach or violation of the Data Use Agreement, the Privacy Official will take reasonable steps to cure the breach or end the violation. If this is not successful, the Plan must discontinue Disclosure of PHI in the LDS to the recipient and report the problem to the Secretary of HHS.

***2. De-Identification of Information***

a. The Plan may Use and Disclose health information that has been De-identified. Further, if reasonable, to the extent possible, the Plan will Use and Disclose De-identified information.

b. The Plan will be responsible for all requests to De-identify PHI and all requests to Re-identify all previously De-identified PHI.

c. The Plan will be responsible for implementing the process of De-Identifying of PHI.

d. The De-identification determination will be made by the Workforce Member Disclosing the PHI by one of the following methods:

i. The Plan will retain or designate an expert (“identity expert”) who will be responsible for determining if PHI is De-identified. The identity expert must be someone who has appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods related to De-Identification. The identity expert will determine if the data is De-Identified using generally accepted statistical and scientific principles and methods and, if the identity expert determines that the PHI is De-identified, will submit a memorandum to the Plan certifying that the submitted PHI has been De-identified. The memorandum submitted to the Plan by the identity expert must contain the following information:

I. A description of how the generally accepted statistical and scientific principles and methods were applied in De-identifying the submitted PHI;

II. A statement whether any code or other means of record identification may exist that would allow the De-identified information to be Re-identified;

III. A statement that in his or her professional opinion, the identity expert believes that the De-identified information, used alone or in combination with other information, could not be Used to identify the Individual who is the subject of the information or that the risk of identification is small; and

IV. The signature of the identity expert.

ii. If the Plan does not have actual knowledge that the PHI could not be used alone or in combination with other information to identify an Individual who is subject of the information, then it may De-Identify the information by removing all the following identifiers of the Individual or relatives, employees or household members of the Individual:

I. Names;

II. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;

III. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

IV. Telephone numbers;

V. Fax numbers;

VI. Electronic mail addresses;

VII. Social security numbers;

VIII. Medical record numbers;

IX. Health plan beneficiary numbers;

X. Account numbers;

XI. Certificate/license numbers;

XII. Vehicle identifiers and serial numbers, including license plate numbers;

XIII. Device identifiers and serial numbers;

XIV. Web Universal Resource Locators (URLs);

XV. Internet Protocol (IP) address numbers;

XVI. Biometrics identifiers, including finger and voice prints;

XVII. Full face photographic images and any comparable images; and

XVIII. Any other unique identifying number, characteristic, or code.

e. If the Workforce Member has any questions regarding De-identified data, the Workforce Member should contact the Privacy Official who will make the final decision on designating PHI as De-Identified

f. The Plan, as part of the De-identification process, will be responsible for creating a method for Re-identifying PHI that has been De-identified. Such method must be approved by the Privacy Official and must comply with the following:

i. The code or other means of recording is not derived from or related to information about the Individual, and cannot otherwise be used to identify the Individual; and

ii. The Plan does not disclose the code or other means of record identification for any other purpose except that for which the mechanism for Re-identification was approved, and does disclose the mechanism for Re-identification.

***3. Re-Identification of Data***

a. The Plan will be responsible for handling all requests for Re-identifying PHI.

b.In the event that the Plan receives a request, or otherwise determines that it is necessary for De-identified PHI to be Re-identified, the Plan will consult with the Privacy Official. The Privacy Official will be responsible for making the final decision as to Re-identification under this Section 3. The Privacy Official will approve a method for Re-Identifying PHI that has been De-Identified.

c. Requests to Re-Identify previously De-Identified PHI must be approved by the Privacy Official and the requirements of HIPAA must be met.

# DEFINITIONS

The following are definitions of key terms used in this Procedure. Any terms used in this Procedure, but not otherwise defined herein, shall have the meaning set forth in the HIPAA regulations, 45 CFR §§ 160.103, 164.103, 164.304, 164.402 and 164.501.

**Covered Entity means** (a) a health plan, (b) a healthcare clearinghouse, or (c) a health care provider who transmits any health information in an electronic form in connection with a transaction covered under 45 CFR Subtitle A, Subchapter C, Parts, 160, 162 and 164.

**Data Use Agreement means** a required agreement between the Plan and a Limited Data Set recipient setting forth the obligations regarding the Use or Disclosure of PHI contained in the Limited Data Set.

**De-identify or De-identification means** a data set whereby all 18 specific PHI identifiers have been removed from the data. As an alternative, less than all of the 18 specific identifiers are removed and an expert opines that the data cannot be Re-Identified. In either case, there is no reasonable basis to believe that the information in the data set can be used to identify an individual.

**Disclosure (or Disclose) means**, with respect to PHI, the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

**HHS means** the U.S. Department of Health and Human Services.

**Healthcare Operations means** any of the following activities of the Covered Entity to the extent that the activities are related to covered functions:

1. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR § 3.20), population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

2. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing or credentialing activities;

3. Except as prohibited under 45 CFR §164.502(a)(5)(i) (prohibited use of genetic information for underwriting), underwriting, enrollment, premium rating and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance);

4. Conducting or arranging for medical review, legal services and auditing functions, including fraud and abuse detection and compliance programs;

5. Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

6. Business management and general administrative activities of the entity, including, but not limited to:

a. Management activities relating to implementation of and compliance with the requirements of HIPAA;

b. Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that PHI is not disclosed to such policy holder, plan sponsor, or customer;

c. Resolution of internal grievances;

d. The sale, transfer, merger or consolidation of all or part of the Covered Entity with another Covered Entity, or an entity that, following such activity, will become a Covered Entity, and due diligence related to such activity; and

e. Consistent with the applicable requirements of HIPAA, creating de-identified health information or a limited data set, and fund raising for the benefit of the Covered Entity.

**HIPAA means** the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191), 42 U.S.C. § 1320d, et. seq., and the regulations issued thereunder, 45 CFR Parts 160 and 164, as amended from time to time.

**Individual** **means** the person who is the subject of PHI and who is also a participant or former participant in the Plan or a covered spouse, dependent or beneficiary under the Plan.

**Individually Identifiable Health Information means** information that is a subset of health information, including demographic information collected from an Individual, and that:

1. Is created or received by a health care provider, health plan, employer, or health care clearing house; 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; and

3. Identifies the Individual or with respect to which there is a reasonable basis to believe the information can be used to identify the Individual.

**Limited Data Set or (“LDS”) means** a data set for Use and Disclosure of PHI for the purposes of research, public health or health care operations that is not completely De-Identified. The data set excludes 16 specified identifiers in accordance with applicable law but includes complete dates, city or town, and five digit zip codes.

**Plan means** the Trinity Health Corporation Welfare Benefit Plan (“Welfare Plan”) and the Trinity Health Corporation Retiree Benefit Plan (Grandfathered) (“Retiree Plan”), with respect to the benefit programs thereunder that constitute “health plans,” as defined in 45 CFR § 160.103. For the Welfare Plan, the benefit programs that constitute health plans are the medical/prescription drug, dental, vision, employee assistance, flexible healthcare spending account and healthcare reimbursement account program components of the Plan. For the Retiree Plan, the benefit programs that constitute health plans are the medical/prescription drug, dental, vision and healthcare reimbursement account program components of the Plan. The Welfare Plan and the Retiree Plan are each a Covered Entity. Whenever reference is made to the Plan’s action, the activities of the Plan Sponsor on behalf of the Plan shall be treated as the action of the Plan.

**Plan Sponsor** **means** the “plan sponsor” as defined in section 3(16)(B) of ERISA, 29 U.S.C. § 1002(16)(B) and means Trinity Health Corporation and, except where context indicates otherwise, employees and agents of Trinity Health Corporation and the other participating employers in the Plan who are responsible for Plan administration functions.

**Privacy Official means** the person designated by the Plan or Plan Sponsor to oversee and administer the Plan’s compliance with these Procedures and HIPAA.

**Protected Health Information or PHI means** Individually Identifiable Health Information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes Individually Identifiable Health Information: (a) in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (b) in records described at 20 U.S.C. 1232g(a)(4)(B)(iv); (c) in employment records held by a the Plan Sponsor or a Covered Entity in its role as employer; and (d) regarding a person who has been deceased for more than 50 years.

**Re-identify or Re-identification means** that a De-identified data set is modified so that the identities of the individuals represented in the data set is restored.

**Use (or Uses) means**, with respect to PHI, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

**Workforce or Workforce Member** **means** employees and other persons whose conduct, in the performance of work for the Plan, is under the direct control of the Plan or Plan Sponsor or one of its affiliated entities on behalf of the Plan, whether or not they are paid by the Plan or Plan Sponsor or one of its affiliated entities. The Workforce Members are described in Section 2.a.i. of Human Resources Operating Procedure No. 122, Minimum Necessary Use or Disclosure of

Protected Health Information.

**RELATED PROCEDURES AND OTHER MATERIALS**

* Human Resources Operating Procedure No. 120 (Use or Disclosure of Protected Health Information)
* Human Resources Operating Procedure No. 123 (Business Associate Agreements)
* Enterprise Information Security Procedures

**APPROVALS**

**Initial Approval: 04/14/2003**

**Subsequent Review/Revisions: December 20, 2016**