Integrity & Compliance Procedure ICR.6

EFFECTIVE DATE: ***June 1, 2020***

PROCEDURE TITLE:

Research Records Retention, Ownership and Access

To be reviewed every three years by:
Research Integrity & Compliance Committee

REVIEW BY: ***July 1, 2023***

PROCEDURE

This Procedure implements the requirements of Integrity & Compliance Policy No. 1 *Integrity and Compliance Program* which requires Trinity Health to establish policies and procedures to ensure Trinity Health's operations fully comply with applicable laws, regulations and professional standards, including promoting the conduct of ethical and compliant research.

Trinity Health is committed to maintaining the highest ethical standards in conducting Research and the protection of Human Subjects. This commitment is fundamental to Trinity Health's mission, core values, and vision. Trinity Health Investigators, external Investigators, research staff, and all others with access to research records, data, and information share an obligation to retain such information in a suitable, secure, and designated location for the required time period, and to make such information available for collaborative research and review when appropriate.

1. Research records and data must be retained in sufficient detail and adequate time period to enable appropriate responses to questions about accuracy, authenticity, primacy and compliance with laws and regulations governing the conduct of the research.

2. Department of Health and Human Services (DHHS) regulations require records relating to research be retained for at least 3 years after completion of the research. [45 CFR 46.115(b)]

3. For Investigational New Drug (IND) research, the Food and Drug Administration (FDA) requires sponsors and investigators to retain records and reports for 2 years after a marketing application is approved for a drug. If a drug application is not approved, records and reports must be maintained until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA is notified.

4. For Investigational Device Exemption (IDE) research, the FDA requires the Investigator or Sponsor to maintain records for a period of 2 years after the latter of the following dates: 1) the date on which the investigation is terminated of completed; or 2) the date that the

records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

Maintaining and managing research records is an essential element of all research projects in Trinity Health. Such maintenance and management assists Trinity Health in supporting findings, protecting intellectual property and ensuring compliance with federal and state regulations.

I. Retention of Research Records

Research records and data arising out of the design, conduct or reporting of research conducted in Trinity Health by any research team member or individual tasked with such responsibilities are to be retained for a minimum period of seven years after the submission of the final report on the research project.

The retention period of records and data may be extended, but never reduced, under the following circumstances:

- Language in a sponsored agreement funding the research specifies a longer retention period;
- Federal or state laws or regulations impose retention periods longer than seven years;
- The entire duration of any intellectual property rights related to research;
- For any allegations arising out of research, including, but not limited to, misconduct or conflicts of interest, the records must be retained until the disposition of the charges plus an additional seven years; and
- If research data qualifies for inclusion as a designated record set, as defined by the Health Insurance Portability and Accountability Act ("HIPAA").

It is the responsibility of the Principal Investigator, in conjunction with research team members, to retain data according to the language in this procedure and comply with federal and state laws and federal grant or contract requirements with respect to the retention of research data.

II. Ownership, Recording and Management of Data

A. Ownership

Unless specified under contract or required by law, Trinity Health and its Ministries own any and all tangible research property, including data, information and/or other records of research conducted by, on behalf of Trinity Health or at Trinity Health locations. As such, unless specified under contract or required by law, data will be maintained, managed and stored at an appropriate site within Trinity Health as chosen by the Principal Investigator, unless approval is received for off-site storage.

Under this section, Ministries engaging in research have the following responsibilities but are not limited to:

- Abiding by the terms of sponsored project agreements, including commercially sponsored clinical trials;
- Understanding ownership rights of the data being collected, publishing rights and obligations created by collecting the data in the event data is not owned by Trinity Health;
- If stored off-site, notification and approval of where data is stored;
- Securing intellectual property rights or Data Sharing Agreements.

In the event a Principal Investigator leaves Trinity Health, or the research project concludes, an agreement may be negotiated between the Principal Investigator and Trinity Health, where the Principal Investigator may retain his/her research records, including the research data. The agreement must include that Trinity Health retains absolute right to access the data for reasonable cause and with reasonable notice. If feasible, before leaving Trinity Health, the Principal Investigator shall archive a copy of research records and data to remain at Trinity Health. The original data retained by the Principal Investigator will remain accessible to Trinity Health and the Investigator must oblige a reasonable request with cause by Trinity Health for the return of all data. The original data stored off-site must be retained and managed according to this procedure.

B. Management of Records

The Principal Investigator shall assume primary responsibility for maintenance and management of the data during the entirety of the retention period, including if the data is stored off-site. The Principal Investigator's responsibilities under this section include, but are not limited to:

- The identification, collection and management of research data as custodian for Trinity Health;
- Adopting a system of organization for the collection of data and informing research team members of the system and the expectations;
- Developing processes for the collection and maintenance of research data in coordination with the research team members;
- Maintaining records in accordance with all applicable federal and state laws, including HIPAA and requirements of Trinity Health policies and procedures.

III. Access to Records

Designated individuals from Trinity Health have the right of unrestricted access to all research records, information, and data arising from research conducted or sponsored by Trinity Health regardless of the location of stored data.

The Principal Investigator shall assume responsibility and delegate qualified study team members access to the research records, data, and information. The records, data and information gathered during a research endeavor will be made available to qualified sub-Investigators, appropriate staff, external sponsors and designated governmental officials, where such access is appropriate. The Principal Investigator's responsibilities include but are not limited to:

- Understanding the agreements and contract terms that dictate access to records, data and information;
- Developing procedures for research team members to access data, records, information and specimens, where appropriate;
- Developing or ensuring appropriate safeguards are present to protect research records subject to HIPAA requirements or that contain sensitive processes and materials; and
- Understanding applicable federal and state regulations and policies governing research data sharing and making data available to other researchers and institutions whenever appropriate. If data, records, and information are to be shared, the Principal Investigator must ensure that all protected health information is removed according to HIPAA and other laws protecting information.

SCOPE/APPLICABILITY

This Procedure is intended to apply to all individuals engaged in any form of Human Subjects Research in Trinity Health, no matter the source of funding. This includes Investigators, their study coordinators, and Research staff external to Trinity Health (e.g., non-Trinity Health employees) performing Research activities either (i) on Trinity Health property or (ii) which involve Trinity Health patients or data, regardless of the location in which the Research is conducted. This procedure does not apply to records collected for audit purposes.

Finally, this Procedure is intended to apply to Human Subjects Research conducted by any Ministry, unless the Ministry has a pre-existing procedure that includes all elements of this Procedure. Each Ministry that conducts Human Subjects Research will comply with all elements of this Procedure, and may add procedures that do not conflict with this Procedure.

DEFINITIONS

Designated Record Set means, as defined under 45 C.F.R 164.501, "(1) [a] group of records maintained by or for a covered entity that is (i) [t]he medical records and billing records about

individuals maintained by or for a covered health care provider; (ii) [u]sed, in whole or in part, by or for the covered entity to make decisions about individuals. (2) [f]or purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information.

Investigator means the Principal Investigator (PI) and all other research staff, regardless of title or position, who are engaged in or responsible for the design, conduct, or reporting of research.

Ministry means a first tier (direct) subsidiary, affiliate, or operating division of Trinity Health that maintains a governing body that has day-to-day management oversight of a designated portion of Trinity Health System operations. A ministry may be based on a geographic market or dedication to a service line or business. Ministries include Mission Health Ministries, National Health Ministries, and Regional Health Ministries.

NIH means the National Institutes of Health, an operating component of the Department of Health and Human Services.

Policy means a statement of high-level direction on matters of strategic importance to Trinity Health or a statement that further interprets Trinity Health's governing documents. System Policies may be either stand alone or Mirror Policies designated by the approving body.

Procedure means a document designed to implement a policy or a description of specific required actions or processes.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Data means data collected, compiled and created, regardless of form or media, for research performed or conducted at Trinity Health or its Ministry locations and the events and processes leading to those results.

RESPONSIBLE DEPARTMENTS

Further guidance concerning this Procedure may be obtained from the Trinity Health Integrity & Compliance Department or Trinity Health Office of General Counsel.

RELATED PROCEDURES AND OTHER MATERIALS

- Steneck, Nicholas H., The Office of Research Integrity, *Introduction to Responsible Conduct of Research* (2007) available at https://ori.hhs.gov/sites/default/files/rcrintro.pdf
- Office of Management and Budget, Circular A-110, Sec. 53, Retention and Access Requirements for Records

- U.S. Department of Health and Human Services, National Institutes of Health, Grants Policy Statement (October 2007)
- Section 42 CFR Parts 50 and 93. Final Rule, Public Health Service Policies in Research Misconduct. *Federal Register*, Vol. 70, No. 94; Tuesday, May 17, 2005, pp. 28370
- 45 CFR 160 and 164 Health Insurance Portability and Accountability Act Privacy Rule
- 45 CFR 164.316 - Policies and procedures and documentation requirements.
- 45 CFR 164.530 Administrative requirements
- Trinity Health Records Management Policy
- National Institutes of Health (NIH), Statement on Sharing Research Data (NOT-OD-03-032; Released February 26, 2003)
- National Institutes of Health (NIH), NIH Grants Policy, Part II Subpart A, Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources
- Public Health Service, Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding. *NIH Guide*, Volume 25, Number 23, July 12, 1996

APPROVALS

Initial Approval: June 1, 2020

Subsequent Review/Revision(s):