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 advancing the ethical treatment of Research participants by adhering to the ethical principles of biomedical and behavioral Research codified in the Belmont Report, the *Ethical and Religious Directives for Catholic Health Care Services*, and complying with all federal, state and local regulations and Trinity Health's Research Code of Conduct and Research policies and procedures. All individuals involved in Research are responsible for assuring that Research participants' rights and safety are protected and that Research and its review are conducted ethically.

**Trinity Health Research Community**

The Trinity Health Research Community, which includes: Investigators; study coordinators; Trinity Health, Ministry and external Institutional Review Board ("IRB") members and staff; and research staff external to Trinity Health (e.g., non-Trinity Health employees) ("Trinity Health Research Community") performing Research activities (i) on Trinity Health or Ministry property (ii) which involve Trinity Health patients or data, regardless of the physical location or (iii) Trinity Health or Ministry staff who conduct Research elsewhere, but within the scope of their employment ("Trinity Health Research"), will uphold the basic ethical principles set forth in the Belmont Report:

- **Respect for Persons:** Every research participant should be fully informed of the Research, including the risks and benefits, freely agree to participate and understand they may discontinue from participation without penalty. Vulnerable populations, including but not limited to children, fetuses, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged individuals, and any other persons with
diminished autonomy must be provided additional safeguards to ensure they are adequately informed and protected.

- **Beneficence:** All Trinity Health Research shall be conducted with the goal of maximizing benefits while minimizing the risks to research participants. Research participants shall not be subjected to any form of unreasonable risk of harm.

- **Justice:** Research participants shall be recruited and selected in an equitable manner. Trinity Health will not employ methods of enrollment that include coercion or undue influence that remove the voluntary participation of research subjects.

Trinity Health Research Community members engaged in Human Subject Research shall be appropriately educated on the ethical principles, regulatory requirements related to U.S. laws on Human Subject protections, and applicable Trinity Health and Ministry policies and procedures. At a minimum, Research Community members are expected to have fulfilled the educational and training requirements included in the *Education and Training Requirements for Individuals Involved in Human Subjects Research Procedure* and its corresponding Appendix.

**Investigators**

Principal Investigators are responsible for the overall conduct of Research including minimizing risks and maximizing benefits to the participants. All Investigators must be qualified to conduct the Research.

The responsibilities of Investigators conducting Research at or on behalf of Trinity Health or one of its Ministries include but are not limited to:

- Complying with all applicable federal and state laws, regulations and Trinity Health and Ministry policies and procedures;

- Ensuring that all Research Community members that are delegated responsibilities are properly trained and educated on procedures and Protocol(s);

- Explaining (or assuring the delegation thereof) to potential participants selected equitably in clear and comprehensible language, that the activity is experimental, the objective of the Research, the possible risks, alternatives to participating, sources of funding and conflicts of interest, if they exist, the possible benefits, and the other regulatory required elements of informed consent;

- Obtaining voluntary prospective informed consent without the potential for coercion or undue influence from participants and informing the participants of their rights to withdraw from participation at any time, unless a waiver applies or the Research meets an exemption category. Documenting consent unless a waiver of documentation of consent is granted or the Research meets an exemption category unless a waiver applies or the Research meets an exemption category;
• Obtaining authorized third-party consent when children and those with diminished capacity to consent are involved, unless a waiver is granted or the Research meets an exemption category or an IRB determines that some or all of the participants are not capable of consent;

• Obtaining each participants' HIPAA authorization, unless a waiver of HIPAA authorization, Limited Data Set or preparatory to Research applies (refer to the Trinity Health procedure Research Involving Protected Health Information);

• Implementing adequate provisions to protect the privacy of all participants and confidentiality of the Research data; and

• Adequate planning to monitor the data collected to ensure the safety of participants according to the degree of risk of the study.

Institutional Review Board

The Trinity Health IRB of Record, Ministry IRBs and, in certain instances, external IRBs act as the sole bodies authorized to review and approve or disapprove Trinity Health Research. Therefore, each IRB is tasked with the responsibility of protecting Human Subjects involved in Research. IRB reviews must consider the potential benefits of Research, but the most important consideration should always be protecting each research participant.

When Trinity Health's IRB of Record or a Ministry IRB, regardless of location, is making a determination of engagement in potential Human Subjects Research that is conducted or supported by a U.S. federal department or agency, the IRB shall uphold the commitment to research participants and the pledge made in the Federal Wide Assurance ("FWA"), and uphold the Department of Health and Human Services Office of Human Research Protections ("OHRP") and the Food and Drug Administration ("FDA") regulations that apply to all Human Subjects Research, including but not limited to:

• Formally review and approve all Research Protocols that involve Human Subjects prior to the initiation of the study, free from external influence and coercion;

• In the process of review, require modifications in order to provide approval or the IRB must disapprove proposed Research activities;

• Consist of a diverse body of individuals representing the interests and various perspectives of each respective community;

• Ensure equitable selection of participants;

• Exercise the right to observe the consent process and review or audit any study for which IRB approval or exempt determination was made;
• Ensure that vulnerable participants and study populations are afforded appropriate levels of protections and are free of the potential for coercion and undue influence from the researchers;

• Act as the sole determining body of serious or continuing noncompliance, protocol deviations and unanticipated problems and determine whether to suspend or terminate approval of previously approved Research. In the event of such actions, the IRB will promptly report to all requisite parties including, but not limited to, the Investigator, appropriate institutional officials, OHRP, and FDA; and

• Disclose all conflicts and require abstention from participating in reviews where there is an appearance of or an actual conflict.

SCOPE/APPLICABILITY

This Policy is intended to apply to the Trinity Health Research Community performing Trinity Health Research. This Policy is also intended to apply to individuals engaged in Human Subjects Research that meets an allowable exemption under the Common Rule and FDA Regulations.

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

DEFINITIONS

Human Subject under 21 CFR 102 means an individual who is or becomes a participant in Research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. Human subject under 45 CFR 46.102(e)(1) means a living individual about whom an Investigator (whether professional or student) conducting Research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Investigator means the individual in charge of a clinical trial or a scientific grant, including: the development of Protocol, carrying out the planned Protocol and analyzing and reporting the results of the trial or grant 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.

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.

**Protocol** means the document that defines the background, rationale, objectives, design, methodology and organization of a clinical research project.

**Research** (under 45 CFR 46.102) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Trinity Health Research Community** means Investigators, study coordinators; Trinity Health, Ministry and external Institutional Review Board (IRB) members and staff; and research staff external to Trinity Health (e.g., non-Trinity Health employees) ("Trinity Health Research Community") performing research activities (i) on Trinity Health or Ministry property (ii) which involve Trinity Health patients or data, regardless of the physical location or (iii) Trinity Health or Ministry staff who conduct research elsewhere, but within the scope of their employment.

**RESPONSIBLE DEPARTMENT**

Further guidance concerning this Procedure may be obtained from the Trinity Health Integrity & Compliance Department.

**RELATED PROCEDURES AND OTHER MATERIALS**


- Final Rule, *Public Health Service Policies in Research Misconduct*. Federal Register, Vol. 70, No. 94; Tuesday, May 17, 2005, pp. 28370

- 42 CFR Parts 50 and 93

- The Office of Research Integrity, Definition of Research Misconduct [https://ori.hhs.gov/definition-misconduct](https://ori.hhs.gov/definition-misconduct)


- 45 CFR 164 (Security and Privacy)

- 45 CFR 46

- 21 CFR 56

- 21 CFR 50.20 and 45 CFR 46.116 (General requirements for informed consent)

- Legal Policy No. 3 - [Records Management](#)
• Functional Records Management Schedule


**APPROVALS**

**Initial Approval:** February 1, 2020

**Subsequent Review/Revision(s):**