



TRINITY HEALTH CODE OF CONDUCT
Supplement for Research

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Code of Conduct – Supplement for Research

It is the expectation of Trinity Health and its affiliated Ministries (hereinafter referred to collectively as "Trinity Health") that all research team members will perform research with the highest ethical and professional standards. Research team members include investigators, sub-investigators, Institutional Review Board ("IRB") members and staff, research directors and coordinators, and all others performing services in Trinity Health's research community. Trinity Health's Mission calls us to serve together in the spirit of the Gospel as a compassionate and transforming healing presence within our communities. Guided by our Core Values, we are committed to performing research supportive of the public good and for expanding the frontiers of scientific knowledge, and are driven by our commitment to the delivery of people-centered care that leads to better health care, improved health outcomes, and overall lower costs for our patients, residents, members and the communities we serve.

Trinity Health has established a system-wide Integrity and Compliance Program to support all who work in our health care ministry in understanding and following the laws, regulations, professional standards, and ethical commitments that apply. The Trinity Health Code of Conduct describes behaviors and actions expected of all who work in Trinity Health. This **Code of Conduct – Supplement for Research** provides additional guidance to individuals engaged in the performance of research, including medical research involving human subjects. If you have any questions regarding this information, please contact your Ministry's Institutional Signatory Official, IRB Chair, Research Integrity Officer (RIO), or Research Director or Integrity & Compliance Officer using the contact information provided on page 9. The complete [Trinity Health Code of Conduct](#) is available on Pulse, Trinity Health's corporate intranet site.

Supporting Right Relationships

As an engaged team member of Trinity Health's research community, you are expected to support Trinity Health's research activities as applicable to your role and responsibilities, including:

- Support and management of significant research activities, leveraging Trinity Health's strengths, including national scale, integrated care system, advanced electronic health records, and clinical data warehouse;
- Adherence to Trinity Health research compliance policies and procedures, ensuring that all research supports and aligns with Trinity Health's Mission, Vision and Core Values; is conducted with high ethical standards; and adheres to applicable laws and regulations; and
- Support the external dissemination and publication of research findings to benefit the broader health care and scientific community and enhance Trinity Health's prestige and competitive position in the health care industry.

Conducting Ethical Research

All individuals participating in research activities in Trinity Health are expected to conduct such activities in an ethical manner. This includes presenting research goals and intentions, reporting methods and procedures, and conveying interpretations in an honest and transparent manner. Investigators will be independent and impartial, and communication with other investigators, research participants, and with the public will be open and honest. In addition to actions and behaviors described in the Trinity Health Code of Conduct, the following is expected of all individuals working in the research community:

- *Research Human Protections and Ethics Fundamentals.* Trinity Health research team members are expected to adhere to ethical principles and comply with all federal, state, and local regulations governing research, including those outlined by the U.S. Department of Health and Human Services Office of Research Integrity, the U.S. Department of Health and Human Services Office for Human Research Protections, and the U.S. Food & Drug Administration's Regulations Relating to Good Clinical Practice and Clinical Trials. Adherence to the ethical principles outlined in publications such as the *Belmont Report*, *Nuremberg Code*, *Declaration of Helsinki*, and the *ICH Guidelines for Good Clinical Practice* are also expected when performing any research on behalf of Trinity Health.
- *Relevance of Research.* Trinity Health research team members will make every effort to ensure research is relevant and does not unnecessarily duplicate research previously carried out elsewhere. Research within Trinity Health should employ scholarly and scientific rigor, and demonstrate integrity in obtaining, recording and analyzing data, and in reporting and publishing results. Trinity Health research team members shall ensure the dissemination of scientifically sound information from clinical trials and other types of research. Relevant information shall not be withheld to permit the full evaluation of the safety, efficacy and utility of the clinical inventions, agents or devices under investigation for the benefit of medicine, patients, science and society regardless of the research outcome.
- *Privacy and Confidentiality.* Maintaining privacy and confidentiality is a demonstration of Trinity Health's Core Value of Respect. Trinity Health research team members have access to confidential and proprietary information, including the personal health information of research participants, and are responsible for maintaining the confidentiality of all information to the extent required by applicable law and/or contract. Medical or other personal information of research participants may only be used or disclosed as necessary in the conduct of operations, care management activities, approved research, quality assurance or measurement activities, or other activities specifically authorized by a research participant. Trinity Health is committed to protecting the privacy and confidentiality of research participants and their families prior to, during, and following any clinical research projects. Trinity Health research team members are required to uphold this commitment in conducting all research activities.

Commitment to Conducting Safe and Medically Appropriate Research

Trinity Health is committed to conducting quality research that is safe and medically appropriate and recognizes the three basic principles presented in the *Belmont Report*: respect of persons, beneficence and justice.

Respect of Persons

All Trinity Health research involving human subjects must be voluntary and comply with federal regulations governing informed consent, including the right to be fully informed with adequate comprehension, of the following:

- The purpose of the research, expected duration of participation, and a description of the procedures to be followed, including those that are experimental;
- The reasonably foreseeable risks or discomforts to the subject;
- A description of the maintenance of confidential records identifying the subject;
- For research involving more than minimal risk, an explanation of compensation, if any, and an explanation of medical treatments available to subject if injury occurs;
- Contact information of resources to handle research and subjects' rights issues and research-related injuries; and
- Subject participation is voluntary and may discontinue at any moment without penalty or loss of benefits to which he or she is otherwise entitled.

Furthermore, all communications with potential or enrolled research participants must be free of coercion and undue influence. Trinity Health is committed to protecting all persons whose capacity for self-determination is diminished by lack of maturity, illness, mental disability, or other circumstances that restrict the liberties of research participants.

Beneficence

All research participants involved in Trinity Health research shall be treated in an ethical manner, both respecting their decisions and protecting them from harm. The focus of clinical trials and all other forms of research must always be the protection of research participants, while maximizing possible benefits to the participants and community and reducing possible harms.

Justice

Trinity Health is committed to justice in all research activities, considering the fair distribution of the benefits and burdens of research to individuals and the common good, giving explicit attention to those who are poor and vulnerable, providing access to research for populations at the margins of society, and ensuring that individuals are not unduly influenced to participate due to their circumstances. All research within Trinity Health is guided by the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs) published by the United States Conference of Catholic Bishops (USCCB) which outline a particular commitment to social justice and a consistent ethic of life.

Publication of Research Results

Dissemination of research findings is an important part of the research process, passing on the benefits of research to Trinity Health colleagues, other researchers, professional practitioners and the community at large. Trinity Health has a fundamental interest in ensuring that any published findings resulting from research performed in Trinity Health are available to the widest possible audience, and at the earliest opportunity, with the most precise accuracy and completeness. Researchers should ensure that their findings are disseminated responsibly and widely through all appropriate media – such as journals, books, chapters, articles, conference proceedings, reviews, software, databases and creative arts. Where research is published, including electronically, members of the Trinity Health research community should be mindful of the following guidelines:

- Researchers must ensure that published reports, statistics and public statements about research activities and performance are complete, accurate and unambiguous and, where appropriate include any negative findings and results which may be contrary to the hypothesis and/or conclusion;
- Publications should contain appropriate reference to the contributions made by all persons who contributed materially to the relevant research, including full disclosure of all authors and/or collaborators and disclosure of any financial support received for the research. Any person who has participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research should be given the opportunity to be included as an author of a publication derived from that research;
- A publication which is substantially similar to another publication derived from the same research must contain appropriate reference to the other publication;
- Researchers must not deliberately include inaccurate or misleading information relating to research activity in curriculum vitae, grant applications, job applications or public statements; and
- In the event that a researcher becomes aware of unintentionally misleading or inaccurate statements about their work, the record should be corrected as soon as possible.

Research Misconduct

Research may involve honest errors, conflicting data or valid differences in the experimental design or the interpretation or judgment of the information. However, research may never involve misconduct, as it may be harmful to individuals and society as a whole. Any action inconsistent with Trinity Health's principles of integrity may constitute research misconduct subject to disciplinary action. All claims of fabrication, falsification, plagiarism, failure to meet clear ethical and legal requirements in proposing, performing or reviewing research or in reporting results shall be fully investigated to ensure all allegations of research misconduct are properly addressed in compliance with Trinity Health's policies.

Examples of research misconduct may include, but are not limited to, the following examples:

- Risking the safety of human participants, or the wellbeing of animals or the environment;
- Willful concealment or facilitation of research misconduct by others;

- Failure to honor the confidentiality the researcher promised or was contractually obligated to maintain as a way to gain valuable information from a party internal or external to Trinity Health;
- Deliberate misuse of funds acquired for support of research, including (but not limited to) failure to comply with the terms and conditions of grants and contracts; misuse of Trinity Health resources, facilities and equipment; and/or failure to identify correctly the source of research funds (financial misconduct);
- Deliberate destruction of one's own research data or records to avoid the detection of wrong doing or the deliberate destruction of someone else's data or records without authorization;
- Altering or fabricating information, including: dates, results or medical records;
- Retaliation against a person who acted in good faith and reported or provided information about alleged research misconduct;
- Material failure to comply with relevant federal, state, or other statutes or regulations applicable to the conduct and reporting of research;
- Failure to comply with a direction of a Trinity Health IRB upon which an approval to proceed with the research was granted or failing to notify a Trinity Health IRB of significant protocol changes that may affect a prior decision to approve the research proceeding;
- Failure to reveal material conflicts of interest to Trinity Health, sponsors, colleagues or journal editors when submitting a grant, protocol, or manuscript or when asked to undertake a review of research grant applications, manuscripts or to test or distribute products;
- Making false or misleading statements that are contrary to good faith reporting of alleged research misconduct or failing to declare any conflicts of interest when reporting alleged research misconduct; or
- Involvement in misleading publications; for example:
 - Failing to appropriately include as authors other collaborators who prepared contributions with the understanding and intention that it would be a joint publication;
 - Failing to provide collaborators with an opportunity to contribute as an author in a joint publication when they contributed to the research with the understanding and intention that they would be offered this opportunity;
 - Falsely claiming someone else's data as his or her own;
 - Knowingly agreeing to publish as a co-author without reviewing the work including reviewing the final draft of the publication;
 - Failing to obtain consent from a co-author before naming him or her as such in the work;
 - Portraying one's own work as original or novel without acknowledging prior publication or publication of data for a second time without reference to the first;
 - Willfully misrepresenting and misinterpreting (for any reason) findings resulting from conducting research activities;
 - Condoning or not reporting any of the actions listed above by another Trinity Health colleague; and/or

- Encouraging or facilitating another researcher to carry out scholarly misconduct (e.g., a manager telling his subordinate to falsify data) or otherwise creating an environment that promotes misconduct by another.

Conflicts of Interest in Research

Trinity Health is dedicated to ensuring the design, conduct or reporting of research is not biased, or does not have the appearance of bias, due to a conflict of interest. All potential personal, professional, and/or financial conflicts of interest shall be reviewed in accordance with Trinity Health's Conflicts of Interest policies and/or procedures and adequately addressed to minimize or eliminate any actual or potential conflicts of interest. Please review Trinity Health's [Disclosure of Financial Conflicts of Interest in Public Health Service Funded Research procedure](#) for an understanding of required disclosures involving public health service funded research.

Document Retention and Records Management

Proper management and retention of resulting data is part of conducting research in a responsible, ethical manner. Sufficient materials and data must be maintained in order to justify the outcomes of any research and to defend the results if ever challenged. While some data and materials are required to be retained by law, funding agency, or publisher requirements, the central aim is that sufficient materials and data be retained to justify the outcomes of the research and defend them if ever challenged. Please review Trinity Health's research-related data retention policies and procedures for further guidance on the types of documents and length of time necessary to ensure the ethical handling of research records.

IRB Responsibilities

The IRB's primary responsibility is to protect the rights and welfare of human subjects in research. In doing so, the IRB monitors human subject research to determine that it is conducted ethically and in compliance with Federal regulations and institutional policies. The IRB fulfills these responsibilities by conducting prospective and continuing reviews of human subject research, including review of the research protocol, federally-funded grant applications or proposals, informed consent process, procedures to be used to enroll subjects, and any adverse events or unanticipated or unexpected problems arising from the research. The IRB has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving research participants regardless of the source of funding or where the research is performed.

Institutional Responsibilities

Trinity Health is committed to:

- Conducting all research activities consistent with the highest standards of ethics and integrity and in accordance with all federal and state laws and regulations;
- Development of policies, procedures and guidelines on good research practices that ethically support those participating in research in Trinity Health;
- Promoting integrity in research and scholarship;
- Fostering a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training;
- Discouraging any acts of research misconduct;
- Dealing promptly with allegations or evidence of possible research misconduct; and
- Managing conflicts of interest to prevent bias or the appearance of bias in research.

Where to Find Help

If you have a question or concern about possible violations of law, regulation or the Code of Conduct, you are encouraged to seek answers by contacting a member of your organization's senior management team or one of the following resources:

- Your Ministry's Institutional Signatory Official
- Your IRB Chair
- Your Research Integrity Officer (RIO)
- Your Ministry's Integrity & Compliance Officer
- The Trinity Health Integrity and Compliance Line at 866-477-4661 or you may file a written report online at www.mycompliancereport.com using access code "THO."

Thank You!

We appreciate your taking time to review this ***Code of Conduct – Supplement for Research*** and your commitment to performing research with the highest standards of ethical behavior, consistent with Trinity Health's Mission and Core Values. Your dedication and support is critical to this important effort.