Human Research Protection Program & Institutional Review Board (HRPP/IRB)
Standard Operating Procedures

FINANCIAL CONFLICT OF INTERESTS

POLICY

Each funded and/or FDA-regulated research project submitted to the IRB for review must be accompanied by a Disclosure of Conflict of Financial Interest Statement for each principal investigator, sub-investigator, and all key research personnel directly involved in research activities and/or interacting with research subjects.

It is the Policy of TriHealth, Inc. ("TriHealth") to preserve integrity and independence in the exercise of professional and leadership judgment at TriHealth. Conflicts of Interest can compromise such integrity and independence if not identified, assessed and either eliminated or appropriately managed. Preserving such integrity and independence in clinical research studies conducted on TriHealth premises ("Research") is essential to protect the safety and well-being of human subjects and the integrity of the study data and results. Therefore, all Research Team Members always have a duty to fulfill their obligations to TriHealth, and otherwise to conduct Research in an impartial and unbiased manner, in the best interests of TriHealth and the human subjects, and in strict compliance with this Conflict of Interest in Clinical Research Policy (this "Policy").

The **Compliance and Audit Committee of the TriHealth Board of Trustees** (the "Committee") has the ultimate responsibility for implementation, compliance monitoring, and enforcement of this Policy. The Committee may delegate responsibilities to the Chief Compliance Officer, the Research Compliance Officer, and such other staff as it deems appropriate ("Delegates"). The Committee will also from time to time adopt changes to this Policy and adopt procedures and guidelines that supplement and are consistent with those set forth in or required by this Policy and related policies, as it considers necessary and appropriate to fulfill its charge. This Policy focuses on the identification of Individual Conflicts of Interest of Research Team Members. Conflicts of Interest arising from interests of TriHealth itself or of TriHealth Institutional Officials are identified, addressed, and managed pursuant to the TriHealth Corporate Policy on Conflict of Interest (#08_CC24.00 [Previously 13 ER03.00]).

The Committee shall establish such procedures, guidelines, forms, and tools as it considers necessary to implement this policy.

All Research Team Members shall cooperate with the Committee and its delegates in the administration and enforcement of this Policy and such related policies, procedures, and guidelines.

OVERVIEW

Public trust in the research enterprise and the legitimacy of its powerful role in society require a constant amenability to public scrutiny. Consequently, it is always necessary to assure the continued confidence of the public in the judgment of scholars and clinicians and in the dedication of academic

research institutions to the integrity of the research enterprise. The strength of this assurance is based on the assumption that scholars are honest and conduct their research with the highest standards and integrity.

This policy is intended to serve the subjects of human research. This policy is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them as to avoid conflicts of interest. Thus, an integral part of the policy is disclosure whereby individuals regularly review their professional activities.

Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. Conflicts involving the IRB itself or conflicts involving the institution must be managed. In order to manage such conflicts, the IRB must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

DEFINITIONS

Public Health Services (PHS): means the public health services of the U.S. Department of Health and Human Services and any components of PHS to which the authority may be delegated including the National Institutes of Health ("NIH").

FDA-regulated research: FDA-regulated research involves studies that use test articles (like drugs or devices) to gather information about their safety and effectiveness in humans, and where the data will be submitted to or inspected by the FDA. FDA regulation requires applicants submitting marketing applications for drugs, biologics, or devices to certify the absence for certain financial interests or to disclose financial interests of researchers who conduct clinical studies covered by the regulation at 21 CFR 54.4(a). The FDA may refuse to file any marketing application that does not contain a disclosure of financial interests or a certification that the applicant acted with due diligence to obtain researchers' disclosures but was unable to do so.

Family Member: includes: (1) A Research Team Member's spouse and children; and (2) the following persons if they live with the Research Team Member, the Research Team Member manages their financial affairs, or the Research Team Member is aware without inquiry that they hold the interest or position in question: (a) the Research Team Member's parents, siblings, grandchildren and their spouses; and (c) the Research Team Member's spouse's parents, siblings, children, grandchildren and their spouses.

Individual Conflicts of Interest or Individual Financial Conflict of Interest (FCOI): situations in which personal interests, particularly Significant Financial Interests (SFI), cause competing loyalties that compromise, or have the appearance of compromising, an Investigator's (or Research Staff's) objectivity in meeting duties or responsibilities. If an Investigator's (or Research Staff's) objectivity in designing, conducting, or reporting Research, or other scholarly work is directly or substantially biased by Significant Financial Interests or other interests, the Investigator's judgement in the collection, analysis, review, and interpretation of data may be compromised, along with the decisions, for example, on the

hiring of staff, procurement of materials or equipment, sharing of results, writing of protocols, safety of Human Research Participants, use of statistical methods, and mentoring of students.

Organizational Conflicts of Interest (OCOI): a situation in which TriHealth, or any of its senior management or trustees, has an external relationship or financial investments or holdings (including ownerships in businesses, stocks, licenses, royalties, intellectual property rights, patents, and certain gifts) with an entity that it itself has a financial interest with TriHealth that might affect or possibly appear to affect organizational processes for the design, conduct, reporting, review, or oversight of human participant research.

Scholarly or Scientific Conflicts of Interest: conflicts that arise when a scholar or researcher's impartiality is biased by the potential for professional or personal gain, such in review and commenting on manuscripts, funding applications, tenure or promotion records, or other publications.

Significant Financial Interest (SFI): anything of monetary value or potential monetary value, to an Employee and the Employee's Immediate Family, which is, or appears to be, reasonably related to the individual's Institutional Responsibilities with certain exclusions. SFI refers to that received in the past 12 months and includes but is not limited to the following:

(1) "With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity...and the value of any equity interest in the entity..., when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value."

(2) "With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity..., when aggregated, exceeds $5,000, or [in which] the investigator...holds any equity interest."

(3) "Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests."

(4) Compensation or payments for service on boards or provision of executive advisory services to non-TriHealth Entities, excluded are Federal, State, local government agencies, or Institutions of higher education

PURPOSE

The purpose of this Policy is to set forth the responsibilities of Research Team Members with respect to disclosing, identifying, and documenting Individual Interests in and with other organizations or individuals that fund or sponsor Research or are otherwise interested in or affected by the outcome of Research at TriHealth. The disclosure obligations set forth in this Policy will be done by all Research Team Members, which includes both employed and non-employed individuals. This is separate and distinct from the annual disclosure process/questionnaire that must be completed by Institutional Officials under the Trihealth Corporate Policy on Conflict of Interest. This Policy is intended to supplement (not replace) any applicable state laws governing Conflicts of Interest applicable to charitable, nonprofit corporations, to the extent that other federal or state laws may impose more restrictive conflict of interest standards, and it is to be read in conjunction with other related TriHealth policies, including but not limited to the TriHealth Corporate Policy on Conflict of Interest.

PUBLIC DISCLOSURE

TriHealth shall ensure that this Conflict of Interest in Clinical Interest Policy is, at all times, available via the TriHealth website.

SCOPE

- **Entities Covered by the Policy**
  For purposes of this Policy, "TriHealth" includes the parent organization of our health system and all its managed or controlled affiliates. Affiliates not managed or controlled by TriHealth are covered under this Policy only to the extent specifically adopted by such affiliates.

- **Individuals Covered by the Policy**
  This Policy applies to Research Team Members, who include, but is not limited to all individuals who are principal investigators and sub-investigators of a Research study, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of such Research Study, including collaborators or consultants, whether or not such individuals are employed by TriHealth (collectively, "Research Team Members").

WHAT IS A CONFLICT OF INTEREST?

In general, a potential for a Conflict of Interest arises when a Research Team Member, or a Family Member of a Research Team Member, holds an Interest that may compromise or have the appearance of compromising the integrity or independence of that individual. An Interest may include a Financial Interest (e.g., a compensation arrangement, ownership interest) or an Associational Interest (e.g., an uncompensated position on the board of directors or the scientific advisory board of an entity or an unpaid speaker or course instructor role) held personally by a Research Team Member or Family Member of a Research Team Member in or with an outside entity or individual that funds or sponsors Research or is otherwise interested in or affected by the outcome of Research at TriHealth. The mere existence of such an Interest does not necessarily result in a Conflict of Interest. However, it is important that any such Interest is disclosed by the Research Team Member and evaluated by the Committee or its delegates, and that appropriate steps are taken to eliminate or manage any potential or actual conflict before the Research Team Member holding the Interest becomes involved in Research that could be biased by the Interest.

DISCLOSURE

The following requirements and procedures have been developed to enable TriHealth to identify, evaluate, eliminate, or manage Financial or Associational Interests of Research Team Members and their Family Members that can compromise or create the appearance of compromising integrity and independence in the exercise of professional and leadership judgment by the Research Team Member in the context of, or directly or indirectly relating to, a Research study.

The Principal Investigator for a Research Study shall be responsible for the monitoring and enforcement of timely and complete compliance with these disclosure obligations by all Research Team Members of the Study; the Principal Investigator shall report any instances of noncompliance promptly to the Hatton Clinical Research Regulatory Affairs Administrator and Chief Compliance & Privacy Officer.

All investigators and key research personnel directly involved in research activities and/or interacting with research subjects must submit a disclosure as to whether any of the financial interests/arrangements listed below apply to themselves or to an individual in their immediate family (such as spouse, dependent children, or members of their household) in relation to the study. The reporting period is 12 months preceding the date of their disclosure.

1. Having been an executive, director, or employee of the sponsor of this study.
2. Having received remuneration from a sponsor/funding agency when the aggregated value received during the 12-month period preceding the disclosure exceeds $5,000.
3. Having received reimbursed or sponsored travel that is related to investigator's responsibilities for this study.
4. Having equity interests (e.g. stocks, stock options, or other ownership interests) of any value for a non-publicly traded company or that exceeds $5,000 for a publicly traded company during the 12-month period preceding the disclosure.
5. Having income related to intellectual property rights and interests (e.g. patents, trademarks, service marks, and copyrights).
6. Having agreed to or plan to accept recruitment bonuses for enrolling subjects into the research.
7. Receiving any significant payments of other sorts not aforementioned including monetary values more than $5,000. These may be in forms such as a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation, or honoraria.

Disclosure Prior to Commencement of TriHealth Research or When Adding a New Research Member to TriHealth Research

Research Team Members must complete an **annual COI Questionnaire** that can be accessed and referenced by the TriHealth IRB via an internal database. Research Team Members must disclose all individual interests that they hold, or expect to hold in the future, on the COI Questionnaire. Research Team Members cannot participate in research at TriHealth if they do not complete an annual COI Questionnaire (i.e., a Principal Investigator may not add a Research Team Member to a study delegation of authority log until an annual COI Questionnaire is completed by the Research Team Member and included in the TriHealth Research COI Questionnaire Database). Additionally, any Research Team Member who answers "yes" to any questions on the COI Questionnaire cannot be added to a research study that is under TriHealth IRB oversight until the COI Questionnaire is reviewed and evaluated by the TriHealth IRB and the Research Team Member is approved by the TriHealth IRB to participate in the study. TriHealth IRB approval of a Research Team Member to participate in a research study may be contingent on implementation of a COI management plan or process.

Any new Research Team Member who would like to participate in research at TriHealth must complete an annual COI Questionnaire for inclusion in the TriHealth Research COI Questionnaire Database. A new Research Team Member cannot participate in research at TriHealth if he/she does not complete an annual COI Questionnaire (i.e., a Principal Investigator may not add the Research Team Member to a study delegation of authority log until an annual COI Questionnaire is completed by the Research Team Member and submitted to the TriHealth Research COI Questionnaire Database). Additionally, any new Research Team Member who answers "yes" to any questions on the COI Questionnaire cannot be added to a research study that is under TriHealth IRB oversight until the COI Questionnaire is reviewed and evaluated by the TriHealth IRB and the new Research Team Member is approved by the TriHealth IRB to participate in the study. TriHealth IRB approval of a Research Team Member to participate in a research study may be contingent on implementation of a COI management plan or process.

Annual Disclosure During the Course of a Funded Research

Each Research Team Member participating in a Funded Research must complete and submit the COI Questionnaire annually during the course of the Funded Research Study (the "Annual Disclosure"). Such disclosure shall include any information that was not disclosed initially, as well as updated information regarding a previously disclosed Individual Interest (e.g., the updated value of a previously disclosed equity interest). The Annual Disclosure shall be submitted no later than the day prior to the first anniversary of the commencement of the Funded Research, and similarly on each anniversary thereafter for the duration of the research.

Continuing Disclosures

If, during the conduct of a study or prior to study closeout, a Research Team Member becomes aware of a new Individual Interest of himself/herself or one of his/her Family Member's that the Research Team Member would have been required to disclose on the COI Questionnaire, the Research Team Member must, within thirty (30) days of discovering or acquiring such Individual Interest (e.g., through purchase, marriage, or inheritance), disclose such interest and submit an updated annual COI Questionnaire.

All information disclosed by Research Team Members during the disclosure and review process described herein will be confidential, except as necessary to implement this Policy or as otherwise required by law.

ASSESSMENT AND MANAGEMENT OF CONFLICTS OF INTEREST

Review and Assessment of Individual Interests of Research Team Members

- **Reviewing Individual Interests Disclosed Prior to Commencement of a Study**
  Any Research Team Member who answers "yes" to any questions on the required annual COI Questionnaire cannot be added to a research study that is under TriHealth IRB oversight until the COI Questionnaire is reviewed and evaluated by the TriHealth IRB and the Research Team Member is approved by the TriHealth IRB to participate in the study. TriHealth IRB approval of a Research Team Member to participate in a research study may be contingent on implementation of a COI management plan or process. Prior to approval of a proposed study by the TriHealth IRB and expenditure of funds (PHS-funded, sponsor or otherwise), TriHealth, acting through the Committee and its delegates shall review all of the Interests disclosed on the COI Questionnaires submitted by the Research Team Members to assess whether such Interest is related to the Research and, if so related, whether the Individual Interest gives rise to a Conflict of Interest.

  An Individual Interest is related to the Research when the Committee, or its delegates, reasonably determines that the Individual Interest: (i) could be affected by the Research; or (ii) is in an entity whose financial interest could be affected by the Research.

  A. A Conflict of Interest exists when the Committee, or its delegates, reasonably determines that the Individual Interest could directly and significantly affect the design, conduct, or reporting of the Research.

B. The Committee may involve the Research Team Member in its determination of whether an Individual Interest is related to the Research. A Research Team Member may be asked by the Committee, or its delegates, to produce evidence to support the Committee's consideration.
C. Any Research Team Member who potentially has a Conflict of Interest with respect to a proposed Research study must not be present during any meeting in which the Committee conducts its evaluation, except to answer questions of the Committee and to provide information the Committee needs for its deliberations. Such conflicted individuals will in no event be present during the deliberations and vote of the Committee.

- **<u>Reviewing Individual Interests Disclosed or Discovered During an Ongoing Study</u>**
    A. If, in the course of an ongoing Research study, a Research Team Member discloses a new Interest or a new Research Team Member added to an ongoing study answers "yes" to any questions on the required Conflict of Interest Questionnaire, the Committee, or its Delegates, shall within sixty (60) days review the disclosure of the new Interest(s), determine whether it is related to the Research and, if so related, whether the Individual Interest gives rise to a Conflict of Interest.
    B. If, in the course of an ongoing Research study, the Committee identifies an Interest that was not disclosed timely by a Research Team Member, or was not otherwise previously reviewed by the Committee, the Committee shall, within sixty (60) days, review the Interest, determine whether it is related to the Research, and, if so related, whether the Individual Interest gives rise to a Conflict of Interest. In addition, if a Conflict of Interest was not timely identified or disclosed, the Committee shall, within one hundred and twenty (120) days of its determination of noncompliance, complete a retrospective review of the Research Team Member's activities and the Research study to determine whether any Research conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

- **Development, Implementation and Enforcement of a Conflict Management Plan and Conduct of Retrospective Review**
    A. <u>Conflict Management Plan</u>. If the Committee, or its delegates, determine at any time, whether prior to a Study, in the course of a Study or prior to study close-out, that any Interest gives rise to a Conflict of Interest, then the Committee shall either take steps to eliminate the Conflict of Interest or develop and implement a written Conflict Management Plan (including, without limitation, communication of the Conflict Management Plan to all members of the Research Team), and take all such other steps, including, as necessary conducting a retrospective review, as required by this Policy and other applicable TriHealth policies and procedures. The primary purpose of a Conflict Management Plan will be to prevent decision-making with respect to the conduct of a Research study from being influenced by the Conflict of Interest. Each Conflict Management Plan shall specify the actions that either have been or shall be taken to manage such a Conflict of Interest and be consistent in all other respects with the guidelines adopted by the Committee from time to time.
    B. <u>Retrospective Review</u>. When a Conflict of interest is not identified or managed in a timely manner (including failure by a Research Team Member to disclose a Conflict

of Interest, failure to review or manage such Conflict of Interest, or failure by a Research Team Member to comply with a Conflict Management Plan), the Committee or its delegates shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Research Team Member's activities and the Research study to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The retrospective review shall be documented, including all the following key elements:

i. Project number;
ii. Project title;
iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
iv. Name of the Research Team Member with the Conflict of Interest;
v. Name of the entity with which the Research Team Member has a financial conflict of interest;
vi. Reason(s) for the retrospective review;
vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
viii. Findings of the review; and
ix. Conclusions of the review.

- **<u>Communicating Findings Internally within TriHealth</u>**
  The Committee, or its delegates, will promptly communicate its findings and recommendations regarding the Conflict of Interest and any Retrospective Review or Conflict Management Plan, as applicable, to both the Institutional Review Board and the Hatton Institute for Research.

- **Management Plans**
  The convened IRB reviews any disclosures of significant financial interest upon receipt of and at the time of initial and continuing review. The IRB develops and approves plans to manage the interest, as appropriate, to minimize the risk of imparting bias into the research. Management plans are typically tailored to the specific study and/or sponsor and the researcher's financial interests.

  Examples of special protections used in management plans may include, but are not limited to:
  - Disclosing the potential COI to the subjects in the informed consent form;
  - Reducing the researcher's role in the research (less interaction with subjects, less data analysis),
  - Adding an independent monitor to the study team to make sure that the research procedures are transparent,
  - Precluding the conflicted research from obtaining informed consent from subjects; or
  - Blinding the conflicted research to treatment arm(s), or
  - Requiring researchers to disclose their financial interest in presentations and publications related to the research.
- **Institutional Conflicts of Interest (ICOI)**
  Institutional Conflict of Interest: a situation in which the financial interests of TriHealth or a TriHealth official, acting within his or her authority on behalf of the institution, may pose risk of

undue influence that affect the research, education, clinical care, business transactions, or other activities of TriHealth.

TriHealth IRB requires that the financial interests of TriHealth must be identified, disclosed, and reviewed to prevent or manage institutional conflicts of interest that may affect (or reasonably appear to affect) institutional processes for the design, conduct, reporting, review, or oversight of research.

Institutional financial interests can be created by gifts, payments, royalty income, or other financial benefits provided to TriHealth from for-profit entities or from equity interest held by TriHealth in the entities. Examples of institutional financial interests include:

- Payments resulting from the transfer (licensing) of technology created at TriHealth to an entity, including royalties, milestone payments, and other licensing fees;
- Equity in (i.e., ownership of) a company (publicly or non-publicly traded) resulting from the transfer of TriHealth technology or from direct investment;
- Gifts, including gifts-in-kind of goods or services, from a potential sponsor (i.e., a commercial company), from a philanthropic unit of the sponsor, or from an individual affiliated with a sponsor; and
- Covered Official relationships where an institutional official receives payments, honoraria, royalties, equity, options and warrants, company positions (e.g., board directorships and/or management), or gifts.

A potential Institutional Conflict of Interest situation arises when the company also sponsors research at the TriHealth or manufactures products to be studied or tested at TriHealth or under its auspices.

Institutional Conflict of Interest Management

Institutional Conflict of Interest management strategies include, but are not limited to:

- Permitting the research to proceed, subject to a plan for managing the Institutional Conflict of Interest and any personal conflicts of interest (COI);
- Permitting the research to proceed, with divestiture of the financial interests of TriHealth and individual investigators; or
- Prohibiting the research from taking place at TriHealth.

Management plans are reviewed and approved by the Conflict-of-Interest Committee. Plans should address the nature of the conflict, conflict mitigation steps, and the party responsibility for implementing and monitoring the plan.

Examples of ICOIs

- An investigator proposes to conduct human subject research that would test or evaluate TriHealth intellectual property that is licensed to an external entity.
- Where TriHealth is entitled to receive royalties from the sale of a technology that is proposed to be the subject of a TriHealth research project.

PHS-FUNDED STUDIES – OTHER PUBLIC DISCLOSURE AND RESPORTING REQUIREMENTS

A. <u>Reporting and Public Disclosure of Conflicts of Interest Prior to the Expenditure of Any PHS Funding</u>.

Pursuant to PHS regulation at 42 CFR 50, each researcher responsible for the design, conduct, or reporting of research funded by the PHS must disclose any significant financial interest (SFI). SFI is defined as a financial interest consisting of one or more of the following interests that reasonably appear to be related to the researchers' organizational responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any renumeration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. (For purposes of this definition, remuneration includes salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value);
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators must also disclose any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state of local government agency, an institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

Prior to the expenditure of funds in connection with a PHS-Funded Research Study to be conducted at TriHealth, TriHealth shall provide to PHS a Conflict-of-Interest report (a "COI Report") regarding an Interest found to be a Conflict of Interest and its implementation of a Conflict Management Plan. Such report shall include information concerning the Research Team Member's role in research, nature and value of the Interest, name of entity, key elements of the Conflict Management Plan and any other information required from time-to-time by the PHS funding rules. For any Conflict of Interest identified during the course of an ongoing PHS-Funded Research Study, TriHealth shall provide such COI Report to PHS within sixty (60) days and make any public disclosures of such Conflicts of Interest as may be required by the PHS Conflicts of Interest Regulations.

B. Reporting and Public Disclosure of Conflicts of Interests Following a Retrospective Review.

If a Conflict of Interest is discovered upon a retrospective review and bias is found, TriHealth must report this to PHS promptly and submit a mitigation report to PHS and make any public disclosures of such Conflicts of Interest as may be required by the PHS Conflicts of Interest Regulations. Each report submitted to PHS pursuant to this Section shall include the Research Team Member's role in research, nature and value of the Interest, name of entity, key elements of the Conflict Management Plan and any other information required from time-to-time by the PHS funding rules.

C. Other PHS Reporting and Public Disclosure Requirements

TriHealth shall comply in all other respects with applicable legal and regulatory requirements in effect from time to time with respect to Conflicts of Interest affecting a PHS-Funded Research study, including, without limitation, filing reports with PHS, updating those reports, making information pertaining to certain disclosed Interests publicly available on the TriHealth website, and maintaining records relating to all COI Questionnaires and other disclosures of potential Conflicts of Interest, including TriHealth's review and response to such disclosures and all actions under this policy or retrospective reviews, if any, for at least three (3) years from the date that the final expenditure report for the study is submitted to PHS, or such other date as set forth in PHS funding rules.

EDUCATION

Education is required of each individual initially and at least every three years. The education will be done through a CITI course module when the researcher is up for renewal, which is every three years.

Education is required immediately when financial conflict of interest policies are revised in a manner that changes researcher requirements, a researcher is new to the organization, or a researcher is non-compliant with financial conflict of interest policies and procedures.

PERIODIC REVIEW; SUPPLEMENTATION AND MODIFICATION OF THIS POLICY

The Committee or its delegates shall periodically review this Policy and recommend changes as it considers necessary and appropriate to the Board of Directors for its approval.

VIOLATIONS OF THIS POLICY

Each Research Team Member has an obligation to report to the Chief Compliance Officer or Research Compliance Officer any situation s/he believes to be a violation of this Policy.

If the Committee or its delegates have reasonable cause to believe that a Research Team Member has failed to make a disclosure required by this Policy or has otherwise failed to comply with this Policy, it/they will inform the Research Team Member of the basis for such belief and afford such person an opportunity to make the disclosure. If, after hearing the response of the Research Team Member and making such further investigation as may be reasonable and warranted in the circumstances, the Committee or its delegates determine that the Research Team Member has in fact failed to make the

disclosure, it/they may take appropriate disciplinary action (e.g., ineligibility to participate in research studies, and sanctions under applicable medical staff bylaws).

Research Team Members are encouraged to contact **Chief Compliance Officer or Research Compliance Officer** or their designees, regarding any questions concerning their obligations under this Policy.

REFERENCE
45 CFR.109(b); 21 CFR 54.4(a-d); 21 CFR 54; 21 CFR 56.109(b); 45 CFR 50 Subpart F

PROCEDURE

Disclosure

Investigators and key research personnel are responsible for completing a Financial Conflict of Interest disclosure at the time of the initial submission of a new research project.

Investigators and key research personnel are required to disclose any new financial interest relevant to the research within 30 days after they become aware and they must also report at the time of continuing review if any conflict has developed since last review.

PHS-funded research only - All sponsored travel must be reported, either in advance of it happening or within 30 days thereafter, for PHS funded research. Researchers and staff must submit a letter explaining any travel reimbursement or sponsored travel of the researchers and research staff related to institutional responsibilities. (at a minimum travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration).

Review

The IRB Staff ensures that disclosure forms are included in the submission documents and completed appropriately for the IRB Chair's initial review. The IRB Chair conducts an initial review of all IRB applications and accompanying disclosures. If a significant financial interest is disclosed, the IRB Administrator or designee forwards the disclosure to the TriHealth Conflict of Interest Committee (COI). The COI Committee evaluates the disclosed interest and provides a recommendation regarding the conflict management plan. The convened IRB reviews the COI committee's recommendation to determine whether the management plan is appropriate and finalizes decision prior to research approval.

AAHRPP Elements I.6.A, I.6.B, III.1.B

SIGNATURES:

Lorraine Stephens MD 10/27/2025

Lorraine Steph s, MD Date
Vice President for Academic Affairs
TriHealth Institutional Official

Yury Gonzales MD 10/27/2025

Yury Gonzales, MD, FACP Date
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