SOP: TRI 107 Version 2.0	CONFLICT OF INTEREST	Supercedes Document : Version 1.0

Approved by:

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1. POLICY

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 have a duty at all times 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 (#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.

2. 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").

"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.

3. 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.

4. PUBLIC DISCLOSURE

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

5. SCOPE

A. Entities Covered by the Policy

For purposes of this Policy, "TriHealth" includes the parent organization of our health system and all of 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.

B. 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").

6. 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.

7. 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.

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

1. Research Team Members must complete an **annual COI Questionnaire** that can be accessed and referenced by the TriHealth IRB via the **TriHealth Research COI Questionnaire 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.

2. 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.

B. 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.

C. 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.

8. ASSESSMENT AND MANAGEMENT OF CONFLICTS OF INTEREST

A. Review and Assessment of Individual Interests of Research Team Members

1. 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.

a. 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.

b. 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.

c. 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.

d. 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.

2. Reviewing Individual Interests Disclosed or Discovered During an Ongoing Study.

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.

3. Development, Implementation and Enforcement of a Conflict Management Plan and Conduct of Retrospective Review.

a. Conflict Management Plan. 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 Conflict of Interest and be consistent in all other respects with the guidelines adopted by the Committee from time to time.

b. Retrospective Review. 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 of the following key elements:

(1) Project number;
(2) Project title;
(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
(4) Name of the Research Team Member with the Conflict of Interest;
(5) Name of the entity with which the Research Team Member has a financial conflict of interest;
(6) Reason(s) for the retrospective review;
(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
(8) Findings of the review; and
(9) Conclusions of the review.

4. Communicating Findings Internally within TriHealth. 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.

9. PHS-FUNDED STUDIES – OTHER PUBLIC DISCLOSURE AND RESPORTING REQUIREMENTS

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

1. 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.

10. 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.

11. 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.

12. RESPONSIBILITY

The IRB Coordinator or designee is responsible for maintaining complete files on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements.

The TriHealth Hatton Research Institute is responsible for collecting and maintaining required an annual COI Questionnaire from all TriHealth Research Team Members in the TriHealth Research COI Questionnaire Database.

13. APPLICABLE REGULATIONS, GUIDELINES

45 CFR 46.103, 46.115

14. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

15. ATTACHMENTS

None