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| <b>Policy Name:</b> Management of Research Conflict of Interests        |                                          |
| <b>Policy Owner:</b><br>Research Activities and Compliance Committee    | <b>Effective Date:</b><br>01/30/2024     |
| <b>Approved By:</b><br>System Performance Alignment & Innovation (SPAN) | <b>Last Reviewed Date:</b><br>01/30/2024 |
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## **1.0 Scope:**

### **1.1 Applicable Entities:**

This policy applies to:

- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals
- Texas Health Physicians Group
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities (except those listed in the Formulation and Adoption of System-Wide Policies and Procedures in Section 4.1.6 or in Section 4.1.7)

### **1.2 Applicable Departments:**

This policy applies to all departments.

### **1.3 Applicable Personnel:**

Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record.

## **2.0 Purpose:**

- 2.1 To describe the process to evaluate and manage financial interests related to research in which Texas Health Resources (THR) and its wholly owned entities are engaged.
- 2.2 This process is required for transparency and to determine whether a Conflict of Interest should be eliminated or managed to protect the integrity of the research process and study outcome.
- 2.3 This policy applies to THR, as the Institution, investigators, study staff and subrecipients (i.e., subcontractor).

## **3.0 Policy Statements:**

- 3.1 The Conflicts of Interest Committee membership will be the same as the Research Activities and Compliance Committee.

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- 3.2 THR Institutional Conflict of Interest (COI) process requires disclosure of all conflicts of interest as described in this policy.
- 3.3 All Investigators, study staff and subrecipients shall complete a separate THR COI disclosure for each study they are participating on. Specific instructions on completing the THR COI disclosure will be provided as needed by the THR Human Research Protection Program Office (HRPPO).
- 3.4 Research staff will provide a disclosure update to the HRPPO at the time of any change in their prior disclosure.
- 3.5 The HRPPO shall complete the review of all COI disclosures and apply the standard Management Plan (see section 4.0) as applicable and appropriate to the reported COI.
  - 3.5.1 The HRPPO review of COI disclosure will be prior to IRB review.
  - 3.5.2 The Management Plan determination will be acknowledged by the affected individual.
  - 3.5.3 The HRPPO will require the communication of the management plan to the IRB and that it be reflected as appropriate in the study's Informed Consent Form (ICF) and Institutional Review Board (IRB) application. Note all references to IRB is to the IRB that will be considered the specific IRB of record for each specific study.
  - 3.5.4 Though the IRB has the authority to decide whether a management plan for a conflict of interest is appropriate as part of the approval of the study, THR has the final decision of whether a study may be initiated at THR. THR as an institution has the right to deny implementation of any IRB approved research project that is inconsistent with THR's institutional conflict of interest policies and procedures.
    - a. Management plans approved by the IRB that have been elevated to a higher requirement than the management plan determined by the HRPPO will be considered acceptable by THR.
    - b. Management plans approved by the IRB that have been diminished to a lower requirement than that determined by the HRPPO will be elevated to the THR Conflicts of Interest Committee for final decision.
    - c. All decisions of the THR Conflict of Interest Committee are final.

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- 3.6 If the individual cannot or does not wish to accept the Management Plan as determined by the HRPPO utilizing the above guidance, the Conflict will be elevated to the Conflicts of Interest Committee for review and final decision.
- 3.7 The HRPPO will request the review and decision of the conflict by the Conflicts of Interests Committee on any conflicts outside the standard Management Plan when the individual with the conflict is unable to meet Management Plan requirements, or that requires an institutional consensus decision.
- 3.8 As required, the final determination of the management plan will be provided to the funding or regulatory agencies.
- 3.9 A copy of the determinations and Management Plans shall be maintained in the HRPPO records for a minimum of 3 years.
- 3.10 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:
  - 3.10.1 Their first research project is initiated in conjunction with or as an employee of THR or THR wholly owned entity.
  - 3.10.2 Financial conflicts policies are revised in a manner that changes investigator requirements.
  - 3.10.3 Non-compliant with financial conflicts policies and procedures.
- 3.11 An Institutional Conflict of Interest describes a situation in which the financial interest of an institution may affect or appear to affect the research. Officials and staff of THR and THR entities must refrain from involvement in decisions affecting research in which they have personal financial or professional interest, or in which the institution or institutional leadership have significant financial or other interests that may influence research conduct or outcomes.
- 3.12 Violations of this policy or proscribed Management Plans can lead to:
  - 3.12.1 Loss or restriction of privileges to conduct research
  - 3.12.2 Other employment actions as allowed by Human Resources Policies and Procedures
- 3.13 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the research.

#### 4.0 Policy Guidance:

- 4.1 The following charts will be used by the HRPPO to determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interests) of the research.

##### 4.1.1 Guideline for industry-initiated, federally funded multi-site study

| Research Activity                                                                                | Amount of Financial Remuneration* |                                |                                |
|--------------------------------------------------------------------------------------------------|-----------------------------------|--------------------------------|--------------------------------|
|                                                                                                  | \$5,000 - \$10,000                | \$10,001-\$50,000              | >\$50,000                      |
| Allowing the conflicted investigator to be the PI                                                | Yes                               | Yes                            | No-unless compelling reasons   |
| Allowing the conflicted investigator to be a participating investigator                          | Yes                               | Yes                            | No – unless compelling reasons |
| Allowing the conflicted investigator to treat enrolled subjects                                  | Yes                               | Yes                            | No – unless compelling reasons |
| Allowing the conflicted investigator to recruit subjects                                         | Yes                               | No – unless compelling reasons | No                             |
| Allowing the conflicted investigator to obtain consent                                           | Yes                               | No – unless compelling reasons | No                             |
| Allowing the conflicted investigator to independently determine eligibility of enrolled subjects | Yes                               | No – unless compelling reasons | No                             |
| Require disclosure in the informed consent document                                              | See 2.13.4                        | See 2.13.4                     | See 2.13.4                     |

##### 4.1.2 Guideline for investigator-initiated multi-site study

| Research Activity                                                       | Amount of Financial Remuneration* |                   |                                |
|-------------------------------------------------------------------------|-----------------------------------|-------------------|--------------------------------|
|                                                                         | \$5,000 - \$10,000                | \$10,001-\$50,000 | >\$50,000                      |
| Allowing the conflicted investigator to be the PI                       | Yes                               | Yes               | No-unless compelling reasons   |
| Allowing the conflicted investigator to be a participating investigator | Yes                               | Yes               | No – unless compelling reasons |

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| Allowing the conflicted investigator to perform research-related procedures on enrolled subjects | Yes        | Yes        | No – unless compelling reasons |
| Allowing the conflicted investigator to recruit subjects                                         | Yes        | No         | No                             |
| Allowing the conflicted investigator to obtain consent                                           | Yes        | No         | No                             |
| Allowing the conflicted investigator to independently determine eligibility of enrolled subjects | Yes        | No         | No                             |
| Require disclosure in the informed consent document                                              | See 2.13.4 | See 2.13.4 | See 2.13.4                     |

**4.1.3 Guideline for industry-initiated, federally funded or investigator-initiated single-site study**

| Research Activity                                                                                | Amount of Financial Remuneration* |                   |                                |
|--------------------------------------------------------------------------------------------------|-----------------------------------|-------------------|--------------------------------|
|                                                                                                  | \$5,000 -\$10,000                 | \$10,001-\$50,000 | >\$50,000                      |
| Allowing the conflicted investigator to be the PI                                                | Yes                               | Yes               | No – unless compelling reasons |
| Allowing the conflicted investigator to be a participating investigator                          | Yes                               | Yes               | No – unless compelling reasons |
| Allowing the conflicted investigator to perform research-related procedures on enrolled subjects | Yes                               | Yes               | No – unless compelling reasons |
| Allowing the conflicted investigator to recruit subjects                                         | Yes                               | No                | No                             |
| Allowing the conflicted investigator to obtain consent                                           | Yes                               | No                | No                             |
| Allowing the conflicted investigator to independently determine eligibility of enrolled subjects | Yes                               | No                | No                             |
| Require disclosure in the informed consent document                                              | See 2.13.4                        | See 2.13.4        | See 2.13.4                     |

**4.1.4 Guideline for including a conflicts of interest disclosure(s) in the informed consent form or like document**

| Conflict of Interest Activity | Threshold Amount of Financial Remuneration Requiring Disclosure in Informed Consent Document* |
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| Consulting fees, honoraria (including payments from a third party, if the original source is a financially interested company), royalties, gifts, or other payments, or "in kind" compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement).                                                                                 | Financial relationship in the aggregate has in the prior calendar year exceeded the de minimis amount established in PHS regulation (presently \$5,000) or are expected to exceed that amount in the next twelve months. |
| Equity interests (or entitlement to the same) in a publicly traded financially interested company                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Value of equity interest at the disclosure date exceeds the defined de minimis amount established in PHS regulation (presently \$5,000) (see exceptions below).                                                          |
| Equity interests, including stock options in a non-publicly traded financially interested company (or entitlement to the same).                                                                                                                                                                                                                                                                                                                                                                                                                                | Any amount                                                                                                                                                                                                               |
| Royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work.                                                                                                                                                                                                                                                                                                                                                                                        | Any amount                                                                                                                                                                                                               |
| Non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution). This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested company or from the institution (**note <i>prohibition</i> on milestone payments tied to the achievement of particular research results). | Any amount                                                                                                                                                                                                               |
| Service as an officer, director, or in any other fiduciary/governance role for a financially interested company, whether or not                                                                                                                                                                                                                                                                                                                                                                                                                                | Any amount                                                                                                                                                                                                               |

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| remuneration is received for such service.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |            |
| The occurrence of 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 institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. | Any amount |

## 5.0 Definitions:

- 5.1 The term “conflict of interest (COI) in research” refers to situations in which financial or other personal considerations may compromise — or have the appearance of compromising — an investigator’s professional judgment in conducting or reporting research. A COI depends on the situation and not on the actions or character of an individual investigator.
- 5.2 A financial interest means:
- 5.2.1 With regard to any publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, greater than \$0 and less than \$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); 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
  - 5.2.2 With regard to any non-publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, greater than \$0 and

less than \$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).

**5.3 Significant financial interest means:**

- 5.3.1 With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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 and any payment for services not otherwise identified as 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 reasonable measures of fair market value
- 5.3.2 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 twelve 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)
- 5.3.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
- 5.3.4 Compensation of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest
- 5.3.5 Board or executive relationship

**6.0 Responsible Parties:**

- 6.1 Texas Health Research Activities and Compliance Committee (RACC) has responsibility for the oversight and implementation of this policy.

**7.0 External References:**

Not applicable.

**8.0 Related Documentation and/or Attachments:**

8.1 THR HRPP Policy

8.2 THR Dualities and Conflicts of Interest Policy

**9.0 Required Statements:**

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.