



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.09, **Conflict of Interest in Research**

PURPOSE: To protect the objectivity in research conducted at or by Texas Tech University Health Sciences Center (TTUHSC) and to protect faculty, staff and TTUHSC from the consequences of conflicts of interest as a result of interaction with public and private sectors by identifying and managing such conflicts in accordance with requirements established by the Public Health Service¹, as well as guidance from the Office of Human Research Protections to Institutional Review Boards².

REVIEW: This OP will be reviewed by February 1 of every even numbered year (ENY) by the Assoc. Vice President for Research, with recommendations for revision forwarded to the Executive Vice President for Research.

POLICY/PROCEDURE:

1. Introduction

TTUHSC recognizes its responsibility as a public institution to promote interaction between its employees and the public and private sectors as an important component of its research, educational and service activities. TTUHSC recognizes that interaction between the public and private sectors may give rise to conflicts of interest.

The potential for conflict of interest arises due to the nature and scope of activities engaged in by TTUHSC and its employees. Conflicts of interest may be actual, potential, or perceived and, if not identified and managed, may compromise the integrity of TTUHSC, its employees and its research. TTUHSC assumes that conflicts may occur in the normal conduct of activities. However, it is essential that any significant potential for conflicts of interest be disclosed to, reviewed, and where necessary, managed by TTUHSC. TTUHSC recognizes that conflicts of interest may arise between TTUHSC, its employee(s) and the public and these institutional conflicts must also be identified and managed in accordance with this policy.

TTUHSC encourages recruitment, retention, and recognition of individuals who promote interactions with industry, the business community and other public or private entities consistent with their primary appointment. TTUHSC recognizes that such activity may conflict with other institutional interests and that such conflicts must be resolved or managed.

2. Applicability

This policy applies to Investigators and Designated Officials as defined in this policy, and to TTUHSC where it invests in or accepts philanthropy of commercial research sponsors or otherwise has a proprietary financial interest in research activity. This includes Institutional Officials as defined in this policy.

This policy also applies to sub-recipients, sub-contractors or collaborators of TTUHSC involved in a research study unless the institution has its own written policy on conflict of interest that is in accordance with 42 CFR Part 50 Subpart F.

¹ 42 CFR Part 50 Subpart F – “Responsibility of Applications for Promoting Objectivity in Research”, effective October 1, 1995. See also the Department of Health and Human Services, Public Welfare, “Responsible Prospective Contractors”, 45 CFR 94.1 et.seq.

² Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, 69 Fed. Reg. 26393 (May 12, 2004)

This policy does not apply to:

- Matters regarded as “conflict of commitment” which are handled through the faculty/staff evaluation process or under separate HSC policies
- Small Business Innovation Research (SBIR) Program Phase I applications³.

3. Definitions

- a. “Conflict of Interest” exists when it is reasonably determined that a Significant Financial Interest could affect the design, conduct or reporting of research. This includes situations where financial considerations may compromise (or have the appearance of compromising) an Investigators’ professional judgment in conducting or reporting research, impacting the collection, analysis and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human subjects and statistical methods.
- b. “Research” means a systematic investigation designed to develop or contribute to knowledge, including social sciences and behavioral research. The term encompasses basic and applied research and product development.
- c. “Investigator” means the principal investigator, co-investigators, Research Personnel and any other TTUHSC person who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by an external agency, or funded by internal resources.
- d. “Research Personnel” means individuals other than the Investigator who participate in the research, make decisions about eligibility to participate in research, analyze or report research data, or submit manuscripts concerning research for publication. Clinical trial coordinators and laboratory personnel both fall into this category.
- e. “Family Member” means the Investigator’s spouse (or spousal equivalent) and/or dependent children.
- f. “Designated Officials” mean those individuals who serve on TTUHSC Review Boards with authority to approve or deny research activity.
- g. “Institutional Official (IO)” means an individual responsible for negotiating or signing on behalf of TTUHSC sponsored research agreements or contracts, including those for clinical trials.
- h. “Compelling Circumstances” are those facts that convince the Conflict of Interest Committee (COIC) that a financially interested individual(s), or TTUHSC, should be permitted to conduct the research, including human subjects research, pursuant to a management plan to minimize the conflict. Any decision by the COIC shall not preempt a decision by a TTUHSC Review Board (Institutional Review Board, Institutional Animal Care and Use Committee, Institutional Biohazard Committee(s) and Radiation Safety Committee) to the contrary.
- i. “Financially Interested Company” means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research, or any entity as the agent of or with an equity interest in the company. This includes, but is not limited to the research sponsor, competitors of the sponsor, manufacturers/licensees of the investigational product, or the investment industry (stockbrokers, investment bankers, venture capital firms or investment firms).
- j. “Significant Financial Interest” for individuals means anything of monetary value, including, but not limited to salary or other payments for services (e.g., consulting fees or honorarium); equity interests (e.g., stock, stock options or other ownership interests); and intellectual property rights (patents, copyrights and royalties from those rights). Significant Financial Interest is the

³ The SBIR is an extramural research program for small businesses that is established by the PHS awarding components and certain other federal agencies under the Small Business Innovation Development Act and includes the Small Business Technology Transfer (STTR) Program.

aggregate of the individual, his/her Family Members or of any foundation, trust, or entity controlled or directed by the individual or his/her Family Members from which they have or will derive a benefit. See Attachment B, Examples of Significant Financial Interests.

A Significant Financial Interest does **not** include:

- (1) Salary, royalties, or other remuneration from TTUHSC;
 - (2) Royalties and honoraria for published scholarly or creative works that in the aggregate for the individual, and/or Family Member does not exceed \$10,000.00;
 - (3) Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
 - (4) Income from service on advisory committees or review panels for public or non-profit entities;
 - (5) An equity interest, when aggregated for the Investigator and his/her Family Member, that does not exceed \$10,000.00 as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a five percent (5%) ownership interest in any single entity.
 - (6) Salary, royalties, or other payments that when aggregated for the investigator and his/her Family Member, are not expected to exceed \$10,000 from any single entity during the next 12 month period.
 - (7) Payments to TTUHSC that are directly related to the reasonable costs incurred in the conduct of the research project as specified in the agreement with TTUHSC. This excludes any bonus or milestone payments that are in excess of reasonable costs incurred, which must be disclosed under this policy.
 - (8) Interests held directly through funds such as mutual funds, pension funds, or other institutional investment fund in which the Investigator or his/her Family Member do not control the selection of investments.
- k. "Significant Financial Interest for TTUHSC" means:
- TTUHSC is entitled to receive royalties from the sale of the investigational product that is the subject of the research;
 - When, through technology licensing or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded sponsor of the research, including human subjects research.
 - When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) of greater than \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly traded sponsor of research at the institution.
- l. "TTUHSC" Review Board(s) means one or more of the research oversight bodies, including, but not limited to the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biohazard Committees (IBC and RDBC), and Radiation Safety Committee (RSC).
- m. "Unit Head" means department chair, area coordinator, director, or in the case of colleges that do not have areas or departments, the dean.

4. Conflict of Interest Committee (COIC)

- a. Establishment of Committee. A TTUHSC Conflict of Interest Committee (hereafter referred to as "COIC") is established to review conflicts of interest. **The COIC and any sub-committees established under this policy shall be considered "medical committees" as defined under Texas Health & Safety Code, §161.031, and/or other applicable state and federal statutes.** All documents generated by, submitted to, or for the purposes of fulfilling COI Committee duties are confidential and privileged as "medical committee documents".
- b. Members. The COIC will consist of at least nine voting members.
 - 1) Each School (Medicine, Nursing, Allied Health Sciences, Pharmacy, Graduate School of Biomedical Sciences) shall appoint at least one faculty member from that School to serve on the COIC.
 - 2) The Executive Vice President for Research (EVPR) shall appoint four other members of the COIC, one of whom shall be appointed from the community and have no family or financial ties to TTUHSC.
 - 3) The Director of the Research Integrity Office and a representative of the Texas Tech University System (TTUS) General Counsel shall serve as non-voting Ex-officio members.

Committee members should be individuals who have sufficient seniority, expertise and independence to evaluate the competing interests at stake and make credible and effective recommendations. All voting members of the COIC shall be independent of the direct line of institutional authority for research, including human subjects research oversight at TTUHSC.

At least two members of the Committee shall be familiar with ethical issues impacting human subjects research. Each member will be appointed to a 3-year term and may be reappointed.

- c. Members with a Conflict. Members of the COIC shall not participate in reviews, deliberations or decisions in which the member has an actual or perceived conflict of interest as determined by the COIC. Those with a conflict may provide information requested by the COIC.
- d. Meetings.
 - 1) *Chair and Vice-Chair.* The COIC Chair and Vice-Chair will be elected to one-year terms by a simple majority vote of the full COIC. Votes may be cast by email. The Chair and Vice-Chair may be re-elected by the COIC for successive terms.
 - 2) *Quorum.* Five (5) voting members must be present for a quorum for all other business. A quorum may include members present via telephone conference call.
 - 3) *Materials.* Each member of the COIC shall be given a copy of the agenda, minutes from previous meetings, the Forms to be reviewed and any other information necessary for conducting reviews of Forms disclosing Significant Financial Interests.
 - 4) *Minutes.* Written minutes shall include the date of the meeting, presence of members and guests and absence of members, COIC actions taken on each Significant Financial Interest reviewed and managed, including the number of members voting for or against, the number abstaining and notation of members not participating due to a conflict of interest. The Chair and/or Vice Chair shall notify the Investigator or TTUHSC Institutional Official of the action taken to manage any identified conflicts of interest.
 - 5) *Additional Information.* The COIC may request the Investigator(s) and other interested parties to appear before the COIC to provide information regarding the disclosed significant financial interests. The COIC may also request a written statement from or presence of a representative from the Office of Technology Commercialization about the current status of an investigator's research relationship(s) or agreement(s) involving a potential conflict.

- 6) *Records.* The COIC shall retain all records of Disclosures and COIC meetings for three (3) years after the conclusion of the research project.

5. Prohibition on Payments for Results.

TTUHSC will not accept sponsored research or contracts, if payments are conditioned on a particular research result or are tied to successful research outcomes. All issues relevant to research with human subjects must conform to IRB Policies and Procedures and applicable federal requirements.

6. Disclosure of Significant Financial Interests

a. Researchers and Designated Officials

- 1) *Annual Disclosure.* All Investigators and Designated Officials shall submit the Annual Financial Disclosure Form ("Form") (Attachment A) to the Research Integrity Office, TTUHSC Lubbock, STOP 8146. This disclosure will include Significant Financial Interest of the individual and his/her Family Member:
 - a) That would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor or internal resources; or
 - b) In entities whose financial interest would reasonably appear to be affected by the research or education activities funded or proposed for funding by an external agency or internal resource.
- 2) *Initial Disclosure.* New Investigators and Designated Officials must submit the Form within 30 days of hire/appointment. Individuals added to an existing research project must complete and submit the Form before they can be added to the project. No individual shall be added to a research project until the Form has been reviewed in accordance with this policy.
- 3) *New or Additional Significant Financial Interests.* If during the TTUHSC fiscal year (September 1 through August 31), there is a change in the reported information the individual shall submit an updated Form to the Research Integrity Office, within 30 days of acquiring the new or additional Significant Financial Interest.
- 4) *Certification of Disclosure.* Prior to submitting a proposal for funding to any external agency, each Investigator shall certify on the Office of Sponsored Programs routing form that he/she has disclosed all Significant Financial Interests in accordance with this policy. Where a conflict is identified after review by the COIC, the final COIC management plan shall be submitted with the application. Similar procedures shall apply to all research contracts.

b. Technology Transfer and Intellectual Property.

The Office of Technology Commercialization shall report in writing to the COIC within 30 days of execution of any licensing agreements that would create a Significant Financial Interest for an individual in ongoing or future research. Upon receipt of that document the COIC will follow the review procedures described in this policy.

c. TTUHSC Institutional Disclosure

- 1) *Annual Disclosure.* By September 1 of each year, the Development Office or any office overseeing institutional endowments or investments and the Office of Technology Commercialization shall report in writing to the Executive Vice President for Research and to the COIC all Significant Financial Interests that meet the criteria in 3j above. The list shall also include any other information that may present the appearance of a conflict of interest that could adversely impact public trust in TTUHSC. Upon receipt of that information, the COIC will follow the review procedures described in this policy.
- 2) *New or Additional Significant Financial Interests.* Any new or additional Significant Financial Interests obtained by TTUHSC during the fiscal year shall be reported through the submission of an updated Form.

7. Review by COIC

- a. Initial Review. The Research Integrity Office shall initially review the Form to verify that it has been properly completed and signed. If there is any information that is missing, the Research Integrity Office shall contact the individual who submitted the Form, notifying them of the information that is needed before the Form can be reviewed by the COIC.
- b. Preliminary Review of Completed Form. If a significant financial interest has been reported, the Research Integrity Office shall forward the completed Form to the COIC Chair (or his/her designee), along with a listing of current research projects for that Investigator, to determine whether Significant Financial Interest exists, and if so, whether or not a conflict of interest exists requiring further review by the COIC.
 - 1) Determination of No Significant Financial Interest. If no Significant Financial Interest has been reported, the Form shall be retained and maintained by the Research Integrity Office for a period of three (3) years after it has been submitted.
 - 2) Determination that a Significant Financial Interest Creates a Conflict of Interest. If a Significant Financial Interest has been reported, the COIC Chair (or his/her designee) shall determine if it creates a real or potential conflict of interest and if so, forward the matter to the COIC to manage, reduce or eliminate the conflict before expenditure of funds. If the project involves human subjects research, the potential conflict shall also be shared with the Institutional Review Board (IRB). Notification shall be given that the matter has been referred to the COIC for review and that no project funds will be released until a final determination has been made.
- c. COIC Review Process. The COIC shall review (and where necessary investigate) all information contained in the Form to verify the existence of any conflict of interest. In conducting its review, the COIC may consider one or more of the following factors in determining the existence of an actual, potential or perceived conflict of interest:
 - The type and nature of the financial interest;
 - Who is funding the research;
 - Where and by whom the research study was designed;
 - Who will be collecting and/or analyzing the data;
 - Indication that the Investigator(s) has improperly favored an outside entity or appears to have an incentive to do so;
 - Are there incentives that may lead to inappropriate bias or otherwise effect the research results;
 - Will research with the existence of the conflict violate any federal, state laws or institutional policies;
 - Impact of the financial interest on the integrity of the research data, including the impact the study outcome may have on the payment of any compensation under the research;
 - Risks to the rights and safety of human subjects, where applicable;
 - Risks to the rights and obligations of students and trainees participating in the project;
 - Impact on the availability of research results to the scientific community for use in the public interest;
 - Any other matter pertaining to the disclosed significant financial interest and the funded project, including those outlined in the HHS Guidance for Human Subjects Protection, 69 Fed. Reg. 26393; 26396 (May 12, 2004).

If the COIC review determines that a conflict of interest exists, the COIC shall prepare a written summary report **and Conflict Management Plan** pursuant to paragraph [f] below, placing appropriate restrictions to manage, reduce or eliminate the conflict of interest. An Investigator (or TTUHSC) may develop a proposal for consideration by the COIC on minimizing, reducing or eliminating the conflict of interest. If the COIC determines that no conflict of interest exists, no further action will be taken on the matter.

- d. COIC Review of Projects Involving Human Subjects Research – Presumption Against Participation. Since Significant Financial Risks of an Investigator or TTUHSC involved in human subjects research may present actual or perceived risks to the welfare of human subjects, the COIC shall presume that in the case of an Investigator the individual cannot participate in the research while he/she has the Significant Financial Interests and in the case of TTUHSC, the research cannot be done at or under the auspices of TTUHSC while the Significant Financial Interest exists.
- 1) Rebuttal of the Presumption – Compelling Circumstances. The presumption against participation in all or part of the research may be rebutted upon a showing of compelling circumstances, which will be based upon the nature of the science, the nature of the financial interest(s) and how closely those interests are related to the proposed research and the degree to which the interest may be affected by the research. The analysis should define the stages of the research and the specific activities where there compelling reasons to allow participation. The COIC may rely on the 2001 AAMC Report and the 2008 AAMC-AAU Report, as well as other resources in determining whether or not there are compelling circumstances sufficient to rebut the presumption against participation. The COIC shall prepare a written management plan in accordance with paragraph below if the presumption is rebutted based on compelling circumstances.
- e. Notification.
- 1) The COIC shall send a written copy of any Management Plan to the EVPR, the Office of Sponsored Programs, and the Unit Head.
 - 2) Notification of Institutional Review Board (IRB). The COIC will send a copy of the Management Plan to the Institutional Review Board (IRB). The IRB may accept or reject the COIC's Management Plan. If the IRB rejects the proposed Management Plan, it shall return it, with recommendations, to the COIC for further review and action. The IRB will determine how the conflict of interest should be disclosed to participating subjects.
- f. COIC Conflict Management Plans

If the COIC determines there is an actual, potential or perceived conflict of interest, a written Conflict Management Plan shall be prepared to manage, reduce, eliminate the conflict, or alternatively, deny participation in the research project if a management plan is not feasible.

The COIC is ultimately responsible for development of the Conflict Management Plan, where it can be implemented to manage, reduce or eliminate the conflict. The COIC Conflict Management Plan may require one or more of the following actions to manage, reduce or eliminate the conflict:

- Public Disclosure. This includes, but is not limited to release of relevant information about Significant Financial Interests in all publications and presentations (whether academic or not), to members of the research project. In the case of human subjects research, disclosure shall be required to the research subjects (through the IRB approved informed consent/assent), to state and federal officials in addition to the disclosures previously outlined.
- Limitation of Participation. This may include limiting an individual from (i) serving as the Principal Investigator, (ii) analyzing all or portions of the data, (iii) selecting or enrolling human subjects, (iv) determining whether or not an adverse event report is required; or (v) any other limitation that will reduce or eliminate the conflict of interest. If participation is partially limited, the Management Plan shall include a time line identifying at what points the limitation applies as well as a strategy to restrict the time of involvement to a minimum.
- Monitoring. This can include assignment of a co-investigator or appointment of an independent reviewer(s) or data and safety monitoring committee or similar body to monitor the various stages of the research project. If an oversight body is established, the COIC will specify the frequency of reports to the COIC. Monitoring may also include review of abstracts and manuscripts before submission for publication, review of protocols and changes to protocols, subject accrual, complications and other issues. The plan should include the

frequency of reporting and documentation to the COIC by the Investigator or any reviewer/review body appointed by the COIC to manage the conflict.

- Modification. This can include modification of the research project such that the main purpose of the project is not compromised.
- Divestiture of the Conflicting Interest. The COIC may require the Investigator, his/her spouse to sell or dispose of all or part of the disclosed significant financial interests to reduce or eliminate the conflict of interest.
- Severance of the Relationship(s). The Investigator or his/her spouse may be required to sever any relationships that create an actual or perceived conflict of interest, such as relinquishing a seat on a board of directors or terminating a consulting agreement during the course of the research project.
- Restrictions on Equity Interests. The Investigator, his/her spouse or dependent children may be required to place stock in escrow until a trigger date specified by the COIC, or require that options, warrants and similar interests not be exercised without prior written approval of the COIC (and IRB if human subjects are involved).
- Any other conditions, restrictions, or requirements that will contribute to the management, reduction or elimination of the actual or potential conflict of interest.

8. Institutional Conflict of Interest

TTUHSC may have a conflict of interest in research, including human subjects research, whenever financial interests of the institution or an Institutional Official acting within their authority on behalf of the institution might affect or reasonably appear to affect institutional processes for the conduct, review, or oversight of research. Administrative responsibilities for research should be separate from those of institutional investment or technology licensing and transfer.

a. Institutional Officials

An Institutional Official responsible for negotiating or signing sponsored research agreements or contracts, including those for clinical trials, is subject to the same potential conflicts of interest as an Investigator. Because the involvement of the IO is so direct in the research decisions, this shall be considered an institutional conflict of interest. All IOs shall complete and submit the Disclosure Form for review in accordance with this policy. If an actual or potential conflict of interest exists and the COIC does not approve a Conflict of Management Plan, the research will not be conducted within or under the auspices of TTUHSC.

b. Conflicts of TTUHSC

1) Institutional

Financial relationships between TTUHSC and the commercial sponsor may present or appear to present a conflict of interest, even though TTUHSC has separated research and investment functions. Such agreements should receive close scrutiny. When a Significant Financial Interest of TTUHSC as defined in section 3j, is present, the COIC shall conduct a specific inquiry into whether the research should go forward.

If no conflict management plan is approved by the COIC, the research shall not be conducted within or under the auspices of TTUHSC. Options for resolutions include, but are not limited to, eliminating the conflict or appointment by the COIC of a faculty committee composed primarily of senior faculty to oversee the contractual commitments and review the proposed research and any publications.

2) Conflict of Interest between TTUHSC and Employee

Financial relationships between TTUHSC and the commercial sponsor may present or appear to present a conflict of interest between TTUHSC and one or more of its employees. Examples of such conflicts are:

- a) situations where both TTUHSC and the employee(s) share financial interests in a licensed technology and where disagreements arise between the parties about the commitment of the employee to further research; or
- b) research requested by a sponsor with which TTUHSC has a financial interest through investment or philanthropy and with which the employee disagrees.

Such conflicts shall be referred to the COIC for management. If both parties do not agree on a resolution, TTUHSC will take no retaliatory action against the employee including, but not limited to dismissal, denial of access to research resources, failure to promote or provide raises or other adverse employment action unless the employee was hired specifically for the purpose of working on the designated project. Personnel action against an employee on grounds that are unrelated to this conflict is not precluded.

9. Appeal of COIC Recommendations

- a. Individual. An individual may appeal a recommendation of the COIC to the EVPR. Written notice of appeal shall be given to the EVPR within 10 days of receipt of COIC recommendation, or prior to any action by the TTUHSC predicated on the COIC action, e.g. signing a contract, whichever comes first.
- b. Institutional Appeal. TTUHSC Administration may appeal a COIC recommendation to an ad hoc committee composed of two members from each school that will be appointed by the faculty executive committees of each school. The members of this ad hoc committee should be senior faculty members (Associate or Full Professor, preferably with tenure). TTUHSC shall provide notice of appeal to the faculty executive committees within 10 days of a COIC action. Appointments to the committee shall be made within 10 days of notice. The ad hoc committee shall convene within 5 days of appointment and receive the written administrative appeal. The ad hoc committee will report its recommendation to the Administration and the COIC within 20 working days.

TTUHSC can not be compelled to comply with this policy although it is in the best interest of TTUHSC to do so to maintain the public trust and to protect human subjects where clinical trials are concerned. Failure of TTUHSC to comply with this policy or a management plan will be reported by the COIC to the Chancellor.

10. Certification and Notice

- a. PHS and other Federal Agency Notification. The Office of Sponsored Programs shall report to PHS agencies, including NIH, any conflicting interest (excluding the nature or details about the interest) found by the COIC and a description of how the conflict has been managed, reduced, or eliminated. If any conflict of interest is identified after the initial report to PHS, a subsequent report will be made and the conflict managed, reduced, eliminated at least on an interim basis, within 60 days of the identification of the conflict.
- b. PHS Certification. The Director of Sponsored Programs or signing Institutional Official shall certify on each PHS funded proposal that:
 - There is a written and enforced administrative process to identify, manage, reduce or eliminate conflicting interests;
 - The required report has been or will be submitted;

- Upon request, make information available to the Department of Health and Human Services about all conflicting interests and how those interests have been managed, reduced or eliminated.
- c. National Science Foundation Notification. The Director of Sponsored Programs shall keep the NSF Office of the General Counsel informed if TTUHSC finds that it is unable to satisfactorily manage a conflict of interest under an NSF funded project.

11. Compliance

a. Generally

No research may begin until the conflict has been reviewed by the COIC and the conflict has been managed, reduced or eliminated.

If a breach of the policy occurs, sanctions may be imposed by the COIC following their review. Any breach or suspected breach of policy shall be reported to the COIC or through the Compliance Hotline. A breach includes, but is not limited to, failure to file or update a disclosure statement, intentionally filing an incomplete, erroneous, or misleading form; failure to provide additional information when requested by Unit Head, Institutional Official or COIC; violation of terms of plan for management of conflict approved by COIC.

Any person who believes that there has been a breach of policy is responsible to report the allegation to the COIC or through the confidential Compliance Hotline. Such report may be held confidential. However, if at the conclusion of the investigation, the reporting is considered by the COIC to be malicious or in bad faith, procedures described under the Honesty in Research and Allegations of Scientific Misconduct (HSC OP 73.07) shall be followed to identify and initiate appropriate action. In accordance with HSC OP52.04, no retaliatory action shall be taken against anyone who, in good faith, reports a suspected or actual breach of this policy.

When an allegation of breach of this policy is received by the COIC, the COIC shall initiate an inquiry within 5 working days and may request information or documents from the individual as well as TTUHSC units such as Sponsored Programs. All requested documents should be provided to the COIC within 10 working days. The COIC will make an initial determination of whether or not there has been a breach of this policy and report the finding in writing to the individual and EVPR within 10 working days of receipt of the documents.

If a breach is found, the individual will be requested to respond to the finding in writing and may also appear before the COIC in person within 10 working days. The COIC will make a final determination within 10 working days of receiving the response of the individuals or appearance before the committee, whichever ever is later, and provide a written recommendation to the EVPR, copied to the individual.

Sanctions may include but are not limited to the following:

1. Letter of reprimand
2. Ineligibility of the individual for grant applications or supervision of research personnel
3. Suspension of research privileges
4. Non-renewal of appointment in accordance with Regents Rules Chapter 4
5. Dismissal in accordance with Regents Rules Chapter 4

Sanctions, other than recommendation for non-renewal of appointment or dismissal may be appealed to the EVPR who has discretion to appoint an independent committee to review the process and report back to the EVPR.

12. Amendments or Termination of this Policy

TTUHSC reserves the right to modify, amend or terminate this policy at anytime. Nothing in this policy should be construed as a contract between TTUHSC and its employees or agents.