



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.18 Research Nepotism

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is to establish procedures to implement university policy on nepotism (inclusion of relatives) within research projects in accordance with HSCEP OP 70.08 and 73.09. The contents of this policy are intended to protect the objectivity of the design, conduct, and reporting of research conducted by TTUHSC El Paso researchers and to protect the researchers from the consequences of a potential, perceived, or actual conflict of interest related to nepotism.

REVIEW: This HSCEP OP will be reviewed August 1 of each even-numbered year (ENY) by the chairperson of the TTUHSC El Paso Conflict of Interest in Research Committee (COIRC) and the assistant managing director of the Office of Research (OR) or designee, with recommendations for revision submitted to the vice president for research (VPR) or designee.

POLICY/PROCEDURE

I. Introduction

TTUHSC El Paso policy prohibits employees from approving, recommending, or otherwise taking action with regard to the appointment, reappointment, promotion, salary, or supervision of an individual related to the employee. TTUHSC El Paso recognizes that the conduct of research may necessitate that an employee responsible for a research project must recruit a related individual due to specialized skills and knowledge specific to that individual. In cases such as these, the personal relationship presents the possibility for a conflict of interest resulting in bias in the conduct or reporting of the research. It is essential that conflicts of interest of this nature are appropriately managed to ensure that the integrity of the research is maintained.

II. General Policy

All decisions regarding the recruitment or appointment of research study personnel must comply with HSCEP OP 70.08 such that:

- A. Study personnel appointments shall be made on the basis of the qualifications and suitability of the appointee. The Principal Investigator (PI) of the study must submit justification for the inclusion and compensation of any related individual on their research study.
- B. No employee may perform sole oversight of the research activities of an individual related to the employee. An independent monitor must be designated for the subordinate individual's work related to the research project.

III. Applicability

- A. TTUHSC El Paso. This policy applies to all TTUHSC El Paso investigators/research personnel and applies to all research, regardless of funding.
- B. Non-TTUHSC El Paso. The policy also applies to sub-recipients, sub-awardees or collaborators of TTUHSC El Paso involved in research activities.
- C. This policy is not applicable to non-research related concerns of nepotism. Please refer to [HSCEP OP 70.08](#) for guidance on non-research matters.

IV. Definitions

Conflict of Interest (COI): inclusion on a research study of investigator and research personnel who are related wherein one individual would function as the supervisory entity of the other which could directly and significantly affect the design, conduct, or reporting of the research.

Conflict of Interest in Research Committee (COIRC): a TTUHSC El Paso committee established by HSCEP OP 73.09 which shall review and make decisions regarding matters governed by this policy.

Conflict Management Plan (CMP): A detailed description of the actions taken to address a COI. The plan will set forth the steps to reduce, mitigate, or eliminate the conflict in order to provide a reasonable expectation that the design, conduct, and reporting of research will be free of bias.

Disclosure: The requirement for investigator(s)/research personnel to notify TTUHSC El Paso of all significant interests truthfully and in a timely manner. Disclosures are required to be in sufficient detail to permit a determination of the potential for a COI.

Institutional Official: The Vice-President for Research (VPR) or designee shall serve as the institutional official with authority to require research disclosures from TTUHSC El Paso investigators/research personnel. The VPR or designee and the TTUHSC El Paso COIRC, including the chairperson or designee of that committee, are authorized to review disclosures to determine whether a potential COI exists.

Investigator: the project director or principal investigator and any other person who is responsible for the design, conduct, or reporting of research.

Related Individuals: For the purpose of this policy, individuals are considered related if they fall within the definition of “family member” established by HSCEP OP 73.09. These are defined as the disclosing individual’s:

- Spouse, step-children, spouse’s parents, children’s spouses and step-parents (1st degree within the 1st degree of affinity - marriage);
- Spouse’s siblings, grandparents, grandchildren, sibling’s spouse, step-grandparents and grandchild’s spouses (1st degree within the 2nd degree of affinity – marriage);
- Parent, or child (1st degree within the three degrees of consanguinity – blood);
- Siblings, grandparents and grandchildren (2nd degree of consanguinity – blood);
- Great-grandparents, great-grandchildren, uncle, aunt, nephew and niece (3rd degree of consanguinity– blood); and
- Household members.

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied

research and product development.

Research Personnel: any personnel participating in research regardless of funding source.

V. Responsibilities of Investigators/Research Personnel

- A. TTUHSC El Paso investigators/research personnel shall have the following responsibilities with regard to disclosure and conflict management:

Disclosure. Investigators are required to disclose the name and relationship of all personnel listed on their research projects to whom the investigator is related on their annual research financial disclosure form via the iRIS research administration software.

Requirement for Protocol Review: Investigators/research personnel must submit their disclosure of related personnel prior to final approval being granted by the corresponding research committee.

Changes: Any changes in study personnel to include related individuals must be reported to the COIRC via iRIS disclosure within thirty (30) days. This provision applies in the event that an employee's marriage or reassignment places the employee in a supervisory role over an individual on the study to whom they are related.

- B. Review of Disclosures: Completed disclosure statements will be submitted to the OR, who will conduct a preliminary review to verify that the form has been properly completed and signed. Improperly completed forms will be returned to the respondent for correction. Once properly completed, information from the form will be housed in the iRIS research administration software database available to the OR and Sponsored Programs (SP) personnel. Grant proposals and iRIS submissions will be checked against these records by the appropriate committee. Any proposals/submissions by persons who have disclosed a relationship with other study personnel will be referred to the COIRC Chairperson or designee for an initial determination (See Section VI (A), below). Documentation of completed disclosures will be maintained by the OR for a minimum of 3 years.
- C. Confidentiality of Intellectual Property. Research personnel at TTUHSC El Paso may not share with external entities data or intellectual property that has been obtained from federally- funded, state-funded, private foundation-funded, or institutionally-funded research performed at TTUHSC EP without prior approval.

VI. Conflict on Interest in Research Committee Review

Review of research disclosures is conducted by the COIRC, a committee established by HSCEP OP 73.09.

A. Initial Determination

The VPR delegates authority to the chairperson of the COIRC to review disclosures of related study personnel to make an initial determination if they may pose a Conflict of Interest (COI) to the prospective research project. The chairperson (or designee) may make an initial determination, of (i) "no COI" or (ii) "possible COI." In order to make the initial determination the COIRC chairperson (or his/her designee) will be provided, at a minimum, with the investigator's/research personnel's most recent disclosure and a brief description of the proposed research project(s). The initial review and determination shall be made in writing and reported to the COIRC at its next convened meeting. At any point in the initial review, the COIRC chairperson may elect to refer the matter to the COIRC for input prior to making a determination. Any determination by the chairperson of a possible

COI posed by the related personnel will be referred to the full COIRC for further review.

B. COIRC Review

The convened COIRC shall review and (where necessary) investigate the information on the completed disclosure form as well as a summary of the proposed research project(s) to make a determination as to whether the related personnel may impact the conduct of the research project. A determination that a COI exists will be made when the COIRC reasonably determines that an investigator is related to a subordinate individual of the study personnel.

The COIRC shall also review content of the disclosure to verify that justification for the salary and inclusion of the related study personnel are within acceptable parameters. The COIRC may consider the following factors, including, but not limited to:

- Type of research activities being conducted
- Role of the related individual in the research activity
- Availability of individuals with similar expertise
- Salary for similar expertise and/or study activities being performed; including effort reporting
- Whether incentives exist that may lead to inappropriate bias or otherwise affect the research results;
- Impact of the personal relationship on the integrity of the research data
- Risk to the rights and safety of human subjects, where applicable;
- Risks to the rights and obligations of other study personnel participating in the project

C. Determination of Conflict

If the COIRC makes a determination that that a COI exists, the COIRC shall work with the investigator/research personnel to develop a written CMP in order to determine the best method for managing the conflict. The CMP must include both a description of the compelling circumstances that justify participation of the conflicted investigator(s) in the research project, as well as appropriate actions that will be taken to manage, reduce or eliminate the conflict. The CMP must be reviewed and approved by the COIRC (secure email review and vote is permitted) prior to the expenditure of any funds. If the proposed research involves human subjects or animals, the TTUHSC El Paso Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) must also approve the CMP prior to enrollment of any human subjects or animals in the research. The IRB and IACUC may suggest revisions of the CMP to the COIRC in order to secure their approval. Examples of conditions or restrictions that may be imposed to manage a COI include, but are not limited to:

- Disclosure of personnel relationship to the study sponsor.
- Public disclosure of the COI (e.g., when presenting or publishing the research).
- Appointment of an independent monitor for the subordinate of the related individuals.
 - a) The monitor shall oversee all research activities undertaken by the subordinate individual and is capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the COI.
 - b) The monitor shall be an individual with sufficient training and experience to understand the proposed research protocol and mediate related activities.
 - c) The monitor must be listed among the study personnel for the duration of the study and maintain standard institutional requirements required of research personnel to do so (e.g., completion of standard Collaborative

- Institutional Training Initiative (CITI) training)
- d) Appointment of a monitor does not diminish the responsibility of the PI for the overall conduct of the study.
 - e) Written approval must be obtained from the monitor in instances where the PI must be recused as a result of the COI (e.g., funding/salary requests for the individual they are related to).
 - Audit of study activity or procedures by TTUHSC El Paso Research Compliance personnel as determined by the corresponding research committee for the protocol (IRB, IACUC, Institutional Biosafety Committee).
 - Modification of the research protocol/plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

D. Review of Updated Disclosures

For investigators/research personnel who are added to an ongoing research project and/or investigators/research personnel who experience a change in related status (i.e. in the case of marriage) after a research project has begun, the COIRC will review the disclosure as soon as possible and within 10 business days to make an initial determination of whether a COI exists. If the committee determines that a COI exists, the COIRC will determine what, if any, immediate actions must be taken to protect the objectivity and integrity of the research while a final management plan is being developed. The final plan should be reviewed and voted upon within 60 days of submission of the disclosure.

E. Monitoring Conflict Management Plans

Reports: Investigators/research personnel who have ongoing CMPs shall provide annual, written reports (or at any time upon request from the COIRC) regarding action taken under the CMP. Reports shall be submitted to the COIRC chairperson or designee. Annual reports shall be submitted on or before the anniversary date that the CMP was approved by the COIRC. The chairperson will review the reports and provide a written summary to the COIRC at the next convened meeting. The COIRC may choose to review the report in its entirety.

Audit: Audits of study activities may be performed by research compliance personnel at set intervals and/or at the completion of the study as determined by the IRB, IACUC or IBC. It is the PI's responsibility to comply with audit requests in a timely and complete manner as requested by the reviewing research committee.

A conflict of interest determination made by the COIRC and/or CMP may be appealed to the VPR within thirty (30) days of the date the COIRC notifies the faculty, staff, or student of the COIRC's decision. The decision of the VPR shall be final.

VII. **Non-Compliance**

- A. *Breach.* A breach of this policy by an investigator/research personnel may include, but is not limited to:
- Failure to disclose their related status with a member of their research team in a timely manner;

- Research disclosure forms not submitted in a timely manner as scheduled, a grace period of 30 days following expiration is allowed for individuals without an active CMP;
- Disclosing inaccurate, erroneous or misleading information;
- Failure to provide additional information to the COIRC or VPR regarding a disclosure; or
- Violation of the terms of an approved CMP.

B. Action Upon Breach. If an alleged or actual policy breach occurs, the chair of the COIRC can recommend to the VPR an immediate temporary suspension of the individual's research privileges. In turn, the VPR will consult with the faculty member's department chair to determine if a suspension of the individual's research privileges is warranted. If suspension is warranted and the individual is the PI of the study, then all activity on that protocol must be halted, as no research activity may take place without PI involvement and oversight per institutional policy. If the individual occupies a role other than PI, then the individual and the PI of their study will receive a notification that the individual is to immediately discontinue all research activity; the PI and other research members may continue their work unless the magnitude of the breach necessitates full suspension of study activities. A breach that results in the discovery of a new or previously undisclosed conflict requires that the COIRC shall, within 30 days of becoming aware of the breach, convene to review the significant interest to determine whether it is related to the research project; to determine whether a COI exists; and, if so, shall implement, on at least an interim basis, a management plan that shall specify the actions that have been taken and will be taken to manage such COI going forward. A breach that is determined to constitute intentional non-compliance by an individual will be referred for possible additional sanctions by the VPR.

C. Intentional Breach. If the COIRC determines that the breach was part of an intentional plan to deceive the COIRC or TTUHSC El Paso regarding research activities, the COIRC may recommend additional sanctions to the VPR. These sanctions may include, but are not limited to:

- A letter of reprimand to the investigator with a copy to the investigator's chairperson, dean, and personnel file.
- Temporary or permanent suspension of the individual to submit new applications for external funding and/or research involving human subjects or animals;
- Temporary or permanent suspension of research privileges;
- Non-renewal of appointment or dismissal in accordance with HSC OP 60.01.

The VPR shall make the final determination regarding which sanctions, if any, shall be imposed on the investigator or research personnel.

In accordance with Texas Government Code Section 573, violation of the nepotism statutes is a misdemeanor involving official misconduct and subjects the violator to a fine of not less than \$100 or more than \$1,000, and removal from Texas Tech University Health Sciences Center El Paso employment.

VIII. Amendments or Termination of this Policy

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