



EL PASO COMMUNITY COLLEGE PROCEDURE

For information, contact Institutional
Effectiveness: (915) 831-6740

CAA-1 **Disclosure of Conflict of Interest under the Auspices of El Paso Community College**

APPROVED: February 3, 2022 **REVISED:**
Year of last review: 2022
AUTHORIZING BOARD POLICY: CAA

Classification: Administrative

Vice President or Associate Vice President: Associate Vice President of External Relations, Communications &
Development

Designated contact: Director of Grants Management

OBJECTIVE: To govern the disclosure of individual significant interests and the management and reporting of conflicts of interest in research that is performed at or under the auspices of the El Paso Community College (EPCC).

This procedure is intended to fully comply with the disclosure requirements of federal regulations issued by the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service. Research conducted at EPCC will follow all applicable federal, state or funder guidelines, as well as all applicable EPCC policy and procedures, including standards of conduct and disclosure of activities and financial interest.

PROCEDURE:

I. General Provisions:

A. Definitions

1. *Research* – Any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge and includes both basic and applied research and product development.
2. *Covered Individual:*
 - a. An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, co-investigator, project director, or student who must file and update a financial disclosure statement under this procedure. Compliance with this procedure by a covered individual who is an employee of EPCC is a cause for discipline, including termination from EPCC.
 - b. Compliance with this procedure shall be a condition of participation by an individual not employed by EPCC but otherwise meeting the definition of a covered employee under this procedure shall be conditioned of signing a document certifying the individual is fully informed of this procedure and will fully comply.
3. *Covered Family Member* – includes:
 - a. A spouse;
 - b. A dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and
 - c. A related or non-related, unmarried adult who resides in the same household as the covered individual and with whom the covered individual is financially interdependent as evidenced by the maintenance of a joint bank account, mortgage, or investments.

If the covered individual is in doubt about whether an individual is a covered family member, the covered individual shall resolve the doubt in favor of disclosure.

In disclosing the financial interests, the interests of any legal entity, including foundation or trust controlled or directed by the individual or by the individual or covered family members, is considered to be the interest of the covered individual or covered family member as if the separate legal entry did not exist.

4. *Institutional Responsibilities* – means any of the professional responsibilities of a covered individual on behalf of EPCC, including research, research consultation, teaching, professional practice, EPCC committee membership, or service on an institutional panel such as an Institutional Review Board (IRB).
5. *Reportable Significant Financial Interest (SFI)* – A covered individual’s report of a SFI, when determined to reasonably appear to be related to the individual’s institutional responsibilities must include:
 - a. Payments received from or equity interest in a publicly traded entity when the total amount and source of payments received in the preceding twelve (12) months from that publicly traded entity on the date of disclosure aggregates \$5,000 or more; including salary, other payment for services (consulting fees, honoraria, paid authorship).
 - b. Payments received from a non-publicly traded entity or equity interest in a non-publicly traded entity when the total amount and source of payments received in the preceding twelve (12) months from that publicly traded entity on the date of disclosure aggregates \$5,000 or more; including salary, other payment for services (consulting fees, honoraria, paid authorship; and including stock, stock options, or other ownership or entitlement to such an interest).
 - c. Intellectual Property and Royalties held and any agreement to share in royalties related to those rights and the amount and source of royalty income that covered the individual or covered family member received or had the right to receive in the preceding twelve months.
 - d. Reimbursed or sponsored travel in the preceding twelve months including the purpose of the trip, the identity of the sponsor, the destination, and the duration.
 - e. The value and source of any single gift exceeding \$250 in value, or multiple gifts from a single entity that in the aggregate exceeds \$250 in value, other than gifts from a covered family member.
 - f. A fiduciary position held by a covered individual from a for-profit or nonprofit entity in the past twelve months, including a position as a member of the board of directors, an officer, an executive or manager for which the covered individual received any form of remuneration or reimbursement for expenses, to include the name and principal address of the entity.
6. *Non-Reportable Financial Interest* – The following are not considered SFIs for the purpose of this procedure:
 - a. Salary, royalties, or other remuneration paid to the covered individual by EPCC, if the covered individual is currently employed or otherwise appointed by EPCC.
 - b. Income from seminars, lectures or teaching engagements, advisory or review committees, or reimbursement for travel sponsored by a federal, state, or local government, 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 affiliated with an institution of higher education.
 - c. Income from investment vehicles, such as mutual funds or retirement accounts, as long as the covered individual does not directly control the investment decisions made in those vehicles.
7. *Conflict-of-Interest Official* – An official appointed by the President of EPCC or his or her designee to perform duties required by policy and this procedure and any other associated duties.
8. *Conflict-of-Interest Committee* – A standing or ad hoc committee appointed by the President or her or his designee with whom the Conflict-of-Interest Official may consult in carrying out the duties to be performed under this procedure.

II. Collaborators and Contractors

- A. If research is carried out in cooperation with or through a subgrantee, subcontractor, or collaborator, EPCC will enter into a written agreement with the party, which agreement will provide legally enforceable terms that establish whether this procedure or the financial conflicts of interest policy and/or procedure applies to the researchers of that party.
- B. If the policy or procedure of the party applies to its researchers, that party must specify that its policy/procedure is consistent with the requirements of any applicable federal statutes or regulations. If that party cannot so certify, the agreement must state that the researchers are subject to this policy as covered individuals for disclosing significant financial interests that are directly related to the researcher's at EPCC.
- C. If the policy of the party applies to its researchers, the agreement must specify the time periods for that party to report identified financial conflicts of interest to EPCC. The time period must be sufficient for EPCC to make any reports required by federal regulation.
- D. If the procedure of EPCC applies to researchers of that party, the agreement must specify the time periods for the researchers to submit a financial interest disclosure statement to EPCC to allow EPCC to comply with its review, management, and reporting obligations under federal regulation.

III. Education

- A. Each covered individual must acknowledge annually that the individual is aware of and has read this policy and is aware of the covered individual's responsibilities regarding disclosure of significant financial interest and of the applicable federal regulations.
- B. A covered individual must complete training in regard to this procedure and applicable policies, statutes, and regulations before engaging in research at EPCC, and at least once every three years thereafter. A covered individual who is new to EPCC, must complete the training before engaging in research at EPCC or provide evidence of having completed the training at another institution within the past three years. A covered individual must complete the training immediately if EPCC finds that the individual is not in compliance with this procedure or the individual's management plan, or EPCC revises this procedure in a manner that affects the individual's duties.

IV. Disclosure

- A. Values: In making disclosures under this procedure, the covered individual shall disclose the value of a significant financial interest within the following ranges:

Level	Amount Range
A	\$0 - \$4,999
B	\$5,000- \$9,999
C	\$10,000-\$19,999
D	Amounts between \$20,000-\$100,000 by increments of \$20,000
E	Amounts above \$100,000 by increments of \$50,000

When describing a source, the covered individual shall provide the name and principal address for the source. Covered individuals shall distinguish among information pertaining to the covered individual and covered family members whose financial interests and activities are also reported by the covered individual. The Conflict-of-Interest Official and/or Conflict-of-Interest Committee may request further information about a covered individual's travel in order to determine whether the travel constitutes a conflict of interest.

- B. Documentation: If a covered individual discloses payments, intellectual property interests, or royalties, the covered individual must permit review of any related agreement, contract, offer, letter, or other documentation upon request of:
 - 1. The President of the College;
 - 2. The Conflict-of-Interest Official;
 - 3. The Conflict-of-Interest Committee; or

4. Any other person or entity with administrative responsibility/authority to review financial interest disclosure statements or approving a related management plan.

V. Disclosure Timing:

- A. A covered individual shall submit or update a financial interest disclosure statement:
 1. Not later than the thirtieth (30th) day of initial employment, covering the 12 months preceding the date of disclosure;
 2. Annually, during the annual reporting period (January through March); and
 3. No later than the 30th day after acquiring a new financial interest that require disclosure such as receiving payments, an equity interest, intellectual property rights, or royalties that would require disclosure in an annual financial disclosure statement.
- B. In addition, before a covered individual begins employment in any outside work or activity or receives from an outside source any compensation, or serves on any outside board, a description of the nature and extent of the employment or activity and the range of any compensation must be timely disclosed and approved by the designated EPCC official.
- C. A covered individual who is planning to participate in a PHS-funded research project shall submit a financial interest disclosure statement no later than the time of application for PHS-funded research, except that an individual who is new to EPCC and is planning to participate in an on-going PHS-funded project shall submit the statement no later than the 30th day of initial employment.

VI. Disclosure Statement Review:

- A. The appropriate Conflict-of-Interest Official shall review each financial interest disclosure statement and make two determinations:
 1. Whether any significant financial interest disclosed is relate to the research in which the covered individual is engaged; and
 2. If so, whether a financial conflict of interest exists.
- B. A significant financial interest is related to research in which a covered individual is engaged if the Conflict-of-Interest Official reasonably determines that the financial interest appears to be affected by the research.
- C. A financial conflict of interest exists when the Conflict-of-Interest Official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

VII. Timing of Expenditure of Funds:

Neither EPCC nor a covered individual may expend research funds unless the conflict-of-interest official has determined that no conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of the management plan that has been adopted and implemented in accordance with this procedure.

VIII. Cooperation with Institutional Committees:

The Conflict-of-Interest Official, Conflict-of-Interest Committee, the IRB, and other relevant committees shall cooperate in the consideration of whether a covered individual has a conflict of interest in regard to research and in the development of management plan for that conflict of interest.

IX. Management of Financial Conflict of Interest:

- A. If the Conflict-of-Interest Official determines that a covered individual has a conflict of interest, the Official, in cooperation with the covered individual and the appropriate individuals designated by the Conflict-of-Interest Official and/or Conflict-of-Interest Committee, shall develop a management plan governing that conflict of interest.

- B. If research is on-going and a new covered individual discloses a significant financial interest related to that research or any other covered individual disclose a new significant financial interest related to that research, the Conflict-of-Interest Official shall, not later than 60 days after the filing of the disclosure statement:
 - 1. Review the disclosure statement to determine if a financial conflict of interest exists; and
 - 2. If a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.
- C. If the Conflict-of-Interest Official and/or Conflict-of-Interest Committee learns of a significant financial interest that was not timely disclosed or was not timely reviewed, the Conflict-of-Interest Official shall, not later than 60 days after learning of the interest:
 - 1. Determine whether the significant financial interest is a financial conflict of interest; and
 - 2. If a financial conflict of interest exists, implement an interim management plan or implement other measures to ensure objectivity of the research going forward.
- D. In addition, if a financial conflict of interest was not timely identified or managed, or if a covered individual fails to comply with a management plan, the Conflict-of-Interest Official shall, not later than the 120th day after determining non-compliance:
 - 1. Complete and document a retrospective review and determination as to whether research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research; and
 - 2. Implement any measures necessary with regard to the covered individual's participation in the research between the date that the non-compliance is identified and the date the retrospective review is completed.
- E. For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the financial conflict of interest report, notifying he PHS, and submitting a mitigation report as required by federal regulation.

X. Management Plan Design and Agreement:

- A. A management plan may impose conditions and prescribe actions necessary to manage a financial conflict of interest, to ensure that the design, conduct, and reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed are:
 - 1. Public disclosure of the conflict of interest in presentations and publications;
 - 2. For human subject research, direct disclosure of the conflict of interest to research participants;
 - 3. Appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
 - 4. Modification of the research plan;
 - 5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research plan;
 - 6. Divestiture or reduction of the financial interest; or
 - 7. Severance of relationships that create actual or potential financial interest.

- B. A management plan must be in the form of a written agreement and must:
 - 1. Provide that the covered individual acknowledges receipt of the plan and understands the requirements of this policy and understands and agrees to comply with the required actions and other terms of the plan, including timeframes for required actions; and
 - 2. Clearly identifies each specific person responsible for monitoring compliance with the management plan.
- C. Monitoring and Compliance: Each person conducting research under a management plan shall fully and promptly comply with the plan, and each person identified as having responsibility for monitoring compliance under the plan shall carefully and fully execute those responsibilities.

XI. Posting of FOIC Information:

- A. This policy and each update must be publicly accessible through the internet (EPCC website).
- B. For each financial conflict of interest that is found to exist by the Conflict-of-Interest Official, EPCC will centrally retain and make the following information available to the public, upon request pursuant to the Texas Public Information Act (Chapter 552, Government Code) in regard to each covered individual who contributes to the scientific development or execution of the research project in a substantive, measurable way, including a covered individual who is the project director or principal investigator:
 - 1. The covered individual's name;
 - 2. The covered individual's title and role with respect to the research;
 - 3. The name of the entity in which the significant financial interest is held;
 - 4. The nature of the significant financial interest that constitutes a financial conflict of interest;
 - 5. The approximate value of the significant financial interest by range, or if the dollar value cannot be determined by reference to public prices or other reasonable market value, a statement to that effect.
- C. EPCC will maintain the information required by this section annually. In addition, for any financial conflict of interest of a covered individual whose information is requested under this section, EPCC will make the information required by this section available after the conflict of interest is identified in accordance with deadlines provided by the Texas Information Act.
- D. The information required by this section must remain available for three (3) years after its most recent update.
- E. Federal regulations require that each applicant for funding to the PHS include specific certifications and agreements in regard to this procedure and financial conflicts of interest. Federal regulations also require that EPCC make the reports required by this procedure for PHS-funded research.
- F. Before the expenditure of any funds under a PHS-funded research project, the appropriate EPCC officials will make the Financial Conflict-of-Interest Report to the PHS awarding component in compliance with 42 CFR Part 50, Subpart F and 45 CFR Part 94. In general, those regulations require a financial conflict of interest report regarding those interests that EPCC determines are financial conflicts of interest of subrecipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan related to the conflict of interest. The federal regulations require reporting within a specified period of financial conflicts of interest identified subsequent to an earlier report and requiring updating of reports regarding previously disclosed financial conflicts of interest.

XII. Enforcement:

- A. Timely, complete, and accurate disclosure of activities and financial interests consistent with this procedure is a condition of employment at EPCC, and a covered individual who does not comply with this procedure is subject to discipline, including termination of employment.

- B. For a covered individual who is not an employee of EPCC, compliance with this procedure is a condition of participating with EPCC in the capacity that qualifies the person as a covered individual. EPCC may require the individual to execute a document certifying that the individual knows that compliance with this procedure is a condition of participation.
- C. Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require EPCC to notify the PHS of instances in which the failure of a covered individual to comply with this procedure or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require EPCC to take action appropriate to maintaining objectivity in research. EPCC must make information available to the HHS or PHS awarding component as required by federal regulation.
- D. If the HHS determines clinical research funded by PHS to evaluate safety or effectiveness of a drug or medical advice or treatment has been designed, conducted, or reported by EPCC as required by federal regulation, EPCC will require the covered individual involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XIII. Administration of Conflicts; Records:

- A. The President or his or her designee shall appoint a Conflict-of-Interest Official who is responsible for overseeing implementation of this procedure and who may provide additional procedures and supplementary forms, as appropriate, consistent with this procedure and applicable sponsor regulations.
- B. Records regarding the disclosure of financial; interests and the management of conflicts of interest, including financial interest disclosure statements, a reviewing official's determinations, and other records of EPCC actions, shall be retained for the longer of three years after:
 - 1. The date of creation;
 - 2. The date of termination or completion of a research award or contract, or the submission of the final expenditure report, for research identified in a disclosure statement; or
 - 3. The date of final resolution of any investigation, audit, or similar action involving the records.
- C. Audits: EPCC will provide for regular audits of financial interest disclosure statement to determine individual and institutional compliance with this procedure.