

**OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE****Standard Operating Procedure for Managing Nepotism in Research and Related Conflicts of Interest**

POLICY: Interpersonal relationships that inherently create conflicts of interest are required to be disclosed and managed appropriately to maintain objectivity in research and provide assurance that personnel engaged in research are able to work in an environment free of bias where they can be objectively supervised and evaluated. Personnel appointments on a research grant and/or any other externally funded account established specifically to support research activities are normally restricted to persons who are not members of the immediate family of the Principal Investigator or account manager. Exceptions are limited to appointments specified by name in proposals submitted to, reviewed, and approved by an external funding agency.

PURPOSE: This SOP provides steps necessary to ensure that concerns of nepotism or interpersonal relationships that can potentially influence objectivity in research are properly vetted and managed when related persons or persons involved in an amorous relationship engage in the same sponsored research activity.

BACKGROUND: This SOP operationalizes the regulatory requirements of ECU Policy 06.05.02 and ECU Regulation 10.45.02. Investigators should conduct their affairs in a manner that avoids or minimizes conflicts of interest and must respond appropriately when conflicts of interest arise.

SCOPE: This procedure applies to all students, employees and volunteers who have interpersonal relationships that could potentially affect the design, conduct, or reporting of research or create an environment or circumstances that might appear to favor a particular member of the research team or create an environment where a member of the research team could be subject to undue influence.

DEFINITIONS:

Amorous Relationship: An amorous relationship exists when, without the benefit of marriage, two persons voluntarily have a sexual union or are engaged in a romantic courtship (e.g., dating or engaged to be married) that may or may not have been consummated sexually.

Employment Decision: A decision that includes, but is not limited to, one relating to searching, selecting, or appointing an individual for employment; establishing the terms and conditions of employment; determining compensation; evaluating work performance; instructing or advising; or any other action that assesses, determines, or influences work performance, career progress, or other employment status.

Familial Relationship: A relationship between two related persons. For purposes of this policy, "related persons" includes: father, mother, spouse, domestic partner, sibling, child, aunt, uncle, or other individual resident within the same household.

Investigator: Any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposed for such funding. This definition is not limited to those titled or budgeted as

principal investigator or co-investigator on a specific proposal, and may include, but is not limited to, postdoctoral associates, scientists, clinical and technical staff regardless of classification, or students. The definition may also include collaborators or consultants as appropriate.

Key Personnel: Per ECU policy, key personnel for a research study are individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether they receive salaries or compensation under the protocol. This includes, but is not limited to, individuals involved in conducting research with human subjects through an interaction or intervention for research purposes, including participating in the consent process by either leading it or contributing to it; and those who are directly involved with recording or processing identifiable private information, including protected health information, related to those patients for the purpose of conducting the research study.

Nepotism: Patronage bestowed upon or favoritism granted on the basis of family or amorous relationship without regard to merit.

Undue Influence: A situation in which an individual is able to persuade another's decisions due to the relationship between the two parties.

PROCEDURE:

A. Principal Investigators (PIs)

Principal Investigators of sponsored research projects who include key personnel with whom they have a familial or amorous relationship must exercise objectivity and base selection of such key personnel on the merits of their background and experience as it relates to their qualifications in carrying out the scope of work.

The following procedures must be followed in those instances where a Principal Investigator plans to engage in a sponsored research activity with other key personnel with whom they have a familial or amorous relationship:

1. **At time of proposal submission:**

- a. Have a current annual or project specific COI disclosure on file that discloses any key study personnel with whom he/she has a familial or amorous relationship.
- b. Coordinate with the Office of Research Administration and the Office of Research Integrity and Compliance to establish a research related conflict of interest management mechanism.
- c. Provide rationale and justification to ORIC's Conflict of Interest Officer (COIO) for the selection of key project personnel with whom they may have an amorous or familial relationship by describing how that individual's qualifications are uniquely necessary to support execution of the project.
- d. Develop and submit a fully executed [Mitigation Memo](#) to the COIO that includes the following information:
 - i. Title and sponsor of the project

- ii. Names of investigators on the project who have a familial or amorous relationship and the scope of work that each investigator will have on the project
- iii. The name and department of an independent investigator or the department chair who will oversee administrative and financial matters involving the investigators (performance on the project, approval of travel, approval of expense reports, effort reporting)
- iv. The name and department of an individual who will provide independent review to ensure the integrity of the research data
- v. An alternative reporting structure to eliminate any real or perceived conflict related to salary, working conditions, work responsibilities, evaluation and promotion
- vi. Signatures of all pertinent parties outlined in the Mitigation Memo

2. At Notice of Award or time of funding:

- a. Conflicted investigators must update COI disclosures in AIR if any changes occurred since proposal submission and must continue to disclose their personal relationship in annual conflict of interest disclosures.
- b. Conflicted parties shall ensure the scope of work for each investigator on the sponsored research project is not duplicative.
- c. When a Principal Investigator or the account manager believes the appointment of a family member who has not been specified by name in a proposal is defensible, a case may be made for approval to make the appointment. The following documentation must be submitted to the appropriate chairperson, director, and/or dean for review and either approval or disapproval:
 - i. a CV or resume of the proposed appointee,
 - ii. a statement that includes the job requirements and a justification for the appointment as demonstrated by the candidate's experience and/or training, and
 - iii. a summary of the specific steps taken to publicize the availability of the position; the names of interested and qualified candidates who were considered and the basis for their rejection
- d. Conflicted parties must comply with the provisions of the Management Plan drafted by ORIC that is subject to review.

B. The department chair, director, or dean shall:

- 1. Indicate approval or disapproval of the request and forward it to the Vice Chancellor for Research for final consideration. The Vice Chancellor, following appropriate review and consultation at the University level, will issue a final determination on the request.

2. Ensure reimbursement from the project is approved by an independent person, of equal or higher rank than the PI. This includes approving time and effort certifications, travel, or other sponsor related expenditures on funded research.

C. Office of Research Administration

1. Communicate with the Office of Research Integrity and Compliance (ORIC) upon learning of a sponsored research proposal that lists key personnel who are in a familial or amorous relationship.
2. Coordinate with ORIC to ensure a Mitigation Memo has been executed and submitted to prior to proposal submission.

D. Office of Research Integrity and Compliance

1. Upon notice of award, draft a proposed Management Plan for review by the immediate supervisor(s) and/or department chairs of conflicted individuals.
2. Ensure the final version of the Management Plan is signed by conflicted individuals, any independent investigator and/or department chair, and the COIO.
3. Save fully executed management plans to the shared drive and upload to the electronic COI reporting system.

E. Salary related to project specific sponsored research appointments. Salary for appointments shall be set in the following manner:

1. If the appointee has been designated by name in the proposal, the salary paid may not exceed the total annual value of the salary as specified in the original proposal (or in a subsequently revised budget). Requests for exceptions must have prior written approval of the sponsor.
2. In other cases, the Vice Chancellor for Research may ask Human Resources to review the proposed salary to ensure that it represents compensation that is comparable to that of other University appointees performing similar work.