



KEAN

FINANCIAL CONFLICTS OF INTEREST IN RESEARCH POLICY

Policy Statement

This policy is designed to promote objectivity in research at Kean University by establishing standards that ensure the design, conduct, and reporting of research funded by external sponsors is free from bias resulting from financial conflicts of interest (FCOIs). Significant financial interests that might present a real or perceived conflict of interest with a researcher's university responsibilities can compromise the integrity of research. This policy helps Kean University ensure rigorous ethical standards are in place to protect research integrity as well as meet federal requirements for disclosure and management of outside activities. This policy is distinct from New Jersey's existing disclosure regulations for outside activities, including but not limited to the New Jersey Uniform Ethics Code.

Overview

This policy applies to all Kean University personnel who are responsible for the design, conduct, or reporting of research funded by federal agencies or other external sponsors that require FCOI disclosures, management, and reporting.

Regulatory Framework

This policy is designed to align with the requirements set forth by the U.S. Department of Health and Human Services (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94) and the National Science Foundation. All research projects that involve human subjects require disclosure, review, and management of Significant Financial Interests (SFI) in accordance with Kean University's Institutional Review Board policy and procedures.

Definitions:

- **Conflict of Interest (COI) Committee:** Independent committee charged with reviewing and managing the outside activities of federally funded investigators and those engaged in human subjects' research.
- **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
- **Financial Interest:** anything of monetary value, whether or not the value is readily ascertainable.

- **Foreign Financial Interests:** income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; and reimbursed or sponsored travel received from any foreign entity, including foreign institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).
- **Institutional Deciding Official:** The institutional official who makes final determinations on appeals of findings of FCOI and any institutional actions.
- **Institutional responsibilities:** the professional activities an investigator performs on behalf of Kean University (e.g., administration, teaching, research, public communication, service on review panels, or mentoring).
- **Investigator:** Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.
- **Public Health Service (PHS):** A federal agency within the U.S. Department of Health and Human Services as defined in 42 C.F.R. Part 50.
- **Significant Financial Interest (SFI):**
 - Income or equity interests exceeding \$5,000 from a publicly traded entity;
 - Any equity interest in a non-publicly traded entity;
 - Intellectual property rights and interests (e.g., patents, copyrights);
 - Reimbursed or sponsored travel related to institutional responsibilities.

Policy Requirements

This policy applies to Kean University investigators who are 1) engaging in or proposing to engage in federally funded research or 2) proposing any research involving human subjects. It also applies to individuals who carry out federally funded research as subcontractors, subrecipients, or collaborators where the terms of the agreement dictate that Kean University is the responsible party.

A. Disclosure

Investigators must disclose all SFIs:

- At the time of proposal submission;
- At least annually thereafter;
- Within 30 days of discovering or acquiring a new SFI.

Significant Financial Interests do not include the following:

- Salary, royalties, or other compensation from Kean University for institutional responsibilities.
- Income from personal investments, such as mutual funds and retirement accounts, provided that the investigator does not control the investment decisions made by these funds/accounts.
- Income from seminars, lectures, or teaching engagements sponsored by a domestic government agency, a university, and/or university affiliate.
- Income from service on advisory committees or review panels for a domestic government agency, a university, and/or university affiliate.
- Travel related to institutional responsibilities that is reimbursed or sponsored by a domestic government agency, a university, and/or university affiliate.

B. Review and Management

Kean University's Conflict of Interest (COI) Committee will review disclosures to determine whether an SFI constitutes an FCOI. If an FCOI is identified, a management plan will be developed, which may include:

- Public disclosure of the conflict;
- Monitoring of the research;
- Modification of the research plan;
- Disqualification from participation in the research; and/or
- Divestiture of financial interests.

Investigators may appeal any COI Committee determination that affects their participation in federally funded or human subjects research to the Institutional Deciding Official or their designee(s). Such requests must be in writing and received by the Institutional Deciding Official, with a final determination issued within 60 business days.

C. Training

Investigators must complete FCOI training:

- Prior to engaging in research;
- At least every four years thereafter;
- Within 90 days if this FCOI policy is revised; and
- If found to be out of compliance with this policy.

D. Reporting

Kean University's COI Committee will report identified FCOIs to the appropriate funding agency (e.g., NIH via eRA Commons) prior to expenditure of any funds and within 60 days of identifying any new FCOI.

E. Record Retention

Records of all disclosures, reviews, and actions taken regarding FCOI will be maintained for at least three years from the date of the final expenditure report or as required by the sponsor.

Compliance

Violations of this policy may result in disciplinary action, including termination; removal from federally funded projects; and/or institutional ineligibility for federal research funding. Fraudulent statements or claims (including intentional omissions) in violation of this policy may result in criminal, civil, administrative or university penalties.

Noncompliance with this policy will trigger a retrospective review of the research by the COI Committee within 90 days of discovery. This investigation will include review of the investigator's activities and the federally funded research project to determine whether any research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research. Documentation of the retrospective review will follow federal regulations.

If bias is found, the COI Committee will notify the sponsor promptly and submit a mitigation report to the sponsor addressing the impact of the bias on the research project, and the plan of action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, annual FCOI reports will be submitted in accordance with the regulations and terms and conditions of the award agreement.

If bias is not found, no further action is required.