

CONFLICT OF INTEREST IN HUMAN SUBJECTS RESEARCH

Approved by the Institutional Review Board on January 16, 2007

Policy:

The NJIT Institutional Review Board (IRB) is committed to assuring that researchers fulfill the public's trust in the research enterprise by putting the welfare of research participants ahead of the interests of the institution or of the researcher's personal financial interests. Financial interests are not prohibited, and not all financial interests cause conflicts of interest or affect the rights and welfare of participants in research. However, any interest that may conflict with the rights or welfare of research participants must be disclosed to the IRB. The IRB will determine whether a conflict exists and will manage the conflict in accordance with the best interests of research subjects.

Applicability:

This policy applies to individuals affiliated with NJIT who are involved in the conduct, design, data analysis, or reporting of research involving human subjects and whose research is approved by NJIT's IRB. This policy is supplemental to any other conflict of interest policies adopted by NJIT and/or the State of New Jersey.

Implementation:

Each protocol submitted to the IRB for review must be accompanied by the form approved by the IRB for the disclosure of financial interests in the proposed research project. The IRB may require researchers to submit any additional information it believes necessary to make a determination of conflict of interest or to manage a conflict of interest.

Based on the information submitted by the researcher for review, the IRB will determine:

- a. That there is no conflict of interest
- b. That a real or apparent conflict exists

If the IRB determines that a conflict exists, the IRB will decide on a strategy to manage the conflict. The management strategy adopted must be sufficient to protect the rights and welfare of participants in the research, includes:

- a. the researcher will reduce or eliminate the financial interest;
- b. the financial interest will be disclosed to research participants;
- c. responsibilities for financial and research decisions will be separated;
- d. there will be additional oversight of the research;
- e. an independent body will provide oversight;
- f. modification of roles in the research (e.g. PI change); or
- g. elimination of the conflict

If a conflict of interest arises after the research is approved, the researcher must report the conflict to the IRB. If the IRB determines that a conflict exists which could affect the rights or welfare of the participants in the research, it may take any action it believes necessary to protect the participants.

The below examples are not intended to be an exhaustive list, but they represent examples of potential conflicts of interest that must be disclosed, reduced, eliminated, or otherwise managed prior to the materializing of the conflict.

The following examples illustrate potential or actual conflicts of interest:

- A. Accepting gratuities or special favors related to research, or administrative duties.
- B. Giving paid lectures for entities whose economic or political interests are affected by an investigator's scholarly work.
- C. Undertaking evaluative research when the investigator or the investigator's immediate family members have a financial, managerial, or ownership interest in the sponsoring entity or in the entity producing the product to be tested.
- D. Entering into a paid consultant arrangement with an organization or individual having an economic interest in related research.
- E. Using students or employees to perform services for a company in which an investigator has an ownership or other financial interest.
- F. Accepting support for research under terms and conditions that results be held confidential, unpublished, or significantly delayed in publication.
- G. Providing privileged access to information developed and/or supported by NJIT or independent sponsors, to an entity in which the investigator has financial or other interests.
- H. Purchasing equipment, instruments, or supplies for research from a firm in which the investigator has a financial or other interest.
- I. Influencing the negotiation of contracts between NJIT and outside organizations with which an investigator has a financial interest or other relationship.