INVESTIGATOR CONFLICT OF INTEREST IN HUMAN SUBJECTS RESEARCH

POLICY

The University of Cincinnati (UC) 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 researchers’ personal financial interests. A conflict of interest exists whenever a financial interest held by an investigator or other person involved in a study may adversely affect the protection of the participants or the credibility of the human research protection program. The university will comply with applicable reporting requirements for funding or regulatory agencies. 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 the University of Cincinnati who are involved in the conduct, design, data analysis, or reporting of research involving human subjects and whose research is approved by the IRB. It also applies to members of the IRB, including the IRB Chair(s), and to the Institutional Official.

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 disclosure form must be submitted by each individual involved in the design, conduct, and/or reporting of the research. Such forms must include disclosure of the individual’s financial interests in research. The IRB may require that researchers submit any additional information it believes necessary to make a determination of conflict of interest or to manage a conflict of interest.

1. Based on the information submitted by the researcher for review, and in consultation with the Standing Committee on Conflicts of Interest in appropriate cases, the IRB shall determine:

   a. That there is no conflict of interest; or
b. That a 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. The IRB may request advice on a potential conflict of interest from the University’s Standing Committee on Conflict of Interest, but the final decision will be made by the IRB. The IRB may adopt any of the strategies listed below or any combination of them or the IRB may develop any other strategy that protects the rights and welfare of participants in the research:

a. The researcher will reduce or eliminate the conflict;
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 DSMB or other similar body will provide oversight;
f. Modification of roles in the research (e.g. PI change);

2. If a conflict of interest arises after the research is approved, the researcher must promptly 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.

Per University Rule 10-17-08 Policy on Conflicts of Interest in the Conduct of Research at UC, all employees engage in the design, conduct or reporting of research must complete training regarding conflicts of interest as they relate to the employee’s research responsibilities. This training is required at the time of hiring and then every four years. Per Human Research Protection Program (HRPP) Policy, all individuals engaged in research who have interactions with research participants or with their protected health information must demonstrate their knowledge of human research protection, including conflict of interest, via an HRPP accepted source. This training is required initially and then every three years. Training is also required when financial conflict of interest policies are revised in a manner that changes researcher requirements or a researcher is non-compliant with financial conflict of interest policies and procedures. Failure to comply with financial conflict of interest policies may lead to disciplinary action up to and including termination.

Per HRPP Procedure 323 Documentation and Document Retention, IRB records pertaining to disclosures and management of financial conflicts of interest must be maintained for at least three years after the completion or termination of the applicable study.
For research projects subject to Department of Health and Human Services regulations, disclosure of reimbursed or sponsored travel must be reported using the required conflict of interest form(s). At a minimum travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

**Applicable Regulations, Documents:**

45 CFR 46.107  
21 CFR 54  
21 CFR 56.107  
UC Rule 10-17-08 Policy on Conflicts of Interest in the Conduct of Research at UC  
UC Rule 10-17-09 Employee Financial Interests in Private Companies that are Commercializing University Discoveries, Inventions, or patents  
HRPP Policy IV.03 Demonstrating Knowledge of Human Research Protection by Researchers  
HRPP Procedure 323 Documentation and Document Retention

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<th>Date of Revision: 12/2008</th>
<th>Revised By: J. Gerlach</th>
<th>Summary of Revision: Addition of Other Applicable AAHRPP Domains. No text change within document.</th>
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<td>8/2014</td>
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<td>Revised to address AAHRPP recommendations.</td>
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Date Adopted **March 2015**  
Signature **signed copy on file**