

University Policy 3.03.05**Conflict of Interest in Research****Policy Approval Date: May 13, 2008****Policy Effective Date: June 1, 2008****Procedure Approval Date: July 25, 2011****Procedure Effective Date: August 1, 2011****POLICY STATEMENT**

All learners conducting academic research under the program requirements at Capella University, including all doctoral learners conducting dissertation research and all employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella, are required to ensure that tangible and intangible conflicts of interest do not compromise the objectivity with which their research is designed, conducted, and reported. They are also required to comply with the policies and procedures outlined in Capella University's Human Research Protections (HRP) Standard Operating Procedures (SOPs). All employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella; researchers unaffiliated with Capella who are conducting academic research involving Capella learners, alumni, faculty, staff, and/or their records; and all research supervisors who are overseeing research activities are also required to comply with the policies and procedures outlined in the SOPs. Institutional Review Board (IRB) committee members are also subject to the policies and procedures outlined in the SOPs in the review of research protocols with which they have a conflict of interest in accordance with Title 45 Code of Federal Regulations, Part 46 ([45 CFR 46](#)), with the exception of providing information requested by the IRB.

RATIONALE

Tangible and intangible conflicts of interest in research threaten the objectivity of scientific pursuit and may result in an increased risk of harm to human research participants. The purpose of this policy is to protect the integrity of Capella University's research community and the rights and welfare of human research participants and to ensure that academic, financial, or other personal interests do not compromise the objectivity of Capella's scientific pursuits.

DEFINITIONS**Conflict of Interest**

A conflict of interest is a situation in which academic, financial, or other personal interests have the potential, either actual or apparent, to directly and significantly compromise an individual's or group's professional judgment or objectivity in designing, conducting, reviewing, or reporting research.

- **Intangible interest** is a situation in which academic, political, religious, ideological, or other personal interests have the potential, either actual or apparent, to directly and significantly compromise an individual's or group's professional judgment or objectivity in designing, conducting, reviewing, or reporting research. These interests include, but are not limited to, relationships with research personnel and immediate family.

- o Academic conflict of interest is a conflict that can be described in research situations of intellectual bias in which an individual interferes with the research process for the purpose of intangible personal gain. For example, an individual may move a research study forward because he or she has a personal interest in the research method or potential results. Or an individual may delay a research study in order to strengthen his or her own research proposal for funding or other publication purposes.¹
 - o Conflict of commitment occurs when a researcher engages in activities that compete with the demands for his or her time or loyalties that may compromise the research process. These activities include but are not limited to preparing new research studies; teaching; or working as a paid consultant, officer or employee of a private company. These activities require time and make demands of the researcher's institutional commitments.²
 - o Conflict of conscience occurs when personal beliefs influence objectivity in research.
 - o Ideological conflict of interest occurs when a non-financial conflict of interest compromises the research by causing a conflict between the primary interest represented by the progress of science and the secondary interest represented by the researcher's allegiance to a given school of thought.³
- Tangible interest is a situation in which the conflict of interest can be quantified or measured; as such, it usually involves a financial connection or arrangement between two or more parties involved in the research.
 - o Significant financial interest is anything of monetary value held by the researcher or research team members, their spouses, or dependent children exceeding an aggregate threshold of \$10,000 in a 12-month period or 5 percent ownership or \$10,000 value.

Categories of financial interest include but are not limited to the following:

- Salary or other payments for services (e.g., consulting fees or honoraria)
- Equity interests (e.g., stocks, stock options, or other ownership interests)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)

Financial interest does not include:

- Salary, royalties, or other remuneration from Capella University
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or nonprofit entities
- An equity interest that, when aggregated for the researcher or research team members, their spouses, or dependent children, meets both of the following criteria:

¹ http://cnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/index.html#2_1

² http://www.usc.edu/admin/provost/oprs/private/docs/oprs/brochures/rcr/rcr_books/Conflict_of_Interest.pdf

³ <http://bjp.rcpsych.org/cgi/content/full/193/2/91>

- o Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5 percent ownership interest in any single entity
- o Salary, royalties, or other payments that, when aggregated for the researcher, his or her spouse, and dependent children or the research team members, their spouses, and dependent children, over the next 12 months, are not expected to exceed \$10,000

Conflict of Interest Management Plan

A conflict of interest management plan is a plan or procedure created by the researcher to manage conflicts of interest and adequately protect the human participants in a given research study. The plan must be approved by the Institutional Review Board (IRB) during its review of the research study.

Immediate Family

Immediate family includes one’s spouse, partner, children, parents, in-laws, and siblings.

Researchers and Key Research Personnel

Researchers and key research personnel are individuals, including learners, alumni, faculty, and staff who are responsible for the design, conduct, and reporting of research for a given research study.

PROCEDURES

I. Governance

This policy is governed by the Doctoral Success Center (DSC) within the Academic Research and Scholarship department. All researchers, research supervisors, and Institutional Review Board (IRB) members must disclose and properly mitigate any conflict of interest by consulting the policies and procedures outlined in the HRP Standard Operating Procedures (SOPs) and HRP guidance material. Professional associations and organizations may also have additional requirements regarding conflicts of interest in research. It is expected that those who are subject to this policy will comply with the requirements of those associations and organizations.

II. Conflicts of Interest and the Research Community

A. Researchers

1. Prior to submitting a proposed research study to the Institutional Review Board (IRB) for review and approval, if the proposed research study presents a conflict of interest, the researcher must prepare a conflict management plan that adequately protects the rights and welfare of the research study’s human participants.
2. If a researcher or research supervisor’s conflict of interest status changes during the course of a research study, the individual is required to notify the IRB. The IRB will review the change as a modification to the study.

B. Consultants

A consultant may not participate in the review of any research study with which he or she has a conflict of interest. When contacting an individual to serve as a consultant for a

proposed research study, Doctoral Success Center (DSC) staff will confirm that the individual does not have a conflict of interest.

C. Doctoral Success Center (DSC)

To ensure that DSC decisions are not compromised by academic, financial, or other personal interests, DSC members who have conflicts of interest are required to disclose such interests and recuse themselves from the review of proposed research studies or the conduct of research audits or compliance investigations, except to provide information requested by the DSC.

D. Institutional Review Board (IRB)

1. To ensure that IRB decisions are not compromised by academic, financial, or other personal interests, IRB members who have conflicts of interest are required to disclose such interests prior to reviewing and approving a proposed research study.
2. An IRB member's failure to disclose a conflict of interest may lead to his or her dismissal from the IRB.
3. All IRB members present at convened meetings have full voting rights except those who have a conflict of interest.
4. Prior to approving a proposed research study that presents a conflict of interest, the IRB or a designated reviewer will determine whether the researcher's conflict of interest management plan adequately protects the rights and welfare of the research study's human participants.

POLICY OWNERS

Academic Owner: Doctoral Success Center

Operations Owner: Doctoral Success Center

RELATED DOCUMENTS

University policy 3.03.01 Human Research Protections

Code of Federal Regulations. Title 45 Part 46: Protection of Human Subjects. (2005).

Department of Health and Human Services. (2004). *Financial relationships and interests in research involving human subjects: Guidance for human subject protection*. Retrieved February 12, 2014, from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Public Health Services. (2000). *Subpart F: Responsibility of applicants for promoting objectivity in research for which PHS funding is sought*. Retrieved July 3, 2007, from http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

University of Kentucky, Office of Research Integrity. (2005, July 5). "Researcher conflict of interest/OSPA/IRB coordination." *University of Kentucky Office of Research Integrity and Institutional Review Board standard operating procedures*. Retrieved December 20, 2006, from the University of Kentucky Web Office of Research Integrity Web site: <http://www.rgs.uky.edu/ori/>. Used by permission.

REVISION HISTORY

Original Policy Approval Date: May 13, 2008

Administrative edits as a result of ongoing review: 2-22-10; 4-17-12; 8-6-12; 2-10-14