University Policy 3.03.05

Conflict of Interest in Research

Policy Approval Date: May 13, 2008 Policy Effective Date: June 1, 2008

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POLICY STATEMENT

All students conducting academic research under the program requirements at Capella University, including all doctoral students 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. All employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella; all researchers unaffiliated with Capella who are conducting academic research involving Capella students, alumni, faculty, staff, and/or their records; and all research supervisors who are overseeing research activities are also required to comply with Capella's policies and procedures. Institutional Review Board (IRB) committee members are also subject to the policies and procedures 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.

- <u>Intangible interest</u> 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 <u>Academic conflict of interest</u> occurs when an individual interferes with the research process because of a personal academic interest or bias.

- o <u>Conflict of commitment</u> occurs when a researcher engages in external activities that compete with the demands for their time or loyalties and the research process is compromised.
- o <u>Conflict of conscience</u> occurs when personal beliefs influence objectivity in research.
- o <u>Ideological conflict of interest</u> occurs when there is a conflict between the research findings and the progress of science versus a researcher's allegiance to a specific school of thought.
- <u>Tangible interest</u> 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 <u>Significant financial interest</u> 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 five 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 any of the following:

- 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:
 - 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 five percent ownership interest in any single entity
 - Salary, royalties, or other payments that, when aggregated for the researcher, their 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 students, 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 Office of Research and Scholarship. All researchers, research supervisors, and Institutional Review Board (IRB) members must disclose and properly mitigate any conflict of interest by consulting Capella's policies, procedures, and guidance materials. 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 they have a conflict of interest. When contacting an individual to serve as a consultant for a proposed research study, IRB members will confirm that the individual does not have a conflict of interest.

C. 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 their 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: Office of Research and Scholarship Operations Owner: Office of Research and Scholarship

RELATED DOCUMENTS

University policy 3.03.01 Human Research Protections University policy 3.03.06 Research Misconduct The Common Rule (45 CFR 46)

REVISION HISTORY

Original Policy Approval Date: May 13, 2008

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