

# **Conflict of Interest in Human Research**

## **POLICY**

A conflict of interest in research refers to situations in which a financial or other commitment may compromise, or have the appearance of compromising, a researcher's professional judgment in the design, conduct, or reporting of research. A conflict of interest depends on the situation, not the individual's character or actions.

The welfare and safety of research participants are paramount. All conflicts must be eliminated or managed to ensure that the researcher's interest does not compromise the welfare of participants or the integrity of the data. A conflict management plan, approved by the Conflict of Interest Committee, with terms and conditions appropriate to the conflict, must be implemented to ensure the integrity of Chapman research, appropriate protections for participants, and compliance with University policies.

Chapman has instituted a rebuttable presumption that research personnel involved in the oversight, design, participant recruitment, informed consent process, data analysis, or reporting of results for a human research protocol cannot have an outside financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human research by financially conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to be involved in the study. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk to the study participants and the integrity of the data. The rebuttable presumption does not apply to intellectual property that has not yet been commercialized or where commercialization is not imminent.

## **Disclosure of Outside Activities**

As part of a research study, all Chapman researchers must identify any outside interest (paid or unpaid) for themselves, their spouse/domestic partner, or their dependent children ("close family members") that may be related to the proposed research conducted at Chapman or using Chapman resources (i.e., funding, personnel, students, or facilities). Members of the study team are responsible for proactively disclosing to the IRB any new outside relationships that may have an impact on the study until data analysis is complete and the study is closed with the IRB.

Examples of conflicts include but are not limited to:

- The project results could be relevant to the development, manufacturing, or improvement of products or services of the entity in which the researcher or their close family member has a financial interest.
- The project results could validate a treatment approach that is the same or similar or competitive to the approach developed or offered by the entity in which the researcher or their close family member volunteers consulting time (i.e., has an unpaid commitment).
- The researcher or their close family member is an officer of a company manufacturing, commercializing, or licensing a device, procedure, or other product used in the study.
- The researcher or their close family member has a financial interest in an entity that funds or participates in the project.
- The researcher or their close family member has an unpaid outside relationship with the entity donating research data or other materials that are the focus of the research project.
- The study is self-funded by a researcher or their close family member.
- The study focuses on the efficacy of a device, product, or material developed by a researcher or a close family member and the results of the study will be used to launch a new company.

The IRB will then evaluate whether the management plan is sufficient to protect the rights and welfare of the participants. If the study proceeds, the IRB will specify the acceptable language for the informed consent documents. If the IRB deems the management plan insufficient to protect the rights of the participants, the matter will be referred back to the Conflict of Interest Committee and the researcher.