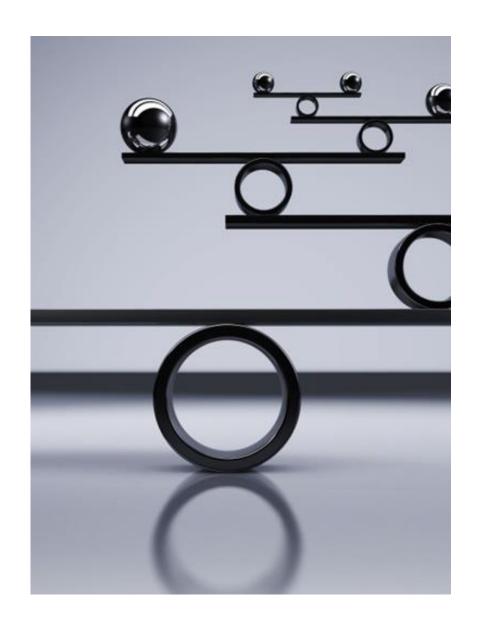


IRB Member Conflict of Interest



IRB Member Conflict of Interest

Objectives:

- Define conflict of interest and why it matters
- Identify commonly encountered individual member conflicts
- Review the HRPP Conflict of Interest Policy
- Identify how to manage individual member conflicts



Conflict of Interest

"Any situation or relationship that biases or has the potential to bias the conduct or outcome of IRB review" (Bankert et al., 2022).



Conflict of Interest

Important that the IRB operates free from inappropriate influence (Bankert et al., 2022)

"No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB" (45 CFR 46.107(d); 21 CFR 56.107(e)).

Conflict Type

Example



Research by Members



Member is an investigator, co-investigator, or listed in the iStar application as personnel



Financial Interest



Member has equity or significant financial interest in the research or sponsor per the USC Conflict of Interest Policy



Loyalty to Colleagues



Member is inclined to support colleague's research beyond mere camaraderie



Member's Area of Expertise



Member tends towards being more lenient or critical of a study that is conducted within their area of expertise



Impact of Decisions



Member is concerned with how a committee decision might affect their own research



Personal Agendas



Member's personal experience or advocacy crosses into inference with review process



Non-IRB Roles



Member has a role outside of the IRB as in-house legal counsel, or is responsible for bringing research funding to the university

Common Conflicts

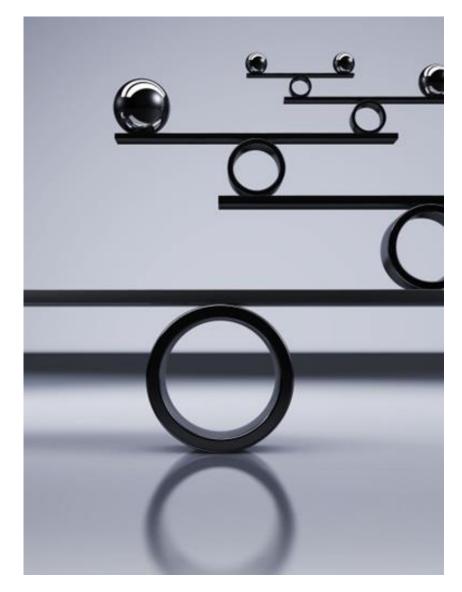


Responsibilities

Conflict Type Who Research by Members Member self-disclosure, iStar application Member self-disclosure, iStar application, Financial Interest Conflict of Interest Committee, diSClose, USC Conflict of Interest Policy Loyalty to Colleagues Member's Area of Expertise Member self-disclosure Impact of Decisions Personal Agendas Non-IRB Roles **IRB**

Common Conflicts





HRPP Conflict of Interest Policy

An IRB member is considered to have a Conflict of Interest if:

The IRB member <u>or a Close Relation of the IRB member</u> (spouse, mutual financial dependent, significant other, or person in an intimate relationship, child, parent, or sibling (including inlaws and step-relations), grandparent, grandchild, niece or nephew, aunt or uncle, or cousin):

https://hrpp.usc.edu/policies/conflicts-of-interest/

https://hrpp.usc.edu/policies/conflicts-of-interest/

HRPP Conflict of Interest Policy

- > Is involved in the conduct of the research
- ➤ Has a supervisory, managerial or ownership interest in the research sponsor, or licensee, or a company having an economic interest in the research
- ➤ Holds equity interest in a research sponsor, or licensee, or in any company having an economic interest in the research
- Receives incentive payments, bonus payments or finder's fees relating to the proposal
- ➤ Has consultation arrangements with an organization or individual having an economic interest in the research, which, when aggregated, is equal to or exceeds \$5,000
- Receives gifts, gratuities, or special favors from the sponsor, which, when aggregated, is equal to or exceeds \$5,000
- ➤ Receives honoraria, ... reimbursements from the sponsor, which, when aggregated, is equal to or exceeds \$5,000
- ➤ Has intellectual property rights related to the research
- ➤ Has entered an arrangement where the amount of compensation/value of ownership interests will be affected by the outcome of the research

Examples

In all examples, does the IRB member have a conflict of interest? What should the IRB member do? Contact the IRB (Analyst, Lead Analyst, AD) for more information? Recuse themself? Abstain from the vote? Vote?

An IRB member is a colleague of the investigator. The investigator sometimes mentors the IRB member's students. None of the IRB member's students are involved in the study that is up for review.

An IRB member is the director of a research group that has submitted a study. The IRB member is not listed as study personnel and was not involved in obtaining or negotiating the contract for the study.

An IRB member has a small amount of individual stock in the pharmaceutical company that is sponsoring the research.

How/When to Disclose a Conflict of Interest

Before the meeting

USC faculty and staff who are study personnel:

- USC diSClose
- iStar application

Unaffiliated members and USC faculty/staff who are not study personnel

• Notify IRB analyst when given an assignment with which there is a conflict

At the meeting

Notify the Chair at the beginning of the meeting and recuse yourself before the study is discussed

Resources

USC HRPP Policy, Chapter 4, Conflicts of Interest

USC Policies and Policy Governance, Conflict of Interest in Research

Minutes of Institutional Review Board (IRB) Meetings, Guidance for Institutions and IRBs, September 2017

Institutional Review Board Management and Function, 3rd edition, Bankert, et al. Chapter 12-7, 2022

