

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 3.8  
Financial Disclosure and Conflict of Interest

***Policy***

Financial Disclosure and Conflict of Interest for IRB Members

No regular or alternate IRB member may participate in the initial, deferral or continuing review, amendment request review, review by expedited procedure, review of unanticipated problems involving risks to subjects or others, review of non-compliance with the regulations or requirements of the IRB or report review regarding any project in which the IRB member has a significant financial interest or a conflict of interest, except to provide information as requested. The policy pertains to interests in business, non-profit and public entities in an area related to the research, where the entity could reasonably appear to affect or be affected by the review, conduct, or reporting of the sponsored project.

An individual cannot serve as regular or alternate IRB member or carry out day-to-day operations of the IRB review process if the individual is responsible for University business function or research development. For example, the Vice Chancellor for Research, the Dean School of Medicine, the Associate Director of the Office of Grants and Contracts, and the Director of Office of Clinical Trials Administration who are responsible for raising funds or garnering support for research cannot serve as a regular or alternate IRB member.

A conflict of interest is defined as a situation in which outside financial interests may compromise, or have the appearance of compromising, an investigator's professional actions or judgments in the design, conduct, or reporting of their research results. A potential conflict of interest may also be present when there is close professional, personal, or financial relationship between an IRB member and an investigator. In such cases, the IRB member must disclose such a relationship to the IRB prior to discussion of the relevant issue, or may choose to remove him or herself from participation in the discussion. Final determination of the presence of an IRB member's conflict of interest and a plan for its management will reside with the IRB Chair, or IRB Vice-Chair should the IRB Chair declare a conflict, in consultation with the IRB Administrator, and if appropriate, the UCSD Conflict of Interest office.

Each IRB member must disclose any business or professional relationships that may represent a conflict of interest or an appearance of conflict of interest in a particular company, their product(s), data, or method(s) in accordance with the same disclosure criteria required by investigators. This disclosure should be given orally and reflected in the meeting minutes for all project reviews where it is relevant. This policy applies to all IRB members and consultants retained for the purpose of providing scientific review of proposed research.

If it has been determined that an IRB member has a conflict of interest associated with a project, the IRB member is excluded from discussion regarding the project except to provide information requested by the IRB, excluded from voting on the project, and must not be present during the discussion and voting. The IRB member with the conflict of interest is not counted towards quorum on that project.

#### Financial Disclosure and Conflict of Interest for Investigators

The principal investigator and all co-investigators must report all actual or potential significant financial interests and any conflicts of interest for partially or fully commercially sponsored studies to the campus Conflict of Interest program office using California Form 700-U or other appropriate form(s) as determined by the Conflict of Interest Office. The forms and additional information regarding conflict of interest and human subjects research are available online from the UCSD Conflict of Interest Office website (<http://ocga.ucsd.edu/>). This disclosure policy applies to the principal investigator, co-investigators, and all personnel responsible for the design, conduct or reporting of the study. The policy pertains to interests in business, non-profit and public entities in an area related to the research, where the entity could reasonably appear to affect or be affected by the design, conduct, or reporting of the sponsored project or any arrangement where the amount of compensation will be affected by the outcome of the research. The IRB takes into consideration whether the potential conflicts of interests might adversely affect subject welfare. The UCSD Independent Review Committee (IRC) work with the investigator to take steps to manage reduce or eliminate the conflict.

Thresholds for disclosure of financial conflicts of interest in all cases will conform at least to the federal guidelines for PHS grants. However, disclosure standards of other agencies (FDA, PHS, OHRP, commercial sponsor, state, or University of California) must also be met in some cases, if they have authority over a project. If the project will be externally funded, the Principal Investigator will have completed the appropriate financial disclosure forms of the funding agency and stated if a conflict of interest was indicated there.

#### Review of Management of Conflicts of Interest

The IRB must ensure that steps to manage, reduce, or eliminate potential or real conflicts of interest have been taken. These steps are taken during the review process. During the initial review process, the IRB will review any potential conflicts of interest that may be present. If the IRB determines that the investigator's financial or other interest could adversely affect subject welfare, the IRB will take appropriate action to approve, disapprove, or require modifications to reduce the conflict and inform study participants and the PHS awarding agency for PHS-funded research.

The UCSD Conflict of Interest program office will also conduct committee-based evaluations of conflict of interest issues and communicate their determinations to the UCSD HRPP. These may result in modifications to Research Plan or consent documents after initial IRB approval, since the IRB review process tends to complete sooner than conflict of interest reviews.

***Procedures***

1. IRB members including Chair and alternates must report conflict of interest(s) and potential conflict of interest(s) during meeting discussions.
2. IRB Administrator or staff designee will review discussions of conflict of interest issues and oversee disclosure in consent documents. The minutes will document the IRB member with the perceived conflict of interest associated with the study, an indication of what the conflict is and that the member was absent for the discussion and vote on the project.

***Applicable Regulations***

[21 CFR 54.1](#)

[21 CFR 54.2](#)

[21 CFR 54.3](#)

[21 CFR 54.4](#)

[21 CFR 54.5](#)

[21 CFR 54.6](#)

[42 CFR 50.601](#)

[42 CFR 50.602](#)

[42 CFR 50.603](#)

[42 CFR 50.604](#)

[42 CFR 50.605](#)

[42 CFR 50.606](#)

[42 CFR 50.607](#)

[UC San Diego Conflict of Interest Office](#)