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. A conflict of interest is defined as direct participation in the research (e.g., protocol development, principal or sub-investigator), or any significant financial interest in the sponsoring company. 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 committee prior to discussion of the relevant issue, or may choose to recuse 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, in consultation with the IRB Administrator, and if appropriate, the UCSD and VASDHS Conflict of Interest offices.

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 leave the room 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 subinvestigators 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, available online from the UCSD Office of Grants and Contracts website
(http://ocga.ucsd.edu/). This disclosure policy applies to the principal investigator,
subinvestigators, 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 and VASDHS Independent Review Committee (IRC) work with the
investigator to take steps to manage reduce or eliminate the conflict.

For the purpose of this document, Significant Financial Interest means anything of monetary
value, including but not limited to, salary or other payments for services (e.g., consulting fees
or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and
intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term
does not include: Salary, royalties, or other remuneration from the applicant institution; Any
ownership interests in the institution, if the institution is an applicant under the SBIR
Program; 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 Investigator and the
Investigator's spouse and dependent children 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; and
salary, royalties or other payments that when aggregated for the Investigator and the
Investigator's spouse and dependent children over a twelve month period are not expected to
exceed $10,000.

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 COI 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. For VA investigators, the matter will also be reviewed by the VA IRC for further action as per VASDHS institutional policy.

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 and approve minutes containing 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  42 CFR 50.602
21 CFR 54.2  42 CFR 50.603
21 CFR 54.3  42 CFR 50.604
21 CFR 54.4  42 CFR 50.605
21 CFR 54.5  42 CFR 50.606
21 CFR 54.6  42 CFR 50.607
42 CFR 50.601