SAINT LOUIS UNIVERSITY INSTITUTIONAL REVIEW BOARD

IRB MEMBER AND CONSULTANT CONFLICT OF INTEREST STATEMENT

Federal regulations [DHHS 45 CFR 46.107(e), FDA 21 CFR 56.107(e)] state: No IRB may have a member participate in the IRB's initial or continuing review of any project in which a member has a conflicting interest, except to provide information requested by the IRB.

To assure compliance with federal regulations, and to ensure that conflicts of interest do not compromise IRB review of research, the Saint Louis University IRB requires board members and consultants to disclose conflicts prior to conducting IRB reviews. This includes all types of review (new protocol, continuing review, report forms, etc.) as well as issues of non-compliance.

A conflict of interest (COI) involves any situation in which an IRB member or consultant has any significant personal or financial interest in the proposed research.

A COI generally includes, but is not limited to 1) participation in the project; 2) a significant financial interest, as defined by the University's Conflict of Interest in Research Policy; 3) immediate family involvement in the project; 4) supervision of the researcher; 5) other conflicting interests. Following is specific information relating to each of these potential conflict of interest situations.

1) *Participation in the project** may include serving as a member of the research team, or mentoring or supervising the conduct of the research.
2) *A significant financial interest*, as defined by the Saint Louis University's Conflict of Interest in Research Policy.
3) *Immediate family involvement* occurs when the IRB member has a spouse, minor/dependent child, or live-in family member participating in the project.
4) *Supervision of the researcher* generally applies to supervisor(s) of the principal investigator.
5) *Other conflicting interests* are interests, such as a moral or political view, that a member believes hinders them from objectively reviewing a submission.

*Pharmacists with no substantive role in the research, but who are listed as study team members to satisfy sponsor requirements are not considered conflicted.

IRB members and consultants are responsible for identifying their COI and disclosing this information to the IRB Chair and/or the IRB Office staff prior to conducting an IRB review.

For research being reviewed at a convened meeting, disclosure of COI is expected prior to protocol review, deliberation and vote.