



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 104
Conflicts of Interest: IRB Members and Staff

Purpose

Any IRB member or consultant with a conflicting interest in a research protocol must disclose that information to the IRB administrative staff. The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data.

Scope

This policy applies to all types of IRB review and to the following groups of individuals associated with the review of a research protocol involving human participants:

IRB Members, IRB Consultants, and Immediate Family Members: Because of the unique responsibilities in reviewing research protocols, IRB members, consultants, and immediate family members' financial relationships may appear to be a potential Financial Conflict of Interest (FCOI) with their institutional responsibilities.

IRB Administrative Staff and selective USA Senior Management: Because of their unique responsibilities in processing and providing institutional support, this policy applies to the administrative staff of the IRB and USA senior management to allow for institutional FCOI to be reviewed.

Policy

The University of South Alabama IRB will follow and adhere to the University's Conflict of Interest policy. The Institutional Review Board policy and procedure compliments the University policy. This policy applies to all research protocols reviewed by the IRB. All members of the IRB engaged in research are required to comply with the policy.

1.0 IRB Member Conflict of Interest

- No IRB or consultant may participate in the IRB initial or continuing review of any project in which he/she has a conflict of interest, except to provide information requested by the IRB. Examples of such conflicts of interest could include: a member of the IRB who serves as an investigator or sub-investigator on research under review by the IRB, or a member who holds a financial conflict of interest in a sponsor or product under study. In cases where the assigned initial reviewer has a conflict of interest, the review must declare that conflict of interest and the protocol will be re-assigned to another reviewer. IRB members with a conflict of interest are recused and not counted towards quorum, whether or not the recused member remains present in the room. This is recorded in the IRB meeting minutes.

2.0 IRB Staff

Institutional staff whose job status or compensation is impacted by research that is reviewed by the IRB must be absent from IRB deliberations and voting. Any case of disclosure of conflict of interest by staff shall be referred to the Director, Office of Research Compliance and Assurance for review and consideration for development of a management plan.

University Related Documents

[University of South Alabama Conflict of Interest Policy](#)
[Conflict of Interest Disclosure Forms](#)

References

Food and Drug Administration (FDA): Guidance for Industry - Financial Disclosure by Clinical Investigators (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm>)

National Institutes of Health (NIH) Conflict of interest information (<http://grants.nih.gov/grants/policy/coi/index.htm>)

National Science Foundation: Policies (NSF): Conflicts of Interest Information (<http://www.nsf.gov/policies/conflicts.jsp>)

Office of Human Research Protection (OHRP): Final Guidance Document (<http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>)

Office of Research Integrity (ORI): Policies/Regs/Statutes: PART 50: Subpart F—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
(<http://ori.hhs.gov/policies/fedreg42cfr50.shtml>)

History:

Effective Date:

Revisions: October, 2018

Responsible Office:

Office of Research Compliance and Assurance