



Title:	IRB Member and Consultant Conflict of Interest		
SOP Number:	2102	Effective Date:	June 2, 2017
Previous Version Dates:			

1 Purpose

This policy outlines the responsibilities of IRB members for making known any potential or perceived conflicts of interest (COI) concerning protocols reviewed by the IRB. No IRB member may participate in the review of any research project in which they have a COI, except to provide information, as requested. It is the responsibility of each IRB member to disclose any COI related to a study submitted for review and to recuse him/herself from the deliberations and vote by leaving the room.

2 IRB Member and Consultant Conflict of Interest

IRB Members and Consultants are responsible for making known any potential or perceived conflicts of interest (COI) concerning protocols reviewed by the IRB. These conflicts could include the IRB member's/consultant's role in any of the following categories of activity with respect to the study in question:

- Acting as Principal Investigator, Co-Principal Investigator or other key personnel
- Personally receiving funding or funded effort from the study, as listed in the study budget
- Acting in a supervisory role over the PI of the study,
- Being involved in research utilizing a competing technology such that the ability to render an objective assessment could be compromised; or
- Being a family member involved in a close personal relationship with a member of the study team (for example, as a spouse or immediate family member)

An IRB member or consultant is considered to have a conflicting interest when the member/consultant or their immediate family has any of the following:

- Involvement in the design, conduct, or reporting of the research with the following exception:

An IRB member who is listed on an IRB protocol as a member of the study's Key Personnel but whose study-related activities are limited to (i) the performance of commercial services for the investigator (or performing other genuinely non-collaborative services meriting neither professional recognition nor publication privileges), while (ii) adhering to commonly recognized professional standards for

maintaining privacy and confidentiality, is not considered to have a conflicting interest on this basis.

- Supervisory role over the principal investigator of the research.
- A conflict of interest management plan issued by the UNC COI Office overlapping with the research.
- Stock ownership or stock options, equity, or other financial interest related to the research valued at \$5,000 or more.
- Personal compensation of \$5,000 or more related to the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, such as an Advisory Board or Board of Directors, regardless of compensation.
- Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

Board members and consultants should make known any conflict of interest prior to the beginning of the Board's discussion of the protocol under review. They must leave the meeting room prior to the Board's deliberation and vote.

Additionally, IRB members are responsible for self-identifying any conflicting interests before conducting review using the expedited procedure, so as to remove themselves from involvement in the review of the research.

The IRB members with a conflict are documented in the meeting minutes as "recused" with reason of "conflict of interest" with a notation that the member was not present for the final deliberation and vote.

3 Definitions

"Immediate Family" means spouse and dependent children.

"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested. The definition is at least as stringent as the level of an investigator's financial interest that requires evaluation as a possible conflict of interest.