

SOP: Conflicting Interests of IRB Members		
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1 PURPOSE

- 1.1 This procedure establishes the process to identify and manage Conflicting Interest, financial or otherwise, of IRB members.
- 1.2 The process begins when an IRB member is asked to review an IRB submission.
- 1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB Members are to use WORKSHEET: IRB Member and Consultant COI (HRP-325)
- 3.2 IRB members are responsible to know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

4 RESPONSIBILITIES

- 4.1 IRB members (regular and alternate) follow these procedures.

5 PROCEDURE

- 5.1 Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research.
- 5.2 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials so the submission can be re-assigned.
- 5.3 If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB staff so the submission can be re-assigned.
- 5.4 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.
 - 5.4.1 IRB staff will record in the meeting minutes the name of the IRB member leaving the room because of a conflict of interest.
 - 5.4.2 The IRB member with a conflict of interest will not count towards quorum.

6 MATERIALS

- 6.1 WORKSHEET: IRB Member and Consultant COI (HRP-325)

7 REFERENCES

- 7.1 21 CFR §56.107(e).
- 7.2 45 CFR §46.107(e).
- 7.3 AAHRPP II.1.D.