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1 PURPOSE

- 1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members, ex officio members, and IRB Staff.
- 1.2 The process begins when:
 - 1.2.1 An IRB member is asked to review an IRB submission;
 - 1.2.2 An ex officio observes or participates in IRB deliberations; or
 - 1.2.3 An IRB Staff member is assigned to pre-review or review an IRB submission.
- 1.3 The process ends when an individual has either identified a Conflicting Interest and notified the IRB Chair, IRB Director, or designee or when an IRB member, ex officio, or IRB Staff 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, ex officio members, and IRB staff are responsible to know the definition of Conflicting Interest as defined in 3.002 (HRP-001) - SOP - Definitions and self-identify when they have a Conflicting Interest.

4 RESPONSIBILITIES

- 4.1 IRB members (regular and alternate), ex officio members, and IRB staff follow these procedures.

5 PROCEDURE

- 5.1 Before pre-reviewing or reviewing a study, IRB members and IRB staff are to determine whether they have a Conflicting Interest with the study.
- 5.2 If an IRB member or IRB staff has a Conflicting Interest for pre-review or review outside a meeting (e.g., exempt or expedited procedure), he or she is to notify the IRB Director or designee and request the submission be re-assigned to others.
- 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, ex officio, or IRB staff has a Conflicting Interest for review of a study at the meeting, he or she is to notify the meeting chair, stay in the meeting only to answer questions about the study, and leave the meeting for discussion and voting regarding that study.

6 MATERIALS

- 6.1 3.002 (HRP-001) - SOP-Definitions.
- 6.2 3.009 (HRP-050) - SOP - Conflicts of Interests of IRB Members, Ex Officio and IRB Staff.
- 6.3 3.014 (HRP-051) - SOP – Consultation.

7 REFERENCES

- 7.1 21 CFR §56.107(e).
- 7.2 45 CFR §46.107(e).