



## SOP: Conflicting Interests of IRB Members and Consultants

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### 1 PURPOSE

- 1.1 This procedure establishes the process to identify and manage situations where an IRB member or consultant has some personal “stake” in a particular outcome regarding a review or a panel deliberation and action, or might appear to be influenced by a Conflicting Interest, such that one’s objective decision-making might be influenced.
- 1.2 The process begins when an IRB member or consultant is asked to review an IRB submission.
- 1.3 The process ends when an IRB member or consultant has both identified having a Conflicting Interest and notified IRB Office staff, or when an IRB member or consultant has determined that he or she does not have a Conflicting Interest.

### 2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/22/2018.

### 3 POLICY

- 3.1 IRB members or consultants are responsible to identify when he or she is an investigator, co-investigator, or is otherwise directly associated with a research study, such that the IRB member or consultant must not participate in the IRB deliberations or voting on submissions that are related to that study.
- 3.2 In addition, an IRB member or consultant who identifies a conflict with either the investigator whose study is under deliberation or because of a financial conflict of interest must not participate in IRB deliberations or voting on submissions related to that study.

### 4 RESPONSIBILITIES

- 4.1 IRB members and consultants follow these procedures.

### 5 PROCEDURE

- 5.1 Before reviewing research, IRB members and consultants are to determine whether they have a Conflicting Interest with research.
- 5.2 If an IRB member or consultant has a stake in the outcome or a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB Office staff so the submission can be re-assigned.
- 5.3 If an IRB member or consultant has a stake in the outcome or 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 Office staff so the submission can be re-assigned.
- 5.4 If an IRB member or consultant has a stake in the outcome or a Conflicting Interest for review of research at a meeting, the IRB member is required to identify their conflict to the panel members present if at convened review and to leave the room for deliberations. If called back into the room by the IRB for informational purposes, the conflicted IRB member must again leave the room for the final discussion and voting by the IRB.

### 6 MATERIALS

- 6.1 CHECKLIST: Non-Committee Review (HRP-402)
- 6.2 TEMPLATE: Meeting Minutes (HRP-501)
- 6.3 POLICY: Conflict of Interest and Conflict of Commitment (HRP-053)

### 7 REFERENCES

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