SOP: Conflicting Interests of IRB Members

1. PURPOSE
   1. This procedure establishes the process by which IRB members disclosure financial interests, and to identify and manage Conflicting Interest of IRB members.
   2. The process begins when an IRB member is asked to make and annual disclosure of financial interests.
   3. The process continues each time an IRB member is asked to review an IRB submission.
   4. The process ends when an IRB member has completed his/her annual disclosure and 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
   1. Added procedures regarding annual disclosure of financial interests.
3. POLICY
   1. Institutional policy requires all IRB members disclose their financial interests related to research to the FCOIRC and members recuse themselves from review, discussion or vote on any research related to a financial interest.
   2. IRB members are responsible to know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.
4. RESPONSIBILITIES
   1. IRB members (regular and alternate) follow these procedures.
5. PROCEDURE
   1. By March 31, or within 3 months of joining the Board, IRB members make their annual disclosure of financial interests through Mount Sinai’s COI disclosure procedure.
   2. Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research.
   3. 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.
   4. 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. If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to:
      1. Notify the IRB chair of the meeting,
      2. Recuse him/herself from the review, discussion and voting,
      3. Stay in the meeting room only to answer questions about the research, and
      4. Leave the meeting room for discussion and voting regarding that research.
6. MATERIALS
   1. Annual Mount Sinai FCOI disclosure form
   2. Definition of Conflicting Interest
7. REFERENCES
   1. 21 CFR §56.107(e).
   2. 45 CFR §46.107(e).
   3. AAHRPP elements I-9, II.1.D