UNIVERSITY OF MIAMI

SOP: Conflicting Interests of IRB Members				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-050	12/10/2021	F. Conte	K. Viamonte	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to identify and manage Conflicting Interest 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 HSRO 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 11/13/2013

2.2 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

3.1 IRB members must know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

3.2 Research Pharmacists [Investigational Drug Services (IDS) Pharmacists] as defined in their job functions and being part of the HRPP are key members of the biomedical IRBs and are not considered to be involved in the design, conduct or reporting of the research when his/her duties are limited to handling and dispensing of investigational products.

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 HSRO staff and return all materials.

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 secondary reviewer, he or she is to notify the HSRO 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.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 21 CFR §56.107(e).

7.2 45 CFR §46.107(e).

7.3 AAHRPP elements I-9, II.1.D