UNIVERSITY OF MIAMI

SOP: COI Review				
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1 PURPOSE

1.1 This procedure establishes the process to review financial interests that could present a conflict of interest (COI) related to a request for approval of new research or modification to previously approved research.

1.1.1 This SOP describes review of interests disclosed in the UDisclose System, as they relate to human subject research studies.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Added guiding principles, definitions and procedures.

3 GUIDING PRINCIPLES

3.1 Financial conflict of interest in research may affect the rights and welfare of human subjects in research; IRBs, institutions and investigators need to consider what actions regarding financial interest may be necessary to protect those subjects.

4 DEFINITIONS

4.1 Financial Interest: See SOP: Definitions (HRP-001)

4.2 Management Plan: See SOP: Definitions (HRP-001)

4.3 Minimal Risk: See SOP: Definitions (HRP-001)

4.4 Related: See SOP: Definitions (HRP-001)

4.5 Related Financial Interest: A Financial Interest that is related to the Human Research

5 POLICIES

5.1 All personnel engaged in Human Research must disclose activities and financial interests related to his/her institutional responsibilities through the UDisclose System.

5.2 The IRB reviews financial interests that are related to the research along with the COIC determination to determine whether the financial relationship creates a bias that might affect the rights and welfare of the human subjects or the reliability of the research data.

5.3 As part of its review, the HSRO considers the determinations of the Office of Disclosures & Relationship Management (DRM) and the UM COI Committee (COIC); however, the IRB's determinations and management plan will replace the COIC's determinations if the IRB's requirements are more stringent and the IRB's requirements will be communicated to the COIC, which will revise the management plan to include the IRB's requirements.

5.4 The procedures described in this policy do not alter or replace this institution's conflict of interest reporting policies.

6 RESPONSIBILITIES

6.1 HSRO and DRMDRM staff members carry out these procedures.

7 PROCEDURE

7.1 HSRO staff check for the following during the IRB pre-review process:

7.1.1 Completion of CITI certification for the COI course (in CITI Program).

7.1.1.1 If one or more study team members has not completed the CITI COI training, the IRB Coordinator will notify the study team.

7.1.2 Financial Interest Review Status for each study team member and Principal Investigator as reflected in the HSRO's electronic system (eProst):

7.1.2.1 HSRO staff will access the Initial study or Modification (with scope: Study Team Member Information) in eProst.

7.1.2.2HSRO staff will review the list of study personnel in the Project Contacts tab. The "Financial Interest Review Status" column will indicate whether or not each person has completed the disclosure process for the study. The table below defines the Financial Interest Review Statuses of the Research Certifications and corresponding actions required.

7.1.2.3 When reviewing Continuing Report submissions, should the HSRO

identify that DRM ancillary review is warranted, HSRO will execute the MANAGE ANCILLARY REVIEWS function to provide access to DRM, and alert as necessary.

If the Financial Interest Review Status of the PI and/or any study team member is:	**Then the IRB Coordinator will:**
• Draft *(see NOTE below)*	Execute the "Request Clarification" activity and include a statement to the effect of, "One of more study team members has not yet disclosed in UDisclose for this study. Please make sure that the PI and study team members have submitted their disclosures."
• Administrative Review	Require the study team to insert COI-
• Administrative Review: Response Pending • Scheduled for Meeting • Meeting Complete: Response Pending • Discloser Review of Plan • Under Management/Mitigation Plan • Review Complete: Preparing Correspondence	related language into the study's consent forms, as these statuses indicate that the individual has a financial interest that requires DRM review and may require management or mitigation. (See sections 7.1.2.3 and 7.2 below for additional information on handling of interests requiring review by COIC.)
If the PI and ALL study team members have a Financial Interest Review Status of:	**Then the IRB Coordinator will:**
• No Review Required • Review Complete • Withdrawn	Proceed with IRB review as usual; contact PI to remove ICF disclosure, if appropriate.

7.1.2.4 The submission may be forwarded to Designated or Committee IRB Review prior to resolution of COIC review, but the IRB reviewer(s) must be informed that an interest disclosed by a team member may require management.

7.1.2.4.1 If the submission is otherwise approvable, the designated reviewer/IRB will select “Modifications Required to Secure Approval” as the determination.

7.1.2.4.2 The IRB determination letter will inform the PI that IRB approval is contingent upon receipt of a final determination from the COIC and compliance with any stipulations put forth therein.

7.1.2.4.3 The PI must then execute the “Submit Response” activity to allow further processing.

7.1.2.4.4 The IRB approval letter and watermarked documents will be released after an HSRO designee has confirmed that the modifications required have been submitted.

NOTE: For IRB Approved studies, or any Initial Submission in Post Review state, if the individual was added to the study team prior to the UDisclose implementation (DATE = TBD), his/her financial interest disclosure review status will always be “Draft,” and can be disregarded.

7.2 Parallel to the IRB review process, the DRMDRM staff will review human subject research related disclosure certifications on which the PI or a team member indicates that he/she has, or is aware of, an interest related to a new study submission or modification.

7.2.1 If the DRM determines that the interest requires review or will be managed by the COIC, the DRM will use the “Manage Ancillary Reviews” activity in eProst to add COI Committee review to the list of required ancillary reviews.

7.2.2 Following review by the COIC, DRM will then utilize the "Submit Ancillary Review" activity in eProst to indicate the COIC's decision and any changes required by the COIC to the ICF, study design, study team member roles, etc.

7.2.3 Prior to forwarding a study/modification that requires COIC ancillary review to IRB review, the HSRO staff will check the Reviews tab to ensure that the COIC ancillary review has been completed and that any changes required by the COIC have been addressed.

7.2.4 If the COIC determines that a COI Management Plan is required, in addition to executing the "Submit Ancillary Review" activity (7.2.2 above), DRM will also utilize the "Private Comment" to email HSRO leadership to convey to them the complete list of stipulations contained within the COI Management Plan. The HSRO will then ask the PI and study team to submit a Modification to address the additional requirements and will execute the "Update Pending Contingencies" activity to indicate a due date for submission of the Modification.

7.3 HSRO checks for final COI clearance prior to releasing the approval letter.

8 MATERIALS

8.1 SOP Financial Conflicts of Interest (HRP-055)

9 REFERENCES

7.1.1 21 CFR Part 54

7.1.2 42 CFR Part 50, Subpart F & 45 CFR 94