



Policy Name: Communicating Conflict of Interest (COI) among IRB, ORSP and University Research COI Committees			
Approved			Date: 11/01/08
Effective Date: 09/10/09	Page 1 of 2	Section: HRPP 1.6	Policy Number: N/A
Replaces Policy: 02/20/09			Dated: N/A

I. POLICY

Disclosures of individual and institutional Conflicts of Interest (COI) are received through a variety of avenues. These may be received through the Annual COI Disclosures, the Institutional Review Board (IRB), the Office of Research and Sponsored Programs (ORSP), and/or by a variety of MUSC Officers and administrators who request a review for potential or real conflicts and are initially reviewed by the MUSC/MUHA Triage Group as part of the MUSC/MUHA Conflict of Interest Operations. Disclosures related to research are processed for review through the University Research COI Committee.

It is the Committee's responsibility to review these requests in a timely manner, to maintain confidentiality, and to communicate their recommendations, findings and actions to the requesting unit and/or impacted unit in either detailed or summary form as appropriate, and to copy the written committee deliberations to the responsible University Officer.

The IRB manager and the Director of the Office of Research Integrity are notified of any disclosure involving human subjects received by the University Research COI Committee or ORSP.

II. PROCEDURE

- A.** Upon disclosure of a conflict of interest in the IRB application (Human Research Conflict of Interest Disclosure Form) the responsible IRB administrator notifies the responsible (corporate or non-corporate) ORSP Manager and the Administrative Assistant for the University Research COI Committee.
- B.** The chair of the University Research COI Committee determines whether an expedited review is appropriate or if full committee review is warranted.
- C.** The IRB administrator, chair and Director of the Office of Research Integrity are notified by letter of the results of the review by the University Research COI Committee.
- D.** If a COI Management Plan is required by the University Research COI Committee, the IRB administrator, IRB Chair, IRB Committee Members and the Director of the Office of Research Integrity are provided with either a summary or the details of the COI Management Plan, as warranted. ORSP is responsible for recording and follow-up of COI management plan as needed, with relevant outcomes being reported to various parties including the IRB.
- E.** The Conflict Management Plan must be reviewed by the IRB prior to IRB approval of the protocol.

- F. The IRB has authority to decide whether the conflict of interest and its management, if any, are appropriate to allow research involving human subjects to be approved.

III. REFERENCES