



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 Conflict of Interest Office. Disclosures of significant financial interests related to research are forwarded for review by the Research COI Committee, which includes membership from the staff of the ORSP and the IRB.

It is this Committee's responsibility to review the 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.

The IRB is notified of any disclosure involving human subjects received by the Research COI Review Committee.

II. Procedure

- A.** Upon disclosure of a financial interest in the eIRB initial protocol application (Human Research Conflict of Interest Disclosure Form) an electronic notice is sent to the Conflict of Interest Office. The COI Officer initiates the review and coordinates the necessary documents between the researchers and the Research COI Committee Chair.
- B.** The chair of the Research COI Committee determines whether an administrative review is appropriate or if full committee review is warranted and notifies the IRB by written communication.
- C.** After review, the Research COI Committee communicates its decision to the MUSC IRB. If the study is approved, the COI Office issues approval in the eIRB system. If a COI management plan is required, the Committee approved plan is provided to the IRB.
- D.** For new studies undergoing full board review, the COI management plan will be made available to the IRB members for review prior to full IRB

approval of the protocol. For studies that were initially reviewed by a convened board and requiring continuing full board review, amendments to add or update related financial interests will also undergo full board review if determined to be a potential conflict of interest. Financial interests that are added to studies that do not otherwise require full board review, and that are determined to be potential conflicts of interest, can be reviewed using the expedited process.

- E.** If an existing financial interest changes or a new financial interest is developed or acquired during the course of an ongoing study, it is the responsibility of the PI to update the IRB application within 30 days of the event in order to initiate the COI review procedure just described.

- F.** All management plans related to sponsored research developed by the Research COI Committee are provided to ORSP plans involving human subjects will also be provided to the MUSC IRB. The Conflict of Interest Office is responsible for recording and monitoring COI management plans with relevant outcomes reported to various parties including the IRB and ORSP.

- G.** The IRB has the final authority to determine whether the approved management plan for any disclosed conflict of interest allows research protocols involving human subjects to be approved. The convened IRB will make this determination for studies requiring full board review. This determination may be made by the expedited reviewer for studies that do not otherwise require full board review.