Financial Conflict of Interest Procedures for PHS Proposals

Start Here

PI identifies PHS application for which he/she is interested in submitting a proposal, identifies Investigators who will be part of the project, and determines the "Title" for the proposed application.

Lead PI creates a new project for PHS proposal via IRBNet (www.irbnet.org); lead PI "shares" project with UMD Investigators. All investigators complete and link their FCOI Disclosures to the new project and sign the project. PI submits project to COI Committee (COIC). Proposal can now be routed.

If disclosures do indicate FCOI, COI Admin will route to COIC for review and notify ORA.

If disclosures do not indicate FCOI, COI Admin will inform investigators.

COI Administrator and COI Chair screen disclosures for applicability and completeness.

COIC reviews disclosures and requests management plans via normal COI disclosure process. Management Plan must be approved by COIC before dispersing of funds. At time of award, sub-awardees without an FCOI policy must submit an FCOI Disclosure under UMD's policy and process. Sub-awardees with an FCOI policy will certify this to ORA (www.umresearch.umd.edu/ORAA/form/um_oraa_forms.html)

Once Management Plan is approved, COI Admin routes to VPR, President, and State Ethics Commission.

COI Administrator notifies ORA.

FCOI training (www.citiprogram.org) must be completed by all investigators at or before time of award.

Funds can be dispersed and research can begin.

Investigators must disclose annually and will be sent reminders by IRBNet.

Investigators must complete FCOI training every 4 years.

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**Investigator** means anyone with responsibility for the design, conduct, or reporting of the research.

**Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**Significant FCOI (SFCOI)** means the value of any remuneration (salary, payment for services, consulting fees, honorarium, paid authorship, stock) received in the prior 12 months, including travel, unless it is reimbursed by a sponsored agreement, the institution, a Federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center, or a research institute, that is affiliated with an institution of higher education.