



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

Financial Conflicts of Interest

Angela Bain, CIP

IRB Administrator | Human Subjects

Office of Research | University of Georgia

203 Tucker Hall, 310 East Campus Road, Athens, GA 30602

Office: 706.542.0798



Definitions



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Apparent Conflict of Interest

An apparent conflict of interest arises when an employee is involved in an activity and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the employee's impartiality.



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Financial Conflict of Interest (FCOI)

A conflict of interest arises when an employee (or employee's immediate family) has a Significant Financial Interest (SFI) that could directly and significantly affect decision making in the design, conduct, or reporting of externally funded instruction, research, or service activities performed on behalf of the University.



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Significant Financial Interest

A financial interest consisting of one or more of the following interests of the investigator (or immediate family) that reasonably appears to be related to the investigator's institutional responsibilities:

- a. With regard to any publicly traded entity
- b. With regard to any non-publicly traded entity (which would include most start-up companies)



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These activities are not automatically prohibited:

- Equity participation in a corporation;
- Service as an officer in a corporation;
- Service on a governing board;
- Service on a scientific or academic advisory board;
- Receipt of funding from an external entity in which an employee has an interest;
- Acceptance of publication royalties, royalties under the terms of the UGA Intellectual Property Policy, or honoraria for papers and lectures



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Where / When must COI be disclosed?

- Initial Submission
- Continuing Review or Modification
- Within 30 days of discovery or acquisition of a new financial interest



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Who is responsible for evaluation and management of conflicts of interest?

Research
Integrity
Officer (RIO)



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University Conflicts of Interest Committee for particularly complicated COI

- Chaired by the VP of Research or designee
- No less than 5 other members
- 3 year staggered terms



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Examples of management, mitigation, or elimination of COI

- Public disclosure of significant financial interests including disclosure on manuscripts submitted for publication and in the consent form to the participants
- Monitoring of research by independent reviewers
- Modification of the research activity plan
- Disqualification of an individual from participation in the portion of the activity that would be affected by that individual's significant financial interest



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Records and Reporting

- All records kept for 3 years after completion of activity
- UGA must report COI to sponsor prior to spending \$\$
- COI must be reported to sponsor within 60 days of identification
- COI for PHS funded research available upon written request from public within 5 days



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In cases where a project to evaluate a drug, medical device or treatment was conducted by an Investigator with a COI that was not disclosed or managed, the University will require investigators to disclose the COI in each public presentation or publication of the results of the research.



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The IRB has the final authority to determine whether conflicts of interest related to human subjects research have been eliminated or managed appropriately.

The IRB will not approve a research protocol where conflicts of interest are neither eliminated nor managed.



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Thank you.



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