

Guidelines for Determining Financial Conflicts of Interest

BACKGROUND:

Federal grants and contracts are funded with taxpayer dollars, and federal regulations are in place to ensure their appropriate use. Among these are regulations that focus on financial activities by investigators that might be perceived as compromising the integrity of the sponsored research. The regulations have the force of law, and complying with them is an obligation for all institutions and researchers who accept federal research funds.

In general, NIH regulations are aimed at identifying any “significant financial interest (SFI)” of key investigators, and then determining whether it may constitute a “financial conflict of interest (FCOI)” that could affect the research. The NIH has specified criteria defining each of these two categories (i.e., SFI or FCOI), and requires institutions that accept NIH (or other PHS or NSF) funds to determine whether they apply to any key investigator listed on any grant, contract, or proposal from those funding sources. If so, the institution is responsible for developing an appropriate plan to manage or eliminate any impact on the research. Investigators are responsible for disclosing all relevant information to their institution, and for complying with the terms of any management plan.

At Emory University, faculty disclose and request approval of their outside financial activities to the Dean’s office online using the eCOI process. For the subset of faculty who are listed as “key investigators” on an NIH-, NSF-, or other PHS-funded project or proposal, each activity must then be evaluated by Emory to determine whether it meets the NIH’s definition of an SFI or FCOI with respect to that specific research.

HOW A FINANCIAL CONFLICT OF INTEREST DETERMINATION IS MADE:

The evaluation is administered by Emory’s COI Review Office. When appropriate, the University’s standing Committee on COI in Research, which is composed of faculty from several schools, makes the determination of whether an SFI or FCOI exists and, if so, how it can be managed, mitigated, or eliminated. Factors commonly considered by the Committee are outlined in greater detail below.

Through the eCOI system and other avenues, the Conflict of Interest (COI) Review Office is notified whenever an Investigator indicates on a disclosure form that his/her Significant Financial Interest is with one of the following entities:

- the entity that sponsors their research project;
- the entity that produces products (equipment, software, compounds, drugs, devices, etc.) or services used in their research project;
- the entity that develops product or services their research project intends to evaluate or develop; or
- an entity with whom they are consulting in an area that overlaps with or is the main subject of his/her research

NIH DEFINITIONS OF SFI AND FCOI THAT APPLY TO PHS-FUNDED INVESTIGATORS:

A **Significant Financial Interest (SFI)** includes any one or more of the following from any single entity outside the home institution for activity that is related to the investigator’s professional qualifications:

- Compensation or honoraria valued at more than \$5,000 per annum
- Receipt of more than \$5,000 in IP licensing fees and/or royalties per annum
- Ownership interests in a publicly-traded entity (i.e., stock/options, dividends, equity) that are valued at more than \$5,000

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- Any ownership interests (i.e., stock/options, dividends, equity) in privately held entities (i.e., start-up companies, LLC's)
- Holding any management position (e.g., director, officer, trustee, management employee) in an entity outside the home institution.
- For PHS Investigators Only -- Reimbursed or sponsored travel in excess of \$5,000 from a single outside entity [Note: this does not include travel that is reimbursed or sponsored by (1) a federal, state, or local government agency; (2) an Institution of higher education; (3) an academic teaching hospital; (4) a medical center; or (5) a research institute affiliated with an Institution of higher education]

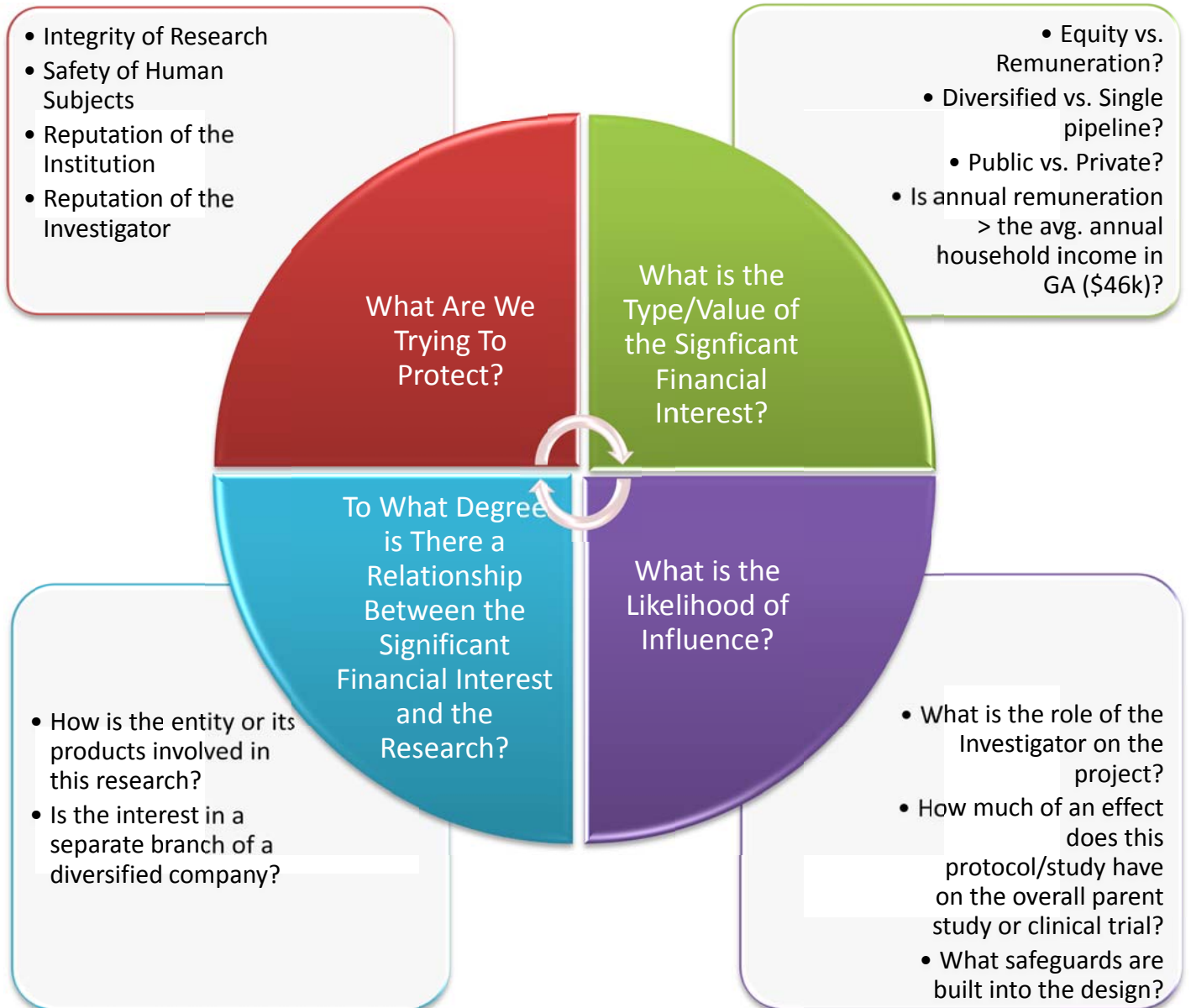
Any SFI as defined above will be reviewed by the COI Office. Those that appear to be related to a research project are also reviewed by the COI Committee. In almost all cases where SFIs are found to be directly related to a research project, a management plan will be required, though these usually involve only public disclosure of the SFI. Only a small minority are deemed to rise to the level of a FCOI.

A **Financial Conflict of Interest (FCOI)** exists when the Institution reasonably determines that a particular SFI could significantly and directly affect the design, conduct or reporting of a **PHS- or NSF-funded** research project. The institution is required to report all FCOIs related to PHS studies to the funding agency. Also, once an FCOI is reported to PHS, the institution is required to report **to the public** the following information upon written request (Note that the involved Investigators will also receive a copy of the Emory response):

- the grant title and number;
- Investigator's name;
- Investigator's role with respect to the project;
- the nature of Investigator's financial interests; and
- either the value of the financial interest (within ranges) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

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When preparing a COI Review the COI Review Committee, with facilitation from the COI Review Office, analyzes the Significant Financial Interest in light certain themes, **including but not limited to the following**, in order to determine whether a Significant Financial Interest rises to the level of a Financial Conflict of Interest:



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POTENTIAL MANAGEMENT PLAN PROVISIONS:

- Disclosure to the study team
- Disclosures in publications and presentations
- Restrictions on study participation
- Revision of the study design
- Reviewer of Data & Publications Divestment of stock/equity in the entity providing the financial interest
- Annual Monitoring
 - Active – Investigator must complete monitoring form
 - Passive – Administrative review of publications & c.v.; receipt by COI Review Office of disclosure to research team