Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 105: Financial Conflict of Interest

POLICY

The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service grants, cooperative agreements and contracts will be free from bias resulting from investigator financial conflicts of interest.

This policy and the procedures outlined below are intended to meet the most recent requirements published by the Federal government regarding Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research, on August 25, 2011 (42 CFR Part 50 Subpart F and 45 CFR Part 94).

PROCEDURES

1. Disclosure of FCOI

1.1 All individual responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement are required to complete a financial disclosure form.

1.2 Financial disclosure forms need to be submitted annually by investigators.

1.3 Within 30 days of discovery of a new transaction or activity that might involve a potential conflict of interest or whenever there is a change in interests that might pose a conflict of interest or whenever there is a change in a previously reported potential conflict of interest.

1.4 Whenever institution revises its FCOI policy that affects requirements of investigators.

1.5 No later than at the time of application for PHS-funded research.

2. Training

As per the regulations (42 CFR 604(b)), all individuals responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement are required to undergo initial FCOI training prior to engaging in research related to any PHS-funded grant and are required to be trained at least every 4 years.

2.1 Training will be done immediately if the institution revises the FCOI policy that affects investigators; if an investigator is new to the institution; and if an investigator is not in compliance with the policy or management plan.

2.2 Training includes the tutorial on the NIH website and reading this policy. Website address is http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

3. Significant Financial Interests

3.1 Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

3.2 Significant financial interest is defined as:

3.2.1 A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities.

3.2.2 Any interest held by the investigator and his/her immediate family in a business entity (company, corporation, or other enterprise) whose financial interests might reasonably appear to be affected by such activities.

3.3 Significant financial interest exists if the value of remuneration received in the last 12 months preceding the disclosure when aggregated exceeds $5,000. Significant Financial Conflict of Interest (SFCOI) might include, but are not limited to, any of the following:

3.3.1 Anything of significant monetary value, including salary or other payments for services such as consulting fees or honoraria;

3.3.2 Direct equity interests, such as stock, stock options, or ownership interests;

3.3.3 Intellectual property rights owned by the investigator, such as patents, copyrights, and royalties from such rights;

3.3.4 Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

At a minimum, travel disclosure shall include (a) purpose of the trip, (b) identity of the sponsor/organizer, (c) destination, and (d) duration.

Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3.4 Significant financial interests do <u>not</u> include:

3.4.1 Salary, royalties, or other remuneration paid by the institution to the investigator if the investigator is currently employed or otherwise engaged by the institution;

3.4.2 Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;

3.4.3 Income from seminars, lectures, teaching engagements, service on advisory committees or review panels sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher education.

3.5 An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

4. Disclosure Review, Management Plans, Dispute Resolution and Appeals

4.1 Disclosure Review

4.1.1 The Senior Associate General Counsel will provide timely review (within 60 days) of completed FCOI Annual Disclosure Forms and FCOI Disclosure Attachments and will notify the Affiliate Vice President for Clinical Services, upon completion of such review. Initial, annual and revised FCOI reports, including all reporting elements required by the regulation to the NIH for this institution and subrecipients will be submitted to the eRA Commons by the NCORP Administrator.

4.1.2 Per the regulations (42 CFR 50.605), reports are required prior to the expenditure of funds, within 60 days of identification for an investigator who is newly participating in the project; within 60 days for new or newly identified FCOI for existing investigators; at least annually (at the same time as when the institution is required to submit the annual progress report to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project and following a retrospective review to update a previously submitted report for significant FCOI that was not disclosed in a timely manner by an investigator, or for whatever reason, was not previously reviewed by the institution within 60 days.

4.2 Management Plans for Reported Conflict of Interest

4.2.1 Upon reviewing an individual FCOI Disclosure Attachment with possible conflict, the Affiliate Vice President for Clinical Services, after discussion with the individual, will decide whether a management plan is needed. Should management of a potential or actual significant financial conflict of interest be required, the Investigator, Principal Investigator, Research Medical Director, Director of Clinical Research, and the Affiliate Vice President for Clinical Services will draft a "Management Plan". These written plans will manage, reduce, or eliminate the significant financial interest(s). Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information.

4.2.2 Management plans may include a single element or several elements, such as:

4.2.2.1 Monitoring of the sponsored program by independent researchers or reviewers, or the institutional officials;

4.2.2.2 Modification to the research or program plan;

4.2.2.3 Appointment of an oversight panel or person to review research;

4.2.2.4 Public disclosure of significant financial interests, including human research participants, researchers, publishers, and/or conference organizers;

4.2.2.5 Limitations on the employee's involvement in personnel decisions on behalf of the institution;

4.2.2.6 Divestiture of significant financial interests; and/or

4.2.2.7 Other arrangements that manage, reduce, or eliminate a potential financial conflict of interest.

4.3 Dispute Resolution

4.3.1 If the Investigator, Principal Investigator, Research Medical Director, Director of Clinical Research, and the Affiliate Vice President for Clinical Services cannot agree on a management plan, the matter will be referred to a Review Panel consisting of the President and CEO, Affiliate Vice President for Clinical Services, and the Senior Associate General Counsel. The President and CEO will be the Chairman of the Review Panel. In such cases, the Investigator may request that a representative of his/her choosing (other than himself/herself) be appointed to the Review Panel for the review of his/her situation, and said request must be approved by the Chairman of the Panel.

4.4 Appeal

4.4.1 If the Investigator does not agree with the recommendation for financial conflict of interest management, he or she may appeal to the Affiliate Vice President for Clinical Services who may request additional information and/or review.

5. Compliance

5.1 As part of the Financial Disclosure Statement, each Investigator must certify that if the Senior Associate General Counsel and the Affiliate Vice President for Clinical Services determine a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the research project and will cooperate fully with the individual(s) assigned to monitor compliance.

6. Enforcement

6.1 Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the Affiliate Vice President for Clinical Services will be considered a deviation from accepted standards of conducting research.

6.2 Alleged violations of this policy will be investigated by the Senior Associate General Counsel, the Affiliate Vice President for Clinical Services, the Director of Clinical Research, and the Research Medical Director who will make recommendations for

action. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous, or misleading disclosure forms; or failure to comply with procedures prescribed by the Affiliate Vice President for Clinical Services. If they determine that the policy has been violated, sanctions may be imposed including, but not limited to, notification of sponsor and termination of award; formal admonition; a letter to the investigator's personnel files. This will be reported to NIH through eRA Commons.

7. Records

7.1 The Senior Associate General Counsel will maintain records of all disclosures and associated activities securely and confidentially in a password protected database.

7.2 All records will be maintained for three years following termination or completion of the project or resolution of any government action involving the records.

7.3 Records will not be routinely provided to sponsors unless such is an agency responsible for communication with sponsors. Disclosure statements and associated information will not be released without notification to the Investigator.

SCOPE

This SOP applies to all Investigators, the Principal Investigator, Research Medical Director, Director of Clinical Research, Affiliate Vice President for Clinical Services, President and CEO, Senior Associate General Counsel, and the NCORP Administrator.