

## **Akron General Health System Research Conflicts of Interest Disclosure**

### **What is required?**

As of August 24, 2012, all investigators, as defined below must have training on the AGMC Research Conflict of Interest policy. Training must be updated every three years. If you have not done this training, please refer to the instructions for completing the Conflict of Interest training module.

In accordance with 42 CFR Part 50, Subpart F, Akron General Health System (“AGHS”) has established policies and procedures that require Investigators (as defined below) to disclose all Actual, Apparent, or Potential Conflicts of Interest, including those that are not financial, *prior* to the submission of a proposal for funding to an external sponsor or for internal review. Such disclosure must be submitted with the Peer Review documents and to the IRRB with a new protocol submission. If a new Actual, Apparent, or Potential Conflict of Interest arises at any time, the Investigator must complete a Conflict of Interest Disclosure Form (“Disclosure Form”) and attach all required supporting documentation within thirty days of discovering or acquiring the conflict. Investigators will be required to update Disclosure Forms annually for the life of the project.

**If an Actual, Apparent or Potential Conflict of Interest is discovered, the project will not be eligible for review by the Institutional Research Review Board, or for internal funding consideration until a resolution plan has been agreed upon.**

### **Who must disclose?**

*Investigator* means the Principal Investigator (PI), Sub-investigator, Project Director (PD), Co-principal Investigators, study coordinators and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research. For purposes of this policy, the term "Investigator" includes the spouse and dependent children of any person listed above.

### **What must be disclosed?**

Each Investigator must disclose Actual, Apparent, or Potential Conflicts of Interest that are related to the Investigator’s Institutional Responsibilities.

An *Actual, Potential, or Apparent Conflict of Interest* (“Conflict of Interest”) occurs when there is a divergence between an individual's private interest and his or her professional obligations to Akron General, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A Conflict of Interest also includes a *Significant Financial Interest* that could directly and significantly affect the design, conduct, or reporting of research.

An *Actual Conflict of Interest* occurs when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research. An *Apparent or Potential Conflict of Interest* arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual’s opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.

*Institutional Responsibilities* are an Investigator's professional responsibilities on behalf of Akron General and as otherwise defined by Akron General in our Research Conflict of Interest Policy, and includes activities such as research, research consultation, teaching, professional practice, institutional committee members, and service on panels such as Institutional Review Boards or other internal boards or committees.

The following examples illustrate Conflicts of Interest:

- Accepting gratuities or special favors related to Research or administrative duties.
- Receiving payment under separate arrangements (for lectures, articles, consulting, etc) from companies or organizations whose economic or political interests are affected by an Investigator's scholarly work
- Undertaking evaluative Research when the Investigator or the Investigator's dependents have a financial, managerial or ownership interest in the sponsoring company or in the company producing the product tested.
- Entering into a paid consulting arrangement with an organization or individual having an economic interest in related Research.
- Using employees of AGHS to perform services for a company in which a staff member has ownership interest or from which he receives any type of remuneration.
- Accepting support for Research under terms and conditions that require results be held confidential, unpublished, or significantly delayed in publication.
- Providing privileged access to information developed with AGHS resources or supported by independent sponsors, to an entity in which the staff member has a political or financial interest.
- Purchasing equipment, instruments, or supplies for Research from a firm in which the staff member has a financial or other interest.
- Influencing the negotiation of contracts between AGHS and the outside organizations with which a staff member has financial interest or other relationship.

*Significant Financial Interest* means an Investigator's monetary interest or other relationship related to his/her Institutional responsibilities including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options or other ownership interests in both publicly [if the aggregate exceeds Five Thousand Dollars (\$5,000)] and **any** amount in non-publicly traded entities); Intellectual property rights (e.g., patents, copyrights and royalties from such rights).
- Excessive reimbursement for conducting a research study (i. e. profit is greater than 20% of total budget).
- **Any** reimbursed travel or sponsored travel related to Institutional responsibilities. This refers to travel, which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be determined by Investigator.

The term Significant Financial Interest does not include:

- Salary, royalties, or other remuneration from AGHS;
- Income from service on advisory or review committees, seminars, lectures, or teaching engagements for or Sponsored by 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 Research institute that is affiliated with an Institution of higher education;

- An equity interest in a publicly traded entity that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity;
- Salary, royalties, or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$5,000 during the next twelve month period.
- Interests and/or Income held indirectly through funds, such as mutual funds and pension funds, in which the Investigator or his/her immediate family does not control the selection of investments

**Disclosure procedures:**

- (1) All Investigators must disclose Actual, Potential, or Apparent Conflicts of Interest and Significant Financial Interests using this form and attach supporting documentation. *The completed form and packet must be submitted with the proposal when the project is undergoing peer review.* Supporting documents should be submitted in a sealed envelope marked confidential.
- (2) **If an Actual or Potential COI is disclosed, the Cognizant Official will develop a Management Plan or identify why one is not necessary. The Research Oversight Committee may be consulted for guidance.**
- (3) Any Management Plan for Conflicts of Interest will be incorporated in a Memorandum of Understanding (MOU), if applicable. The MOU is executed between the Investigator(s) and the Investigator's Cognizant Official prior to the expenditure of any awards funds or submission to IRRB or other internal committee review. However, if Investigator is being paid fair market value for services required to conduct the study and study reimbursement does not exceed 20% of costs, the Management Plan, will consist of disclosure on the informed consent and no further reports will be made to the ROC or AGHS Governance Committee. An MOU is not required in this circumstance.

**Cognizant Official** - means the Investigator's Department Chair, Department Director, Chairman of the Research Oversight Committee, Senior Vice President of Medical Affairs/Chief Medical Officer, or Chief Medical Officer, PPG, depending on to whom the Investigator is accountable (i.e. the "next level up").