AULTMAN		
TITLE: Financial Conflict of Interest Arising in Public Health Service (PHS) Funded Research	**ORIGINAL EFFECTIVE DATE:** 10/23/2012	
	REVISION DATE: 5/12; 8/12; 9/12;1/15; 5/16; 9/18; 4/22	**7**: 7

(This policy rescinds any previous publication covering the same material.)

I. **Policy:** Investigators who engage in Public Health Service (PHS) funded clinical research will disclose all significant financial interests to Aultman on an ongoing basis. Aultman will be responsible for the review, management and reporting of identified conflicts of interest.

II. **Purpose:** The Aultman Health Foundation ("Aultman") and its agents are committed to conducting their institutional activities in accordance with the highest standards of integrity and ethics and in compliance with all applicable laws and regulations related to conflicts of interest and objectivity in research. To promote the ethical conduct of research Aultman has established this policy and related forms and procedures to identify, address and report conflicts of interest in the context of human subject research.

Financial interests in human subjects' research are distinct from other interests inherent in academic life because financial interests are discretionary, and the perception is widespread that they may entail special risks. Specifically, opportunities to profit from research may affect – or appear to affect – a researcher's judgment about which subjects to enroll, the clinical care provided to the subjects, and even the proper use of subjects' confidential health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, review, data collection and analysis, adverse event reporting, or the presentation and publication of research findings.

III. **Definitions:**

A. Agent means an individual employed by the Aultman Health Foundation who is authorized to act on its behalf.

B. Aultman Health Foundation (AHF) is the legal name of the institution associated with our Federalwide Assurance [FWA 00003115]. For purposes of this policy references to Aultman includes the AHF and all of its legal components.

C. Conflict of Interest means a situation in which an investigator or key personnel (or someone in his/her immediate family - spouse, children, and any other person living in the same household) has a significant financial, professional or personal,

interest in the approval or outcome of a study and the interest could affect decisions related to either the design, conduct or reporting of the research, or adversely affect the rights and welfare of research subjects. This applies to all research protocols regardless of funding source, including those that are unfunded. Such conflicts must be identified and managed appropriately.

D. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

E. External Entity means any natural person, corporation, partnership, sole proprietorship, association, organization, holding company, joint stock company, receivership, trust, governmental agency or subdivision regardless of whether organized for profit, nonprofit or charitable purposes. A SFI may exist in an External Entity that:
   a. Sponsors the Investigator's research;
   b. Has made or pledged a gift to Aultman that benefits the Investigator's research;
   c. Has products, services or research interests that could reasonably appear to be affected by the Investigator's research;
   d. Sells goods or services to Aultman that will be used in the Investigator's research.

F. Family Member means the Investigator's spouse and dependent children.

G. Financial Conflict of Interest (FCOI) means an interest of an individual (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research or an individual's interest in any entity whose financial interests would reasonably appear to be affected by the research. Note: Financial interests include (but are 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), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

H. Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the institution including research, research consultation, teaching, clinical practice, institutional committee memberships, and services on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

I. Investigator means the Program Director (PD), Principal Investigator (PI) and any other personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which may include, for example collaborators or consultants.

J. Manage or Management means to take action to address a financial conflict of interest which includes reducing or eliminating the financial conflict of interest to

ensure that the design, conduct and reporting of research is free from bias or the appearance of bias.

K. PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). Examples of PHS funding mechanisms include:
   1. Grants
   2. Cooperative agreements
   3. Career Development Awards
   4. Center Grant of Individual Fellowship Awards
   5. Any activity where funding is provided by PHS (i.e., clinical investigations of the National Clinical Trials Network)

L. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

M. Research means a systematic investigation, study or experiment designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social-sciences research. This term includes basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

N. Research Oversight Committee (ROC) is a designated institutional committee comprised of representatives from the Human Research Review Board (HRRB), administration, legal counsel, and Research Council/Magnet liaison. The ROC is responsible for:
   1. Developing, implementing and overseeing the Aultman Research Compliance Plan;
   2. Human Subjects Research policy development, implementation, review and updates as appropriate;
   3. Developing and implementing training and education programs and monitoring activities;
   4. Conducting audits of specific risk areas identified through routine risk assessments and other means;
   5. Investigating, making determinations and reporting on matters related to non-compliance;
   6. Review of HRRB, investigator, and research staff financial interests to determine and document financial conflict of interests; and
   7. Research project approval to confirm that projects meet all relevant regulatory and institutional requirements in accordance with policy.

O. Significant Financial Interest (SFI) exists when 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

reasonable appears to be related to the Investigator's institutional responsibilities including research, teaching, professional practice, or committee memberships:

1. Publicly traded entities:
    a. The value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds $5,000; or
    b. Equity interest in the entity as of the date of disclosure valued at $5,000 or greater; or
    c. A combination of the two above that exceeds $5,000.
2. Non-publicly traded entities:
    a. Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company); or
    b. Remuneration that exceeds $5,000 from a non-publicly traded entity in the past 12 months; or
    c. Income related to intellectual property rights from any source other than the Investigator's current institution. The NIH provides further guidance on this issue by stating that intellectual property rights and interest upon receipt of income related to such rights and interests exceeding $5,000.
3. Reimbursed or sponsored travel that is related to Investigator's institutional responsibilities. This includes travel that is paid on behalf of the investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.
4. The SFI does not include the following:
    a. Salary, royalties, or other remuneration paid by the institution to the investigator if the investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the Institution;
    b. Income from the authorship of academic or scholarly works;
    c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a);
    d. Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001 (a).

e. 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.

IV. **Procedure:** Successful implementation of this policy assumes a shared responsibility by the Investigator and Aultman.

A. Investigator Responsibilities

1. The Investigator must completely and accurately disclose all SFIs that are reasonably related to the Investigator's institutional responsibilities no later than at the time of application for PHS-funded research and at least annually during the period of award.
2. Financial disclosure reporting submitted as part of the annual National Cancer Institute (NCI) Registration and Credentialing Repository (RCR) will satisfy the annual reporting requirements. If a financial interest is reported via the RCR, the investigator must complete and submit an "Addendum to Investigator's Significant Financial Interest Disclosure Form" to the ROC for review.
3. The Investigator is required to submit an updated disclosure within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
4. The Investigator is required to submit a disclosure for all qualifying reimbursed or sponsored travel. The elements required include the purpose of the trip, the sponsor/organizer, the destination, and the duration.
5. All Investigators must complete Aultman specified training on FCOI prior to engaging in research. Re-training must be completed at least every four years and immediately when any of the following circumstances apply:
    a. An Investigator is new to Aultman;
    b. Aultman revises its conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
    c. Aultman finds that the Investigator is not in compliance with this policy or Management plan.

B. Aultman Responsibilities

1. Maintain a written policy on FCOI that complies with applicable laws and regulations.
2. Make Aultman's FCOI policy available on its public web site.
3. Develop, provide and monitor adherence to FCOI training.
4. Review each Investigator's disclosure of SFI within 90 days of its receipt to identify any potential FCOI in accordance with applicable laws and regulations.
5. All SFI will be reviewed by the Research Oversight Committee (ROC) to determine if the SFI relates to the PHS-funded research and whether a FCOI exists; and if so devise and implement a plan to manage the FCOI.

6. Establish adequate enforcement mechanisms and provide for sanctions or other administrative actions to ensure Investigator compliance with the Management plan.
7. If Aultman carries out research through a subrecipient (e.g., subcontractors or consortium members), Aultman must take reasonable steps to ensure that the subrecipient's FCOI policy is in compliance with Aultman's requirements for disclosure.
    a. If the subrecipient cannot provide such certification, the written agreement between Aultman and the subrecipient shall state that the subrecipient's investigators are subject to Aultman's FCOI policy. Aultman must specify time period(s) for the subrecipient to report all identified FCOI.

C. Management of FCOI
1. To the extent possible and reasonable under the circumstances, the ROC will work with an Investigator to develop the means for the research to take place while protecting the research, its subjects and scientific integrity. Listed below are several possible resolutions for Management of the FCOI that may be recommended:
    a. Public disclosure of FCOI (e.g., when presenting or publishing the research, to staff members working on the project);
    b. For research projects involving human subjects research, disclosure of FCOI directly to participants;
    c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
    d. Modification of the research plan;
    e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
    f. Reduction or elimination of the SFI (e.g., sale of an equity interest); or
    g. Severance of relationships that create the FCOI.
2. Notify the project sponsor, Aultman Human Research Review Board (HRRB), and IRB of record (if not HRRB), of the FCOI and the related Management plan.
3. Determine the appropriate strategies to properly oversee and manage potential conflict(s), taking into consideration the possible remedies as outlined below.
4. Inform the Investigator of the actions taken, and decisions made by the ROC.

D. Reporting of FCOI
1. If PHS is a funding source to any research activity, Aultman will file a FCOI report to PHS, via eRA Commons website. Reporting will occur:
    a. Prior to the expenditure of funds;

b. Within 60 days of any subsequently identified FCOI;
c. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension;
d. Following a retrospective review to update a previously submitted report, if appropriate.

2. The report to the PHS awarding agency will include:
   a. Grant/ Contact number
   b. Program Director/Principal Investigator
   c. Name of Investigator with FCOI
   d. Name of the entity in which the Investigator(s) have a FCOI
   e. Nature of the FCOI
   f. Value of the financial interest
   g. Description of how the FCOI relates to the PHS-funded research
   h. Details of the management plan including:
      i. Confirmation of Investigators agreement with the Management plan
      ii. Institutions plan for monitoring
3. Aultman shall provide a written response to requestors (within five business days of the request) information concerning a SFI that meets the following three criteria:
   a. The SFI was disclosed and is still held by the Investigator;
   b. Aultman determines that the SFI is related to the PHS-funded research; and
   c. Aultman determines that the SFI is a FCOI. Such written response shall include the following information:
      i. Investigator's name;
      ii. Investigator's title and role with respect to the research project;
      iii. Name of the External Entity in which the SFI is held;
      iv. Nature of the SFI; and
      v. Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

E. Noncompliance

1. In the event that a FCOI is not disclosed, identified or managed in a timely manner; or an Investigator fails to comply with the FCOI management plan, Aultman shall within 120 days of its determination of noncompliance conduct and document a retrospective review of the Investigator's research activities.

2. Determination of bias in the design, conduct or reporting of such research will be made by the ROC.
3. If bias is found, Aultman will notify the PHS awarding agency promptly by submitting a mitigation report detailing the impact of the bias on the research and the plan of action to eliminate or mitigate the effect.
4. If the Department of Health and Human Services determines that a research project has been designed, conducted or reported by an Investigator with a FCOI, Aultman shall mandate that the Investigator involved:
    a. Disclose the FCOI in each public presentation of the results of the research; and
    b. Request an addendum to previously published presentations.

F. Sanctions
1. Sanctions and penalties for non-compliance with this policy or Management plan arising from this policy will be determined by the senior administration of Aultman with advice from the ROC and Corporate Compliance Officer. Sanctions may include, but are not restricted to:
    a. Removal of Investigator from participation in research;
    b. Letter of reprimand;
    c. Termination of grant support;
    d. Notification to funding agencies and/or professional journals and societies;
    e. Suspension; or
    f. Dismissal.

G. Maintenance of records
1. All records related to the implementation of this policy (e.g., disclosure forms, minutes of meetings called to Manage conflicts, minutes of the ROC and notifications to funding agencies) shall be maintained by the Director of Research Programs. These records will be kept in a secured fashion for a period of at least three years following the termination or completion of the research activities.

References:

FDA regulations 21 CFR part 54

Federal Public Health Service regulations 42 CFR part 50, subpart F; and 45 CFR part 94

National Science Foundation Grant Policy Manual 510, as amended by 60 FR 35820 (1995).

*Ohio follows federal regulations in this area and does not maintain state rules or regulations governing financial conflicts of interest in clinical research.

Clinical Research Department Significant Financial Interest Disclosure Form

Related Policies:

HRRB Policy: HRRB Member, Consultant, and HRRB Staff Conflicting Interest