

## Conflict of Interest Review Committee



### PURPOSE

In an effort to ensure that the Alabama College of Osteopathic Medicine manages or eliminates Financial Conflicts of Interest, the guiding principles outlined below will inform the CIRC's approach to identifying and addressing Financial Conflicts of Interest. The application of these guiding principles defines various actions or activities that either are not permitted or require prior approval.

ACOM's policy on disclosure of significant financial interests ("SFI") is based on federal regulations which require disclosure of SFI from Non-profit Entities. It is the College's responsibility to review such disclosures and determine whether the SFI in the Non-profit Entity presents a potential financial conflict of interest ("FCOI"). Many Investigators perform services for Non-profit Entities and receive compensation as well as sponsored or reimbursed travel from the Entity. It is the College's position that, generally, independent non-profit organizations that are charitable in nature do not present a risk of financial conflict as such Entities generally are organized to advance a public good or charitable cause and do not seek to advance the financial gain or profit of their supporters or members. The College recognizes, however, that some non-profit organizations are supported, in whole or in part, by for-profit Entities, and often it is not readily apparent when that is the case. The College shall review each disclosure relating to a Non-profit Entity to determine the nature of the Entity, and to determine whether the SFI presents a potential FCOI or if the matter should be referred to the Conflict of Interest Review Committee for further conflict review. This Standard Operating Procedure ("SOP") outlines procedures to be followed in the disclosure and review of SFI in Non-profit Entities.

ACOM's policy on the disclosure of significant financial interests ("SFI") is based on federal regulations which require disclosure of sponsored travel (travel that is paid for or on behalf of an Investigator and not reimbursed to the Investigator directly) or reimbursed travel that is related to Investigator institutional responsibilities and is paid by an Entity other than ACOM. The \$5,000 threshold applied elsewhere in the federal regulations does not apply to sponsored or reimbursed travel, thus, any amount of sponsored or reimbursed travel that is related to Investigator institutional responsibilities paid by an outside entity must be disclosed as a SFI. <sup>1</sup> While any amount of sponsored or reimbursed travel must be disclosed to the College by its Investigators, it is clear from regulatory guidance and comments that institutions have great flexibility in the review of those disclosures and determinations of whether the sponsored or reimbursed travel could "directly and significantly affect" the design, conduct or reporting of College research. Based upon guidance provided by the National Institutes of Health, the Conflict of Interest Review Committee has determined that there are certain types and purposes of sponsored or reimbursed travel that could not "directly and significantly" affect College research and thus do not require review for conflicts of interest. This determination is based upon the nature of the Entity paying for the sponsored or reimbursed travel or the purpose of the travel (e.g. often times the travel paid for by another Entity is for activities that advance the discloser's research and teaching and is considered vital to the discloser's position at the College) and the College's determination that given the academic or Non-profit nature of such Entities or such travel there is little to no risk that the travel could directly and significantly impact related College research.

## DEFINITIONS

Related Entity – any for-profit or non-profit entity in which the Investigator, alone or in combination with his or her Family, holds a Significant Financial Interest.

Family – the Investigator’s spouse and dependent children.

Independent Non-Profit Entity – an Entity which has attained tax-exempt status under the United States Internal Revenue Code, or a similar foreign law or regulation, and is not funded primarily, or controlled by, a for-profit Entity or Entities. For purposes of this SOP, a professional society that exists to advance the field of a particular field of study will meet the definition of an Independent Non-Profit Entity. An example would be an Entity which collects contributions from many different sources and uses that revenue to fund research in the field of a particular disease, including but not limited to the American Cancer Society, the Muscular Dystrophy Association or the Bill and Melinda Gates Foundation, or a professional society that exists to advance the field of a particular field of study, including but not limited to the American Medical Association or the American Chemical Society.

Industry-controlled Non-Profit Entity – an Entity which has attained tax-exempt status under the Internal Revenue Code and which receives a majority of its support from for-profit Entities. An example would be a non-profit organization with the purpose (explicit or tacit) of advancing the commercial prospects of a particular commodity, and which receives most or all of its revenue from for-profit manufacturers and distributors of that commodity. Some examples include but are not limited to the National Dairy Council or the American Coal Council.

Reimbursed Travel – 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.

## PROCEDURE

### **Guiding Principles include:**

1. An Investigator’s first and primary responsibility is to support and advance ACOM’s mission, rather than to advance his or her personal financial interests.
2. Research must be undertaken to advance scholarship and new knowledge and not an Investigator’s or the Investigator’s Family’s personal financial interests.
3. Financial Conflicts of Interest must be identified and either managed or eliminated.
4. Disclosure of Significant Financial Interests and professional activities related to but outside the Investigator’s Institutional Responsibilities is integral to identification of Financial Conflicts of Interest.
5. An Investigator must not attempt to influence the activities of colleagues and subordinates with the intent of enhancing the Investigator’s or the Investigator’s Family’s financial interests.
6. Research results must not be withheld or provided on a preferential basis for the benefit of an Investigator’s or the Investigator’s Family’s financial interests.
7. ACOM’s resources, names and trademarks may not be used for personal benefit.
8. Investigators must disclose any actual Financial Conflicts of Interests and any Significant Financial Interests that may appear to give rise to a Financial Conflict of Interest to students and staff who participate in their research.
9. Extra scrutiny must be given to potential Financial Conflicts of Interest in research involving human subjects.
10. An Investigator may not supervise directly or indirectly any member of his or her Family nor may an Investigator assume the role of advocate or judge regarding a Family member’s employment, salary, or promotion.

## **In regard to Nonprofits:**

1. All Investigators must disclose their SFI in all Non-profit Entities, including sponsored and reimbursed travel.
2. The Conflict of Interest Manager will review the disclosures to determine which Entities are Independent Non-Profit Entities (as defined above) and which are Industry-related Non-Profit Entities (as defined above).
  - a. Disclosures of SFI in Independent Non-Profit Entities have been determined to present little or no risk of FCOI in research and, as such, shall not ordinarily be reviewed beyond the determination that the Entity meets the definition of an Independent Non-Profit Entity as defined above, and that the investigator is not using the relationship for personal gain. This determination is based on the understanding that the nature of such Entities is truly not profit seeking or motivated by financial gain or profit to itself, its members or supporters but rather such Entities exist to advance a more public cause. Through experience reviewing this type of information, the COI Program may develop lists of Non-profit Entities which are routinely considered to not present a risk of FCOI in research, and/or those which are routinely considered to require further review for potential risk.
  - b. Disclosures of SFI in Industry-related Non-Profit Entities shall be reviewed as if they were disclosures of SFI in for-profit Entities.

The Conflict of Interest Review Committee grants the authority to the Compliance Manager to administratively review and process such disclosures:

1. If, after reviewing the disclosure and all relevant information, the Compliance Manager determines that the disclosed sponsored or reimbursed travel is paid by an Entity to allow the discloser to travel to an academic conference, e.g. not a conference hosted by a for-profit Entity in order to advance that Entity's commercial product or services but rather the conference is intended to present new or relevant research or information nationally or regionally in the academic area of study of the discloser, then no further conflict of interest review of the sponsored or reimbursed travel shall be required and the decision entered shall be a determination of no conflict of interest.
2. If, after reviewing the disclosure and all relevant information, the Compliance Manager determines that the disclosed sponsored or reimbursed travel is paid by any Entity to allow the discloser to attend a professional society meeting, then no further conflict of interest review of the sponsored or reimbursed travel shall be required and the decision entered shall be a determination of no conflict of interest.
3. If, after reviewing the disclosure and all relevant information, the Compliance Manager determines that the disclosed sponsored or reimbursed travel is paid by a foreign institution of higher education, a foreign academic teaching hospital, a foreign medical center, a foreign research institution that is affiliated with an institute of higher education, or a foreign government to allow the discloser to collaborate on research, professional practice or teaching with the host institution or host researchers, then no further conflict of interest review of the sponsored or reimbursed travel shall be required and the decision entered shall be a determination of no conflict of interest.
4. If, after reviewing the disclosure and all relevant information, the Compliance Manager determines that the disclosed sponsored or reimbursed travel is paid by a for-profit Entity or Industry- controlled Non- Profit Entity and not for any of the purposes outlined above (e.g., academic conferences and collaborations, local, or professional society meetings) and the aggregated total of travel paid by a single Entity is equal to or less than \$5,000 in the previous 12 month period, then no further conflict of interest review of the sponsored or reimbursed travel shall be required and the decision entered shall be a determination of no conflict of interest.
5. If, after reviewing the disclosure and all relevant information, the Compliance Manager determines that the disclosed sponsored or reimbursed travel does not meet any of the above noted purposes or exceptions, then the travel shall be reviewed by the Conflict of Interest Review Committee for potential conflicts of interest with related research. Or, if the Compliance Manager determines it does meet one of the above noted purposes or exceptions, however, under the facts disclosed and any other relevant circumstances involved, the Compliance Manager determines that disclosed travel has the potential to directly and significantly affect the related research, then the disclosure shall be reviewed by the Conflict of Interest Review Committee for potential conflicts of interest with related research.

**The application of these Guiding Principles requires that Investigators may not:**

1. Accept research sponsorship or gifts, in support of the Investigator's Institutional Responsibilities from a for-profit privately-held Related Entity;
2. Subcontract to a for-profit privately-held Related Entity are typically not permitted, but may be approved on a case-by-case basis (see statement below regarding purchasing goods and services from a Related Entity);
3. Negotiate with ACOM on behalf of a Related Entity, or negotiate with the Related Entity on behalf of ACOM;
4. Involve a student for whom the Investigator is a thesis supervisor in the Investigator's professional activities outside his/her Institutional Responsibilities;
5. Divert research opportunities to a Related Entity, which are more appropriately undertaken at ACOM, such as research sponsorship or other projects;
6. Promote the use of products or services of a Related Entity in the course of the Investigator's Institutional Responsibilities; or
7. Engage in research involving human subjects that could reasonably be expected to affect the financial condition of a Related Entity.

**The application of these Guiding Principles requires that the Investigator obtain prior written approval of the Investigator's Division Head, and in appropriate cases, enter into a management plan, before the Investigator:**

1. Accepts research sponsorship or gifts, in support of the Investigator's Institutional Responsibilities from a publicly-held or non-profit Related Entity;
2. Accepts an in-kind gift from a publically-held or non-profit Related Entity for use in his or her Institutional Responsibilities;
3. Accepts research sponsorship from a Related Entity from which the Investigator receives remuneration (for example, it may be permissible for an Investigator to receive research sponsorship from a Related Entity for whom the Investigator consults if the Division head/Director determines that the consulting scope of work and the research scope of work are separate and distinct);
4. Purchases goods or services from a Related Entity (for example, the Division head, in collaboration with Procurement & Contracts, could determine that the goods and services are not commercially available from another provider);
5. Provides goods, services, or access to facilities to a Related Entity (for example, ACOM may determine to make certain unique facilities available for use by outside entities, in which case a Related Entity could be entitled to use the facilities on the same basis as other entities);
6. Involves a student for whom the Investigator is not a thesis supervisor in professional activities outside his/her Institutional Responsibilities, as an employee or consultant or in any other capacity (such involvement may be beneficial for the student, but the student's educational experience must not be diminished or diverted);
7. Involves staff in the Investigator's Related Entity's activities.
8. Requests an appointment for an individual from a Related Entity to participate in research at ACOM.

## NONCOMPLIANCE

Under institutional authority and, in some cases, pursuant to Federal regulations (42 CFR 50 et seq., 21 CFR 54 et seq.), the Alabama College of Osteopathic Medicine is responsible to maintain and enforce a policy on financial conflicts of interest in research. Under these policies, the College is required to obtain information from researchers on outside financial or business interests, review the information for potential conflicts of interest, manage identified conflicts where possible, eliminate conflicts where management is not possible, and report existing conflicts to sponsors as

required by sponsoring agency rules and regulations. The College may suspend research and/or impose remedial measures on Investigators who fail to disclose interests where required, or who fail to comply with their approved management plan. The Conflict of Interest Review Committee is responsible for Investigations into alleged noncompliance, and for findings of noncompliance, and is supported by the Dean.