

UNIVERSITY OF SOUTH ALABAMA

CONFLICT OF COMMITMENT FINANCIAL CONFLICT OF INTEREST POLICY

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UNIVERSITY OF SOUTH ALABAMA
CONFLICT OF COMMITMENT
FINANCIAL CONFLICT OF INTEREST
POLICY

1. PREFACE

In today's active world of experimentation and exploration, there are many avenues for Employees of the University of South Alabama, as well as for the University of South Alabama itself, to participate with external entities in collaborative research, professional activities, and the development of innovation. Interactions with federal sponsors, state sponsors, industry sponsors, foundations, and professional associations serve the academic, research and public service missions of the University. The experience and enhanced national status that accompany such interactions are shared both directly and indirectly by the University. These outside activities contribute to the richness and diversity of the University academic enterprise.

In this environment, there are expanded opportunities for Employees of the University to engage in financially rewarding external professional and entrepreneurial activities. At the same time, there is a heightened sensitivity to questions of professional ethics and objectivity in research. Situations arise where there may be a divergence, real or perceived, between the private interests of the Employee and those of the public and of the University. These situations may produce a potential Financial Conflict of Interest and have the potential to bias the conduct of the activity or research. Determination of whether a potential conflict or proscribed activity exists, and how to best manage that conflict to reduce any chance for bias, should be based on an assessment of each situation. This policy establishes University guidelines to aid in the identification and resolution of potential or real Financial Conflict of Interest and/or Conflict of Commitment. While not addressed by this policy, the Alabama State Ethics Law, as well as other laws, regulations or policies, may also specifically define and limit the ability of Employees of the University to participate in certain activities.

The existence of potential Financial Conflict of Interest and/or Conflict of Commitment in and of themselves is not automatically detrimental; in fact, their presence indicates a robust professional and research environment. But these potential conflicts must be actively identified, monitored, and managed to ensure that the University's endeavors remain, above all, objective and free from bias. The University is an institution of public trust and must maintain maximum levels of public support to carry out its mission. The University and its Employees are also subject to the provisions of the Code of Ethics for Public Officials, Employees, etc. as described in Chapter 25 of the Title 36, Code of Alabama, 1975 (the Alabama State Ethics Law). Therefore, it is the policy of the University that Employees of the University demonstrate, in all professional and research activities, that their primary obligation is to the University and that they adhere, in all instances, to the highest standards of ethical behavior.

2. SCOPE OF POLICY

The University policy on Financial Conflict of Interest and Conflict of Commitment applies to all Employees of the University of South Alabama as defined below in Section 3.

3. DEFINITION OF TERMS

3.1 Business Entity. A Business Entity is defined as any corporation, partnership, sole proprietorship, firm, franchise, holding company, joint-stock company, receivership, real estate trust, or other legal entity organized for profit and non-profit entities that may provide support to Employees as salary, consulting, or board compensation. The term does not include the University or any other entity

controlled by the University. For Employees, a Business Entity does not include a client to whom they provide professional services as an individual and outside of their University duties.

3.2 Clinical Research. Any study, regardless of funding source, involving the evaluation of a diagnostic or therapeutic drug, a vaccine, or a medical device in preparation for a regulatory evaluation or within a regulatory evaluation process, when the protocol requires approval by the Institutional Review Board of the University of South Alabama.

3.3 Conflict of Commitment. A Conflict of Commitment arises when professional activities apart from the University interfere with the Employee's paramount full-time obligations to students, colleagues, patients and the fundamental mission of the University. Conflict of Commitment only involves questions of obligation and time effort.

3.4 Financial Conflict of Interest. A Financial Conflict of Interest arises when an Employee is in a position to benefit personally from or to influence either directly or indirectly University business, research, or other decisions in ways that could lead to gain for the Employee, the Employee's family, or others. While financial interests should not and, in most cases, do not, compromise intellectual honesty or institutional integrity, under federal law and according to USA policy, they must not have the appearance of compromising the University's values and missions of teaching, research, and public service. Any financial conflict of interest (real or apparent) should be disclosed so it can be managed, reduced or eliminated in accordance with federal regulations and the terms of this policy.

3.5 Financial Interest. Compensation received from external sources to include the following examples:

- Anything of monetary value including, but not limited to, salary, royalties, or other payments for services, including payments for consulting services and services on advisory committees.
- Intellectual Property Rights.
- Equity interests; e.g., owning or having the right or obligation to acquire stocks or stock options or other securities in a business entity.
- Position in a non-USA entity giving rise to a fiduciary duty such as consultant, employee, director, or any position of management.
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- Investigators with funding from the Public Health Service, any sponsored or reimbursed travel (this excludes travel sponsored/reimbursed by government agencies, academic medical centers, public/non-profit institutions of higher education, or their affiliated research institutes).

Examples of "Financial Interest" do not include compensation received from the University:

- Salary, share in royalties in accordance with University policy, or other remuneration from University of South Alabama (USA).
- Intellectual property rights developed in the course of employment at USA and assigned to USA.

3.6 Consulting. Consulting, for purposes of this policy, includes but is not limited to the provision of information and expertise on professional matters and the holding of extramural management positions and/or board memberships.

3.7 Employees. Employees include any person employed by the University full-time or part-time in a faculty position or in an administrative position at or above a director level (Account Code 610100).

3.8 Family. Family is defined to include spouse, child, grandchild, parent, grandparent, sibling, niece, nephew, aunt, uncle, cousin, in-laws, and step relations in those capacities, as well as any person living in the household of the Employee.

3.9 Intellectual Property Rights. Intellectual Property Rights are defined as all products of the human intellect that receive legal protection through patent, copyright, trademark or trade secret law developed by Employees that are owned in whole or part by the University or its affiliated foundations according to the University Patent and Invention Policy.

3.10 Institutional Responsibilities. An Investigator's professional responsibilities on behalf of the Institution, which may include activities such as research, research consultancies, teaching, clinical practice, institutional committee memberships, and service on panels.

3.11 Investigator. The principal investigator, project director or any other person, regardless of position or title, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS), or for a proposal seeking such funding. Since title and position are not indications of who is an "Investigator" as defined by PHS, it is possible for students and postdocs to meet this definition. Senior or key personnel listed on a proposal/award may be considered an Investigator for purposes of submitting a conflict of interest disclosure form. Senior/key personnel are considered to be individuals who have the authority to make **independent** decisions about the direction of the research and the subsequent conclusions about the results. This does not include administrative personnel or individuals who perform routine, pre-defined, or incidental tasks related to the project.

3.12 Public Health Service (PHS). Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of Global Affairs (OGA), and Substance Abuse & Mental Health Services Administration (SAMHSA).

3.13 Sponsored Activity. A sponsored activity is any externally funded research, instruction, public service, or scholarly activity that has a defined scope of work and set of objectives which provide a basis for accountability and sponsor expectations.

3.14 University. University is defined to mean all units of the University of South Alabama, including schools, colleges, hospitals, clinics, and any other components not otherwise listed.

3.15 Gratuity. For purposes of this Conflict of Interest policy, gratuity is defined as favors or gifts, food, beverages, tickets to sporting or entertainment events, transportation, lodging, and similar items or events given by any individual or entity that does business with the University. This definition does not include, however, entities associated with the University of South Alabama (USA) including, but not limited to, the following: USA Health Services Foundation, South Alabama Medical Sciences Foundation, Mobile County Hospital Board, USA National Alumni Association, Jaguar Athletics Fund, the USA Foundation, USA HealthCare Management, LLC, the USA Research and Technology Corporation and subsidiaries, student organizations, and the USA Federal Credit Union.

4. GUIDELINES FOR IDENTIFYING AND MANAGING CONFLICTS

4.1 Conflict of Commitment. Activities outside the University promote professional development and enrich Employee contributions to the institution, to their profession, and to the community. Since an academic relationship can be of great value to a non-university organization, opportunities for outside professional activities may be offered to Employees in part because of their association with the University. Recognizing this name association, Employees are expected to be prudent in the selection of outside professional activities to prevent damage to the University's reputation. Employees should avoid commitments that might compromise the basic scholarly independence central to academic life.

It is incumbent upon the Employee to assure an appropriate balance in the distribution of effort and time between these secondary outside activities and their primary obligations to the University, and to thereby eliminate or minimize any Conflict of Commitment. To reduce the possibility or appearance of a Conflict of Commitment between an Employee's obligations to another organization and to the University, the Employee must file, in writing, his/her plans with the department supervisor before undertaking any activity with that organization (see *External Professional Activities for Pay* form).

4.2 Financial Conflict of Interest. For purpose of this policy, a Financial Conflict of Interest relates to situations in which financial interest or other personal considerations may compromise, have the potential of compromising, or have the appearance to compromise an Employee's objectivity in meeting his/her duties or responsibilities at the University of South Alabama, including research and public service activities. In a modern research institution, there are many opportunities for Employees to find themselves in situations in which a Financial Conflict of Interest could arise. It is appropriate for Employees to have research relationships with business entities, and to share in the academic, professional and financial benefits available to them through consulting and/or commercialization of Intellectual Property Rights. Such activities support the research, educational and economic development missions of the University. It is not appropriate, however, for an Employee's actions or decisions, made in the course of University activities, to be motivated principally by considerations of personal financial gain.

The mere existence of a Financial Conflict of Interest does not automatically imply any impropriety on the part of the Employee, the University, or the Business Entity. Assessing whether a Financial Conflict of Interest is inappropriate and may improperly affect any professional or research activity depends upon the facts of each situation.

It is the policy of the University and a condition of employment that all Financial Conflict of Interest be disclosed both annually as well as per any new activity in order to eliminate or minimize their impact on any professional or research activity. This policy requires disclosure of all interactions that involve any amount of Financial Interest on the part of each Employee or Employee's Family as well as of all interactions that could be reasonably perceived to bias institutional responsibilities.

4.3 Categories of Employee Activities with Potential Financial Conflict of Interest. Activities that may involve Financial Conflict of Interest can be categorized under three general headings listed below. The following examples are merely illustrative and do not purport to include all possible situations within the three categories.

A. Employee Activities Requiring No Reporting

These are activities that might appear to involve a Financial Conflict of Interest but in fact do not. Such activities do not require disclosure or administrative review:

- Employees receiving royalties from the publication of books or for the licensure of patented inventions subject to the Patent and Copyright Policies of the University.

- Employees owning or having equity interest in a company, the exclusive function of which is to accommodate the Employee's external research or consulting activities.
- Employees receiving nominal compensation, in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentations of scholarly work, and participation in accreditation reviews.

B. Employee Activities Requiring Disclosure

The activities listed under this heading suggest a possibility of conflicting loyalties that can impair objectivity, but disclosure and resulting analysis of relationships may render the activity permissible.

- A faculty member requiring students to purchase textbooks or related instructional materials prepared by him/her or members of his/her immediate family, which produces compensation for the faculty member or family member.
- An Employee receiving compensation in any amount or gratuities in excess of \$100 per incident, up to an annual maximum of \$300, from any individual or entity doing business with the institution. Notwithstanding the above, a reportable gratuity includes anything received that a reasonable person might perceive as a conflict of interest.
- An Employee or Family Member serving on the board of directors or scientific advisory board of a business that provides financial support to the University.
- An Employee serving in an executive position in a for-profit or not-for-profit business which conducts business or other activities in an area related to the university duties of the Employee.
- An Employee having equity in a for-profit business which conducts business or other activities related to the Employee's university duties.
- An Employee having a financial interest in a business that competes with services provided by the institution.

C. Employee Proscribed Activities

The activities cited below involve scenarios that are not generally permissible because they involve potential Financial Conflicts of Interest or they present obvious opportunities or inducements to favor personal interests over institutional interest. Before proceeding with such an endeavor, the Employee would have to demonstrate that his/her objectivity would not be affected and University interests otherwise would not be damaged. Thus, it shall be the policy of the University that:

- No Employee shall engage in university research involving a technology owned by or contractually obligated to (by license or exercise of an option to license or otherwise) a business in which the Employee or a Family Member has a consulting relationship, has an ownership interest, or holds an executive position.
- No faculty member shall assign students, post-doctoral fellows or other trainees to university projects or other activities sponsored by a business in which the Employee or a Family Member has an ownership interest.

- No Employee shall participate in university research, clinical trials, or service agreements which are funded by a grant or contract from a business in which the Employee or a Family Member has an ownership interest.
- No Employee shall accept support for university research under conditions that require research results to be held confidential, unpublished or inordinately delayed in publication without prior written approval from the Office of Technology Transfer.
- No Employee shall make referrals of university business to an external business in which the Employee or a Family Member has a financial interest.
- No Employee shall associate his/her own name with the University of South Alabama in such a way as to profit financially by trading on the reputation or goodwill of the institution or gain by reason of his/her official position for his/her personal gain or benefit of any other person or business entity.

4.4 Faculty External Professional Activities for Pay (Consulting). Consulting relationships between University faculty and outside entities can make a positive contribution to the University environment by providing avenues to test and exchange information and ideas. In any outside consulting arrangement, faculty should ensure that there is no conflict with University obligations by disclosing each activity prior to engagement (section 6.1).

A faculty member will be permitted to serve as a consultant, with or without pay, the equivalent of one day per week during the academic year, or 36 days per year. If the faculty member chooses to spread the 36 days per year over the calendar year, then consulting activity will be allowable three days per month, with a maximum of 36 days during the calendar year.

If a faculty member chooses full-time employment at the University for the summer semester, the total 36 days for consulting services applies to the calendar year. For additional information refer to section 4 in the Faculty Handbook.

Clauses in all consulting agreements (including but not limited to clauses on intellectual property, publication, and confidentiality) must be consistent with the policies of the University. The consulting agreement should acknowledge the faculty member's primary obligation to and employment at the University. Any consulting work done is personal to the faculty member and not related to the University. Neither the faculty member nor the company retaining the faculty member as a consultant may use the name of the University in connection with services rendered or results obtained in the course of the consulting relationship.

4.5 Student Involvement in Sponsored Activity. One of the most fundamental purposes of the University is the education and training of students. The University is obliged to ensure that students are able to learn in a free and open environment without fear of recrimination from teachers, advisors or mentors.

It is the policy of the University that students, undergraduate or graduate, involved in research sponsored by a Business Entity or a consulting activity in which an Employee has a Financial Interest are protected from any potential adverse action by the Employee. Appropriate action is required by the Employee and department chair or supervisor to assure the student is provided fair and impartial treatment.

4.6 Clinical Research. Special circumstances apply to the conduct of clinical research. The University and its researchers have ethical obligations to honor the rights and protect the safety of persons

who participate in research conducted at the University. Human subjects must be accorded the highest levels of respect and objectivity, and their informed consent must be truly informed as to all the implications of their participation in the study. The assessment of Financial Conflict of Interest and Conflict of Commitment in clinical studies takes on a heightened and more immediate importance, since even the perception of impropriety can irreparably damage the reputation of both the Employee and the University.

The Institutional Review Board (IRB) requires a protocol-specific disclosure of any relationships or financial holdings, which could give the appearance of a Financial Conflict of Interest as stated in the IRB application. The disclosure is required of the Principal Investigator, each co-investigator and any other person responsible for designing research, directing research, enrolling research subjects, obtaining subjects' informed consent, making decisions related to eligibility to participate in research or analyzing or reporting research data. Information regarding possible Financial Conflicts of Interest of Investigators might influence some potential research subjects as to whether to participate in the research and such information should therefore be provided to potential research subjects in order that they can give appropriately informed consent. The IRB has provided recommended language for conflicts disclosure in informed consent available on the Human Subjects website. The Investigator, each co-investigator and other persons involved in the design, conduct or report of the research must file a disclosure form to the University's IRB, along with the submission of the proposed clinical study protocol, the existence of any of the following examples noted below:

- *Recruitment bonuses* paid per participant, or for reaching an accrual goal within a specific time-frame.
- *Finder's fees* for referral of potential participants.
- Receiving financial support or incentives unrelated to the study in question.
- Serving as a paid consultant or speaker on behalf of a commercial sponsor.
- The study involves Intellectual Property Rights invented by the Employee or any member of their clinical study team.
- Any other financial compensation related to the study.

These disclosures are intended to supplement, not replace, the annual disclosure described below in Section 6.2.

The IRB will take these circumstances into consideration when evaluating the protocol, and will refer any concerns about potential Financial Conflict of Interest or Conflict of Commitment to the Office of Research Compliance and Assurance (ORCA). In collaboration with the designated departmental chair/supervisor, the ORCA will inform the Investigator, in writing, of its evaluation. The following determination(s) may be recommended in such cases:

- No conflict exists that requires management.
- Because of a conflict, the proposed research project should not be conducted.
- A conflict exists, but the proposed research project may proceed provided certain conditions or restrictions are imposed so that the conflict is managed, reduced, or eliminated.

These matters may be referred to the University Conflict of Interest (COC/FCOI) Committee, and the reporting Employee shall be notified of the referral.

4.7 Intellectual Property Rights and Technology Transfer Activities. Today there are enhanced opportunities to share in the commercialization of technology through partnerships with corporate entities. The University and its Employees each has the opportunity to benefit financially from the transfer of technology to the commercial marketplace. Both the University and its Employees should conduct research activities related to Intellectual Property Rights responsibly, act with the utmost

objectivity and freedom from bias, and recognize that their primary obligation is the return of the technologies to the public for its use and benefit.

Any situation in which the research activity could have an impact on the future financial return of Intellectual Property Rights to the Employee should be disclosed as a potential Financial Conflict of Interest both annually and at the time of submission of the research proposal. Disclosures should be made to the Employees department chair or supervisor. Representative examples of such situations include, but are not limited to, the following:

- Proposals for external research support when that research will be performed by an Employee who now receives or may receive in the future, under the University Intellectual Property Policy, revenues from the commercialization of Intellectual Property Rights which arise from the research.
- Proposals for external research support where the research will be sponsored by a company in which the Employee has a financial interest.
- Research grants or clinical studies from a Business Enterprise or Entity with which the University has a financial relationship.

4.8 Publication and Dissemination of Information. The University mission obligates it to disseminate information generated in the course of research performed at the University, thereby fostering an environment of academic freedom. All Employees should adhere to the principles of academic freedom by not unduly restricting or delaying public access to information developed in the course of research at the University.

It is the policy of the University that dissemination of information generated in the course of research performed at the University, through publication, presentation or otherwise, shall not be unreasonably delayed by any research sponsor or contract. Typically, this delay should not exceed the time period necessary for the sponsor to review the contents of the proposed publication/presentation and/or to obtain any necessary intellectual property protection for the information contained therein. In general, the University will not accept sponsored research agreements that prohibit publication or require explicit permission of the sponsor prior to publication. These restrictions contradict the academic mission of the University and present a conflict between the University's obligations to the sponsor and to the public. There may be exceptions in the case where the University accepts restrictions on the publication of the information resulting from the research, other than limited prepublication reviews by research sponsors, to prevent inadvertent divulging of proprietary information provided to the researcher by the sponsor or to ensure that publication will not compromise patent rights of the sponsor.

No Employee shall accept support for university research under conditions that require research results to be held confidential, unpublished or inordinately delayed in publication without prior written approval from the Office of Technology Transfer.

4.9 Faculty Authored Textbooks. Amendments to the Alabama Ethics law passed by the 1986 Legislature place faculty of state-supported institutions of higher education within the purview of the conflict of interest standards set forth in the law. Advisory Opinion No. 1130 issued by the Alabama Ethics Commission on August 21, 1987 concluded that a faculty member "...who is also author is not permitted to make the decision as to whether his or her publication will be used." The opinion approved a process where "...the decision is made by either administrative officials of the institution or a textbook committee composed of other faculty members and administrative officials within the institution."

The purpose of reviewing faculty authored textbooks is the inherent potential conflict which may arise by requiring students to purchase course materials for which the faculty authored and may stand to gain financially. Therefore, faculty must submit self-authored course materials that will be required for student purchase for peer review prior to textbook assignments to such faculty members' students. By

appointment of the dean, each academic department or college/school is required to have a textbook selection committee composed of faculty and administrator(s). The textbook selection committee is responsible for reviewing the materials for the course, considering alternative textbooks or materials, and informing the faculty member and department head and dean of their decision. Considerations may include 1) appropriateness of the text for the course, 2) extent to which text is used outside the University, and cost effectiveness to the students. At minimum, requirements for use of self or co-authored textbooks include:

- Management plan, to include annual monitoring by departmental textbook committee.
- Three textbooks to be placed on reserve in the University Library for student access/use.
- Course syllabus to include a declaration to students disclosing that the textbook is authored by the instructor and copies are held on reserve in the University Library.

5. PUBLIC HEALTH SERVICE (PHS) FEDERAL REGULATIONS, DISCLOSURE AND REPORTING REQUIREMENTS

Federal law requires that institutions have in place a mechanism to identify and manage Financial Conflict of Interest that may exist in relation to federally funded instruction, research, and service activities. The primary purpose of the Public Health Service (PHS) federal regulation is to prevent bias in the design, conduct or reporting of research projects. These conflicts typically occur when an individual has financial interests or business relationships with entities that sponsor their research, license intellectual property or may otherwise benefit financially from the results of the research. An individual may also have financial or business interests with an entity that is not sponsoring the study, but might have a competing product.

Disclosure Requirements. Investigators (as defined above in Section 3.11) are required to disclose financial conflicts of interest related to their institutional responsibilities. In accordance with federal regulations the term “investigator” also includes the spouse and dependent children of the individuals listed. The *Annual Financial Conflict of Interest Disclosure* form on file satisfies the requirement for disclosing financial interests at the time of grant application. Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of financial interests within 30 days of discovering or acquiring a new financial interest. Changes include, but are not limited to:

- Creation of new startup company.
- Changes in personal financial remuneration received from outside entities (e.g., additional consulting).
- Engagement in or changes in a service role or position.
- Submission of an SBIR or STTR application.
- Sponsorship of a research project by a new outside entity.

Investigators must certify that appropriate disclosures have been made at the time of grant application. For all PHS proposals, the *Financial Conflicts of Interest Certification* form is completed by the Principal Investigator submitting the University Transmittal Form. The Certification form shall be updated by the Principal Investigator any time there is a change in the facts reported during the period of award within 30 days of discovering or acquiring a new financial interest.

Each year of a grant or contract, Investigators must complete an *Annual Financial Conflict of Interest Disclosure* form. The annual reporting period to disclose by September 30th each year shall serve as the annual certification.

Disclosure of Sponsored Travel. PHS rules require increased transparency for reimbursement of travel expenses. Investigators must disclose reimbursed or sponsored travel related to the investigator's institutional responsibilities. Travel that is reimbursed or sponsored by federal, state, or local governmental agencies, institutions or higher education, academic teaching hospitals, medical centers, or research institutes affiliated with Institution of higher education does not have to be disclosed. This information specified by PHS with respect to travel includes the purpose of the trip, the identity of sponsor/organization, destination and duration. Reimbursed or sponsored travel is disclosed on a transactional basis via the University or College of Medicine Travel Authorization form. The Designated Institutional Official (department chair or supervisor) will determine if the travel is related to PHS funded research, and if so, whether or not it rises to the level of a financial conflict of interest. Identified financial conflicts of interest are elevated to the Vice President for Research for review.

Review Process. A Financial Conflict of Interest exists when the reviewer(s) reasonably determines that a financial interest could directly and significantly affect the design, conduct or reporting of PHS funded research or educational activities. Investigators cannot make the decision about whether a financial interest must be managed or whether a financial conflict of interest is related to the research. The department chair (or delegated authority) conducts the initial review. If the initial review indicates a potential for Financial Conflict of Interest, then the department chair notifies the applicant and the applicant's college dean. The department chair composes a management plan and forwards the applicant's confidential packet to the Office of Research Compliance and Assurance. At minimum, key elements of a management plan must include:

- Role and principal duties of the conflicted Investigator in the research project.
- Conditions of the management plan.
- How the management plan is designed to safeguard objectivity in the research project.
- Confirmation of the Investigator's agreement to the management plan.
- How the management plan will be monitored to ensure Investigator compliance.
- Other information as needed.

If necessary, a meeting of the University Conflict of Interest Committee will be held for resolution of the conflict.

Violations of federal policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating individual. The University COC/FCOI Committee will review allegations of violations. The decisions of the University COC/FCOI Committee with regard to imposition of sanctions shall be final. If the violation results in a collateral proceeding under College policies regarding misconduct in science, then the University COC/FCOI Committee shall defer decision on sanctions until the misconduct in science process is completed.

Assessing Relatedness of Financial Conflict of Interests to PHS Research. The Designated Institutional Official (department chair or supervisor) makes the determination whether an Investigator's financial conflict of interest is related to the PHS project and could directly and significantly affect the design, conduct, or reporting of the PHS award. The department chair/supervisor may involve the Investigator in making the determination of whether the financial conflict of interest is related to the research. If it is determined that the conflict is related to the PHS-funded award then the department chair/supervisor notifies the applicant and the applicant's college dean. The department chair/supervisor composes a management plan and forwards the applicant's confidential packet to the Office of Research Compliance and Assurance.

Training. Prior to engaging in PHS funded research PHS rules require conflict of interest training prior to engaging in PHS funded research and every four years following the initial training. Additionally,

training maybe required when there is a change in institutional policy, an investigator joins the University, or there is a case of noncompliance.

5.1 Notifying PHS of Conflict of Interest Issues. Upon receipt of an award from PHS, the University is obligated to notify the sponsoring institute or agency, prior to the expenditure of any funds, if a potential conflict has been identified. In general, the regulations require a financial conflict of interest report regarding those interests that the University determines are financial conflict of interests, including financial conflict of interest of subrecipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict of interest and to assess the appropriateness of the Institution's management plan. The Office of Research Compliance and Assurance (ORCA) shall submit the report to the PHS awarding component within 60 days after the determination that a financial conflict of interest exist for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new significant conflict of interest to the Institution during the period of award. A copy of the report will be filed with the official project record.

For any financial conflict of interest previously reported by the Institution, the Institution shall provide an annual report to the awarding component that addresses the status of the financial interest and any changes to the management plan. Annual reports shall specify whether the financial conflict of interest is still being managed or explain why the conflict no longer exists. The Institution must report to the agency the annual financial conflict of interest report at the time of the progress report.

5.2 Subrecipient Compliance and Reporting. Subrecipients are required to comply with all federal policy and certify their compliance on the negotiated subcontract agreement prior to receipt of the award.

If the University carries out the PHS-funded research through a subrecipient, the University will incorporate as part of a written agreement with the subrecipient terms that establish whether the University's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators.

If the subrecipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS regulations. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the University to enable the University to provide timely reports to PHS.

Alternatively, if the University's policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of financial interests to the University. Such time periods shall be sufficient to enable the University to comply with timely review, management, and reporting obligations under the PHS regulations prior to expenditure of funds or within 60 days of any subsequently identified financial conflict of interests.

5.3 Public Accessibility. This policy and each update of this policy will be publicly accessible on the University of South Alabama's website. Additionally, the Institution will make available by written response to any requestor within five business days information regarding specified financial conflict of interest related to PHS funded research. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.

5.4 Retrospective Review and Reporting. If a significant financial interest is identified that was not disclosed by the investigator or reviewed in a timely manner by the institution, the institution has 60 days to determine if a conflict of interest exists and implement a management plan if needed. Additionally, if a conflict of interest is identified as it was not managed due to noncompliance by the Investigator, the Institution has 120 days from the date of noncompliance was identified to conduct a retrospective review of the Investigator's activities and the research project to assess if any bias in the

design, conduct, or reporting of the research as a result. The University Conflict of Interest Committee will conduct the retrospective review of PHS-funded research to determine if the research or any part of it was biased, to include a mitigation plan to address any issues. The Institution will notify the PHS Awarding Component only in cases where bias is found. The report will include information on the impact of the bias on the research and the actions the Institution will take to eliminate or mitigate the effects of the bias. Thereafter, the Institution will submit financial conflict of interest reports annually as prescribed by PHS regulation.

5.5 Procedures

Office of Sponsored Programs

- If applicable, ensure *PHS Financial Conflict of Interest Certification* form is complete in conjunction with submission of University Transmittal form.
- Provide *PHS Financial Conflict of Interest Certification* form to Office of Research Compliance and Assurance after the Authorized Organizational Representative has signed the University Transmittal Form.
- Office of Research Compliance and Assurance after the Authorized Organizational Representative has signed the University Transmittal Form.
- Provide pdf copies of the *Subrecipient Financial Conflict of Interest Commitment* form to Office of Research Compliance and Assurance and other applicable documentation after the Authorized Organizational Representative has signed the University Transmittal Form.
- Provide monthly reports of PHS pending and declined proposal activity to Office of Research Compliance and Assurance. The report will include designated non-PHS agencies compliance with PHS FCOI regulations.

Designated Institutional Official (Department Chair or Supervisor)

- Receive and review, with or without committee assistance, financial conflict of interest disclosure forms to determine whether the investigator has financial interests that could affect the design, conduct, or reporting of the research activities proposed for funding or funded by external agencies.
- Take appropriate action to manage, reduce, or eliminate actual and potential conflicts of interest.
- Notify grant applicant and college dean regarding all conflict of interests related to PHS research. The designated official composes a management plan and forwards the applicant's confidential packet to the Office of Research Compliance and Assurance.
- Maintain confidentially, to the extent permitted by law, all disclosures and records of actions taken to manage financial conflict of interests for at least three years beyond the termination or completion of the award or until resolution of any action by a federal agency involving the records, whichever is longer, and make these records available for audit by authorized agencies.

Although it is expected that the Vice President for Research will remain the Designated Official for purposes of this policy, the Vice President for Research may delegate another individual to carry out these responsibilities if circumstances dictate.

Office of Research Compliance and Assurance

- Institutional certification is based on information provided by the Investigator on the *PHS Financial Conflict of Interest Certification* form.

- For purposes of PHS FCOI compliance, remind the Principal Investigator of the requirement for other designated research personnel identified as “Investigators” such as senior/key research personnel to complete annual disclosure by September 30th each year.
- Ensure that any financial conflict of interest disclosures have been properly addressed prior to expenditure of any award funds.
- In collaboration with the Office of Grants Administration, ensure that subrecipient agreements comply with PHS regulations.
- Ensure conflict of interest training is provided to appropriate individuals as required by PHS regulations. Request to complete training is initiated at just-in-time or upon notice of award.
- Responsible for financial conflict of interest reporting to PHS awarding agencies (pre award and post award) and the plans of the institution for managing such interests.
- Notify Vice President for Research and Office of Grants Administration of any disclosures subsequent to award that require reporting to PHS awarding agency.
- In collaboration with the Institutional Designated Official and Vice President for Research, respond to written request regarding financial conflict of interest disclosures subject to this policy.
- Maintain conflict of interest disclosure form(s), management plans, and other applicable documentation.
- Ensure publication of policy on website.

Office of Grants Administration

- Incorporate as part of a written agreement with the subrecipient terms that establish whether the University’s policy or the subrecipient’s policy on conflict of interest in research will apply to the subrecipient Investigators. The agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the University to enable the University to provide timely reports to PHS.
- Maintain disclosure form(s) determined to be actual conflict of interests, management plans, and other applicable documentation within award files in compliance with PHS regulations and USA record retention standards.
- Provide PHS research activity reports for PHS and designated non-PHS awards that must comply with PHS FCOI regulations. Reports generated include (i) amendments for identifying no cost extensions or a change in Principal Investigator, and (ii) notice of awards.

Office of Health Systems Grants Administration

- Provide just-in-time notices for PHS and designated non-PHS awards that must comply with PHS FCOI regulations.

6. NATIONAL SCIENCE FOUNDATION (NSF) FEDERAL REGULATIONS, DISCLOSURE AND REPORTING REQUIREMENTS.

The Principal Investigator of the grant certifies via the University Transmittal Sheet that he/she has appropriately disclosed financial interests related to the research proposal. Investigators must disclose all financial conflict of interests that would reasonably appear to be affected by the research or in entities whose financial interests would reasonably appear to be affected by the research.

As required by Institutional policy, the NSF requires submission of annual conflict of interest disclosures, as well as updates of financial conflicts of interest on an *ad hoc* basis. In accordance with federal

regulations, the Office of Research Compliance will notify the NSF Office of General Counsel in writing if the University COC/FCOI Committee finds that it is unable to resolve a conflict of interest.

The institution maintains records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

7. REPORTING AND EXPENDITURE OF FUNDS

No expenditure of sponsor funding for research shall occur with respect to any research project for which a determination warrants a management plan unless all reporting requirements have been met. As required by the sponsor's regulation or policies, the Office of Research Compliance and Assurance will report to the funding agency any management plans or financial conflict of interest within 60 days of the interest's identification. The outcomes will be communicated with the University Financial Conflict of Interest committee.

If a PHS or NSF funded project involves evaluation of the safety or effectiveness of a drug, medical device, or treatment and the study has been designed, conducted or reported by an investigator with a conflicting interest that was not disclosed or managed under this policy, the investigator(s) involved must disclose the conflicting interest in each public presentation of the results of the research.

8. POLICY ADMINISTRATION AND IMPLEMENTATION

8.1 Consulting Responsibilities. Each and every time an Employee consults outside the University with a new entity, the Employee is required to complete and file an *External Professional Activities for Pay* form with his/her department chair or supervisor. Should an excess time commitment beyond the consulting time allowed by the University appear likely, the Employee is required to discuss the conflict of commitment with his/her department chair or supervisor and develop an acceptable plan of action. The forms will be kept in departmental personnel files.

8.2 Employee Annual Financial Disclosure Responsibilities. Each year, by September 30th all faculty members and Employees in an administrative position at or above a director level must disclose financial interest that relate to their institutional responsibilities by completing the *Annual Financial Conflict of Interest Disclosure* form and file with their respective department chair or supervisor. This process documents adherence to this Policy, and discloses activity anticipated to occur during the upcoming academic year.

In addition, all faculty members and Employees in an administrative position at or above a director level must disclose to their respective department chair or supervisor, on an ongoing *ad hoc* basis, any current or prospective situation that may raise questions of inappropriate financial conflict of interest.

Each department chair or supervisor is responsible for the timely collection and review of the *Annual Financial Conflict of Interest* form as well as of any *ad hoc* disclosure reports. The department chair or supervisor is responsible for maintaining the confidentiality of the disclosure reports and typically should file the disclosure reports in confidential personnel files. When a disclosure report appears to constitute an inappropriate Financial Conflict of Interest the department chair or supervisor is responsible for determining an appropriate action to address the conflict. If the department chair requires assistance in determining an action to take, the college dean should be consulted.

The school/college deans will file their *Annual Financial Conflict of Interest* form with their appropriate Vice President.

All members of the Institutional Review Board, including lay members, must complete an *Annual Financial Conflict of Interest*. The Chairman of the IRB is responsible for collection and review of these disclosures. Any Financial Interests that may constitute an inappropriate Financial Conflict of Interest or Conflict of Commitment will be referred by the chairman to the appropriate department chair.

8.3 USA Conflict of Commitment/Financial Conflict of Interest Committee. The University Conflict of Commitment/Financial Conflict of Interest Committee (COC/FCOI) is appointed by the President. The University COC/FCOI Committee serves as a University resource with respect to matters involving the general subject of Financial Conflict of Interest and Conflict of Commitment, and in the identification, management, reduction, or elimination of specific inappropriate Financial Conflicts of Interest or Conflict of Commitment. The University COC/FCOI Committee shall be chaired by the Vice President for Research or his/her designee, and shall include the Vice President for Academic Affairs, the Vice President for Health Sciences, the Vice President for Financial Affairs or his/her designee, the University Attorney, and the Director of Research Compliance. It shall also include no less than ten faculty members with broad representation across the University, with at least one representative from each of the Schools/Colleges of Engineering, Arts & Sciences, Nursing, Education, Computer & Information Sciences, Business and Allied Health Professions, and at least three from the College of Medicine. Appointed committee members shall serve three-year-staggered terms.

Upon referral from a Dean of a School or College, the University COC/FCOI Committee shall review all material related to a possible inappropriate Financial Conflict of Interest or Conflict of Commitment. If the University COC/FCOI Committee considers that a Financial Conflict of Interest or Conflict of Commitment could reasonably appear to damage the credibility or objectivity of the Employees work, it will attempt to resolve the matter by recommending steps to manage, reduce, or eliminate that inappropriate Financial Conflict of Interest or Conflict of Commitment.

Agreements between clinical investigators and a clinical study sponsor may be reviewed by the University COC/FCOI Committee, upon referral by the IRB. The University COC/FCOI Committee's determination of any action necessary to manage, reduce, or eliminate an inappropriate Financial Conflict of Interest or Conflict of Commitment in the proposed clinical study protocol will be returned to the IRB for consideration during its discussion of that protocol. The IRB shall take no action to approve or reject the aforementioned protocol until it receives the recommendation of action from the University COC/FCOI Committee.

Conditions or restrictions that may be imposed by the University COC/FCOI Committee to manage reduce or eliminate inappropriate Financial Conflicts of Interest or Commitment may include one or more of the following:

- Public disclosure of financial interests.
- Monitoring of instruction, research, or service by independent reviewers.
- Modification of the instruction, research, or service plan.
- Disqualification from participation in an activity that would be affected by a financial interest.
- Escrow or divestiture of financial interests.
- Severance of the relationship with the Business Enterprise or Entity.
- Other remedy as developed by the University COC/FCOI Committee.

If the University COC/FCOI Committee determines that imposing conditions or restrictions on the research of the Employee with the Financial Conflict of Interest or Conflict of Commitment would be either ineffective or inequitable, and that the potential negative impacts that may arise from a Financial Conflict of Interest or Conflict of Commitment are outweighed by interests of scientific progress,

technology transfer, or the public health and welfare, then the University COC/FCOI Committee may allow the research to go forward without imposing such conditions or restrictions.

The University COC/FCOI Committee review and action on a Financial Conflict of Interest or Conflict of Commitment referred to it by a School/College Dean or the Institutional Review Board must be accomplished within thirty (30) working days of such referral. A quorum of two thirds of the University COC/FCOI Committee must be present to constitute an official meeting to review a Financial Conflict of Interest or Conflict of Commitment appeal. A majority vote will be required to sustain the imposed condition or restriction or to authorize further conditions or restrictions. Any decision made by the University COC/FCOI Committee which concerns faculty tenure or promotion will be referred to the faculty member's respective Vice President.

8.4 Enforcement Mechanisms. The University will not allow Employees to expend instruction, research, or service award funds from any external sponsor, including federal agencies, non-profit or commercial entities, if the Employee has not submitted an *Annual Financial Conflict of Interest*, or if the Employee refuses to accept, document and abide by all conditions or restrictions recommended by his/her department chair, college dean, supervisor or the University COC/FCOI Committee to remedy any inappropriate Financial Conflict of Interest or Conflict of Commitment that has been identified.

8.5 Recordkeeping. All *Annual Financial Conflict of Interest* forms, and records of actions taken by the department chair, dean, Office of Research Compliance and Assurance, University COC/FCOI Committee, and/or University to resolve inappropriate Financial Conflicts of Interest or Commitment will be maintained for a period of at least three (3) years beyond the termination or completion of the activity to which they relate or until the resolution of any action involving those records, whichever is longer. The department chair and Office of Research Compliance and Assurance shall maintain records of all financial disclosures related to PHS or NSF funding for a minimum of six years after the termination or completion of the award to which they relate as required of the University's Records Retention Schedule. The forms will be considered confidential; and the information disclosed in the forms will be available only to individuals duly charged with the responsibility for review.

8.6 Audits. The University may conduct a review of financial conflict of interest disclosure forms to determine individual and institutional compliance with this policy.

9. ADMINISTRATIVE ACTIONS, PENALTIES, AND REPORTS OF VIOLATIONS

9.1 Reporting and Investigation of Violations. Reports of violations of this policy, including violations of a prescribed management plan, will be presented to the appropriate administrative office in which the nature of the conflict occurred. For fiscal and human resource matters, the investigation will be conducted by the Office of Internal Audit and findings provided to the Financial Audit Committee on the Board of Trustees. For activities involving research related violations, review of allegations will be conducted by the Vice President for Research. Following an investigation on financial conflict of interest or conflict of commitment issues, the University President and the University Conflict of Commitment/Financial Conflict of Interest Committee will be provided with a copy of the investigative report. During the investigation, the appropriate designated official will review the report of violation, any response, and any other relevant documentary material. This process may involve of the person submitting the report, the subject of the allegations, and any other persons believed to have factual knowledge of the allegations. All involved parties should be notified if an attorney is to be present. The attorney can act as an advisor only and may not participate in the process (this policy does not prohibit Employees from consulting with an attorney, including the University Attorney's Office).

9.2 Non-Retaliation. No individual will be subjected to retaliation by the College, or by individuals under its direction or control, for good faith reporting of any actual or perceived violation of the requirements in this policy.

9.3 Administrative Sanctions. Failure to disclose conflicts of interest in an appropriate and timely manner or failure to comply with procedures to resolve conflicts of interest as recommended by the Departmental Chair/Supervisor, Financial Audit Committee of the Board of Trustees, or the University Conflict of Interest Committee shall result in administrative sanctions. Breaches of this policy include, but are not limited to, intentionally filing an incomplete, erroneous, or misleading disclosure form, failing to provide additional information as required by the approving authority, or failing to follow an approved plan for managing, reducing or eliminating a potential conflict. Recommended sanctions and penalties for those who knowingly and willfully disregard this policy will be set forth by the appropriate designated official.

Recommended penalties of non-compliance with this policy may include, but are not restricted to:

- Letter of reprimand.
- Notification to professional and/or scientific societies, funding agencies, and/or professional journals.
- Reassignment of duties.
- Suspension or termination of participation in a sponsored research grant.
- Adjustment of research space allocation.
- Adjustment of salary.
- Suspension.
- Dismissal.

9.4 Procedures for Handling Conflicts of Interest. The Departmental Chair/Supervisor (Reviewer), and in consultation with the College Dean, determines the course of action that is in the best interest of the University. If the College Dean has a conflict, the Reviewer must consult with the University Conflict of Interest Committee. In making this determination, the Reviewer may take into account the following factors:

- Possible harm to the University or its employees, officers or others acting on its behalf if the conflict is allowed.
- Possible harm to the interests of students, clients of University services, or others served by the University, if the conflict is allowed.
- Whether reasonable alternative arrangements are possible which would not result in conflicts of interest.
- Consequences to the University, its reputation and future activities if the conflict of interest is not allowed.
- Consequences to the University and its reputation and future activities if the conflict of interest is permitted to continue.
- Educational, research, economic and other interests of the University.
- Rights and interests of the Employee.

The Reviewer may request from the Employee additional information that relates directly to and is necessary to assess and decide the real or potential conflict. Furthermore, the Reviewer may consult with others before making a decision relating to a real or potential conflict of interest.

The Reviewer will issue in writing a report to the Employee who has declared the real or potential conflict of interest, setting out the issues assessed during the review, the decision made and the reasons for the decision. Where the decision is to manage the conflict, a process for doing so will be implemented. If the

activity is related to PHS or NSF funding, for reporting purposes, a copy of the report will be forwarded by the Reviewer to the Director, Office of Research Compliance and Assurance.

A decision concerning an ongoing conflict of interest may be reviewed by the Reviewer at appropriate intervals. The original decision may be reversed or altered.

9.5 Management and Oversight. To assure the integrity of University academic, research and administrative endeavors, the Departmental Chair or Supervisor and if warranted, in conjunction with the University Conflict of Interest committee, will consider potential conflicts of interest and determine whether to Manage, Reduce or Eliminate the conflict. The Departmental Chair or Supervisor will determine whether a potential conflict of interest exists under the terms of this Policy. All identified potential conflicts of interest and/or commitment will be elevated to the next level of review by the college dean or head of the responsible unit. In making this determination, all relevant factors and information, including but not limited to the nature of the conflict, the magnitude of the financial interest and the degree to which it is related to the conflict and the extent to which the academic programs under the supervision of the investigator may be affected by the conflict.

The Department Chair or Supervisor, in consultation with the subject Employee will develop a Management, Monitoring and Implementation Plan (Plan). The Plan must be approved by the college dean or head of responsible unit, and/or the University Conflict of Interest Committee. Where there is no college dean for a specific unit, the Plan must be approved by the University Conflict of Interest Committee. The subject Employee and Departmental Chair/Supervisor must sign the plan, and a copy of the plan must be sent to the applicable dean or director. A comprehensive plan typically includes full description of the external relationship(s), identification of the area(s) of potential conflict of interest or commitment, and management strategies to guard against the escalation to a true conflict of interest or commitment. A *management plan template* is available and should be used as a starting point in plan development.

All identified Conflicts of Interest must be handled by one of the following three approaches:

1. A conflict can be **MANAGED** if the conflict does not seem to be of such a degree that the research or activity, as proposed, would be compromised in regards to academic freedom, integrity or objectivity.
2. The conflict must be **REDUCED** if there is a serious possibility that the research or other activity, as proposed, would be compromised or a serious concern that there could be a conflict with University policies.
3. The conflict must be **ELIMINATED** if the research or activity, as proposed, would be compromised by the conflict. If the conflict cannot be eliminated, the Employee shall eliminate the conflict by either divesting him/herself from all external financial interests or by not proceeding with the research or activity. The following cases are illustrative of unmanageable conflicts:
 - a. When the individual has a responsibility to another organization such that the individual is unable to fulfill his/her University duties.
 - b. When the individual has commitments that are counterproductive to or undermine each other.
 - c. When the individual seeks to provide to a third party Intellectual Property that is under review by the Office of Technology Transfer. This is viewed as unauthorized access to unpublished information resulting from University research or other confidential University sources.

- d. When the individual proposes to enter or enters a consulting agreement with obligations that conflict with University patent policy or with the University's obligations to research sponsors.
- e. When the individual circumvents the University policies and procedures and seeks to conduct or conducts research through a third party or outside the University to the disadvantage of the University and its legitimate interests.

If a disclosure and/or management plan is forwarded to the University Conflict of Interest Committee for resolution, the committee shall:

Review the disclosure(s) and make recommendations for resolution. If necessary, a member of the committee may be appointed to work with the individual having a conflict of interest to develop a plan, between the individual and the University. The University Conflict of Interest Committee will review and recommend approval, disapproval, or changes in the plan.

The University Conflict of Interest Committee may recommend incorporation of such measures in the plan such as:

- Modification of the research plan.
- Monitoring of the research by an independent reviewer.
- Disqualification of the investigator with the conflict of interest from participation in all or a portion of the research.
- Divestiture of significant financial interests.
- Severance of relationships with the business enterprise or entity that create actual or potential conflicts of interest.
- Disclosure of the conflict to the sponsor.
- Transfer of purchasing authority.

9.6 Appeal. If the investigator and supervisor/committee member cannot agree on a management plan, the subject Employee may appeal, in writing, to the entire University Conflict of Interest Committee within ten (10) days of such finding. The Committee, after considering the Departmental Chair/Supervisor's recommendations and the subject Employee's appeal, shall make the final appeal decision within ten (10) days of receipt of the written appeal. The committee's decision is final, and no further appeal is allowed.

9.7 Notification of Federal Agencies. After investigation, if the failure of the investigator to comply with this conflict of interest policy has been determined to bias the design, conduct, or reporting of federally funded research, USA shall promptly notify the awarding agency of the corrective action taken or to be taken.

In situations involving the health or safety of individuals or the potential loss of significant University resources, the Committee may recommend administrative actions necessary to protect these persons and resources pending the outcome of the foregoing procedures. Otherwise, no disciplinary or administrative action will occur until the conclusion of the violation evaluation process as set forth within this policy.

10. GHOSTWRITING

Individuals are prohibited from publishing articles or editorials under their own name that have been authored in whole by industry representatives. Payment from commercial entity representatives to serve as an author of work(s) to which the individual did not substantially contribute undermines the integrity

of the scientific process and is contrary to the values and principles of academia. Additionally, the International Committee of Medical Journal Editors has adopted a set of authorship principles that are viewed as the gold standard applicable for physicians and the scientific community.

Individuals listed as authors on a paper must have contributed significantly to the work. All co-authors should have been directly involved in one or more of the following activities:

1. Planning some component of the work which led to the paper,
2. Writing a draft of the article or revising it for intellectual content, and
3. Reviewing and approving the final manuscript version before it is submitted for publication.