



Financial Conflict of Interest Procedures

Document Name	Financial Conflict of Interest Procedures.
Overall Procedure Statement	The College of Medicine aspires to become an institution that has the highest financial integrity by ensuring disclosure, management and resolution of Financial Conflicts Of Interest (FCOI).
Guiding Principles	<ul style="list-style-type: none"> • Professionalism; • Honesty; • Objectivity; • Integrity; • Stewardship
Related Procedures / Policies	Intellectual Property; Quality Assurance; Research and Consultancy; Conditions of Service
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Procedure Review Period	Every five years
Responsible College Officer(s)	Principal
Responsible College Implementing Officer(s)	Dean of Postgraduate Studies and Research, Director Research Support Centre, Grants Compliance Officer, Risk Management Officer, Finance Officer

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Acknowledgements

Development of any Procedures Guidelines for an institution of higher learning is a demanding task which calls for a high level of analysis and scrutiny of current best practices from other centres as a reference benchmark.

These Procedures seek to develop Standard Operating Procedures relating to FCOI in COM. COM wishes to acknowledge the following for coming up with the initial draft: Prof Adamson Muula, Prof Nyengo Mkandawire, Prof Fanuel Lampiao, Mr Sam Kalulu, Mr Sunshine Kandiello, Mrs Sthemibiso Mshisha.

The COM Research and Publications Committee of COM scrutinised the initial draft, to come up with this final document which has been approved by the COM Academic Board.

List of Abbreviations and Acronyms

Acronym	Full Description
COM	College of Medicine
FCOI	Financial Conflict of Interest
IP	Intellectual Property
MEIRU	Malawi Epidemiology Research and Intervention Unit
MLW	Malawi Liverpool Wellcome Trust
PD	Project Director
PI	Principal Investigator
SFI	Significant Financial Interest
UNC	University of North Carolina
UNIMA	University of Malawi

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1. Introduction

1.1. Vision and Mission

The College of Medicine aspires to become an institution that has the highest financial integrity by ensuring disclosure, management and resolution of Financial Conflicts Of Interest (FCOI).

1.2. Procedures Statement

It is the intent of the College of Medicine to proactively manage FCOI of its employees to prevent and mitigate against outcomes that may be detrimental to grant management, teaching, research, consultancy, operation of regulatory compliance committees, technology transfer efforts, intellectual property rights or the University operations at large. Employees responsible for the design, conduct, or reporting of research; engaging in technology commercialization, and / or related activities; management of research and capacity building grants and / or related activities; engaging in consultancies, private outside work or related activities shall, therefore, report Significant Financial Interests (SFI) and shall work with the University to avoid and manage any FCOI as necessary.

1.3 Procedures Principles

The integrity and reputation of the College of Medicine as an institution of higher learning is dependent on an atmosphere devoid of financial conflict and undue influence that may adversely affect scholarly work, integrity, judgment, conduct of sponsored activities, stewardship of resources so as not to jeopardize the public trust and support that the college enjoys. This is of particular importance where the college and its staff interact with external parties.

While the College of Medicine recognizes the right of its staff and their immediate families to acquire personal financial assets and to establish financial relationships with outside entities, it is of paramount importance that the staff take full responsibility in managing their financial affairs and relationships in a manner that does not interfere with, or improperly influence, the performance of their professional duties and obligations. It is emphasized that the requirement to disclose potential conflicts of interest for external evaluation is not a reflection or assessment of the integrity of the individual nor does the fact that an individual may be determined to have an apparent conflict, imply that the conflict is unethical or impermissible. The overarching principle is that Significant Financial Interests shall be disclosed and, as much as possible, real and apparent financial conflicts of interest are avoided, reduced, eliminated or managed.

Financial Conflict of Interest

Employees of the COM must adhere to the highest ethical and professional standards in financial stewardship. Good judgment is essential as no set of rules can adequately address the myriad of potential conflicts. Employees must avoid situations which interfere with—or reasonably appear to interfere with—their professional obligations to the University. Such situations might create

an appearance of impropriety and, therefore, must be disclosed. When the College determines that a Conflict of Interest may exist with an Employee, the College may, in its sole discretion, prohibit the individual from engaging in the activity presenting a potential conflict; take actions to limit the individual's activity; or implement other measures the College deems reasonably necessary to eliminate the potential conflict. If Employees have questions concerning a potential financial conflict of interest, they must first discuss these concerns with their supervisor and college designated FCOI officers.

Intellectual Property

The College's mission includes fostering invention and the development of new patentable and non-patentable ideas, technologies, methodologies, copyrights and other creations of the human mind. The College attempts to license many of these innovations to commercial entities so the fruits of this innovation may reach the marketplace for the public good and provide resources for further innovation. The College, therefore, must be protected from both real and perceived disclosure of intellectual property with entities in which College inventors have personal or financial interests or are adverse to the College's interest. More information, including applicable definitions, on the College's ownership rights to inventions and works can be found in the University's Intellectual Property Procedures.

2. Situation Analysis

The College of Medicine has in place a number of individual policies that have a bearing on FCOI. These include, but not limited to, the Research and Consultancy Policy, Postgraduate Studies Policy, Intellectual Property Policy and Quality Assurance Policy. COM has a strong research profile and works closely with many local and international research partners (UNC) and research affiliates (MLW, Johns Hopkins, MEIRU, Blantyre Malaria Project). Over the last 5 years COM has managed research grants totalling about 50 million dollars. These funds come from both private and public entities. Handling such amounts of funds requires good financial stewardship and accountability to ensure that the funds are used for the intended purpose. It is critical that all handlers of such funds are of the highest integrity and financial probity. Prior to this, COM had no FCOI Procedure guidelines. Increasingly, research funders are requesting that COM has enforceable FCOI procedures for it to access research grants. It is therefore essential that COM develops enforceable procedures of FCOI in line with good corporate governance practice.

2.1 Noted Key Challenges

The Procedures will address the following key challenges:

- (i) Limited awareness of FCOI among members of staff
- (ii) Lack of training of staff in FCOI
- (iii) Lack of institutional mechanism of disclosing, recording, managing and resolving FCOI among staff members in a contemporaneous manner.

2.2 Intended Procedures Objectives

The procedures will ensure that COM

- (i) Creates awareness of FCOI among members of staff
- (ii) Trains staff in principles of FCOI;
- (iii) Develops procedures for comprehensive management of FCOI
- (v) Establishes mechanisms of disclosure, coordination, management and dispute resolution of FCOI
- (vii) Develops requisite human, financial and institutional capacity in FCOI management.
- (viii) Develop a monitoring and evaluation mechanism for FCOI

3. Applicability

These procedures shall apply to all COM Employees undertaking activities with a risk of FCOI. The procedures shall be read together with other relevant policies including, the Research and Consultancy Policy; Quality Assurance Policy; College of Medicine Research and Ethics Committee guidelines; Intellectual Property Policy; and Conditions of Service Policy of staff in the University.

Persons failing to comply with these Procedures shall be subject to sanctions as provided herein and in the University policies stated above.

4. Definitions

Conflict of Interest: occurs when a COM Employee's financial, professional, commercial or personal interests or activities outside of the University affects, or appears to affect, their professional judgement or obligations to the College.

Disclosure of Significant Financial Interests means an Investigator's disclosure of Significant Financial Interests to COM.

Employee: College Faculty or Staff as defined in the Conditions of Service for Staff.

Entity: any business, company, or other organization, whether public or private, including without limitation any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether for-profit or not-for-profit.

Faculty: all positions identified as Academic and Research Personnel in COM.

Financial Interest: Any monetary or equity interest held by an Employee or their Immediate Family Member which would create an actual or apparent Conflict of Interest.

Financial Conflict of Interest (FCOI): means a Significant Financial Interest that could directly and significantly affect the design, conduct, reporting of funded research or management of funded grants .

FCOI report: means an Institution's report of a financial conflict of interest to a funder and / or awarding body.

Immediate Family Member: an Employee's spouse and or partner, partner(s), child or step child(ren), parent, parent-in-law, sibling, and anyone sharing the employee's household (other than a tenant or employee).

Institutional Responsibilities: means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its procedures on Financial Conflicts of Interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Clinical Monitoring, Data and Safety Monitoring Boards.

Investigator: means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research and grants that is funded, or proposed for such funding. This includes collaborators or consultants.

Manage: means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research or management of a grant will be free from bias.

Management Plan: means a set of guidelines agreed between COM and the Investigator or PD / PI that define how the project or grant is executed, monitored, and controlled, in the context of a real or perceived FCOI

Outside Activity: any paid or unpaid activity undertaken by an Employee outside of the College which could create an actual or apparent Conflict of Interest. Outside Activities may include consulting, participating in civic or charitable organizations, working as a technical or professional advisor or practitioner, or holding a part-time job with another employer.

Project Director: means a Project Director of a research project or a grant.

Principal Investigator: means a Principal Investigator of a research project or a grant.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in these procedures, the term includes any such activity for which research funding is available through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Reportable Outside Activity: any Outside Activity that is required to be disclosed to the University.

Retrospective Review: means the review of possible FCOI conducted after activities of a research or grant are provided, to determine the necessity, appropriateness, quality and probity of the execution of the research or grant.

Senior/key personnel: means the PI / PD and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to a funder.

Significant Financial Interest: means a Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds MK1,000,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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.

(ii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term **Significant Financial Interest** does not include the following types of financial interests:

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 and agreements to share in royalties related to such rights.

(i) Any ownership interest in commercial or for profit entities within the Institution held by the Investigator.

(ii) 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.

(iii) Income from seminars, lectures, or teaching engagements or a research institute that is affiliated with COM; or income from service on advisory committees or review panels.

Staff: any regular, administrative, academic, research, clerical, technical and support positions as defined in University of Malawi Regulation.

Sub-Award: A subaward is when a portion of COM's sponsored project is passed through to another entity in order to complete a portion of the sponsored project's scope of work.

Sub-Awardee: means any organisation, or institution that receives a sub-award.

Subrecipient means a non-Federal entity that expends Federal funds received from a Recipient to carry out a Federal program, but does not include an individual that is a beneficiary of such a program.

University: which shall mean the University of Malawi. The College of Medicine being one of the four constituent Colleges of the University of Malawi.

5. Implementation of Procedures

5.1 COM Obligations

COM shall:

Prior to expenditure of any funds under an externally-funded research project, review all Investigator disclosures of Significant Financial Interests; determine whether any Significant Financial Interests relate to funded research; and determine whether a Financial Conflict of Interest exists.

- (a) Issue COM FCOI Clearance Certificate to PI / PD and all key investigators and stakeholders of a research or grant.
- (b) Maintain an up-to-date, written, enforced Procedures on Financial Conflicts of Interest and shall make such Procedures available via a publicly accessible Web site. The Institution shall make available these Procedures to any interested party within 7 working days of request.
- (c) Inform each Investigator of the Institution's Procedures on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any funded grant and at least every four years.
- (d) Maintain a written register of all the staff who have been informed about the Procedures.
- (e) Inform staff and train immediately when any of the following circumstances apply:
 - (i) The Institution revises its Financial Conflict of Interest Procedures in any manner that affects the requirements of Investigators;
 - (ii) An Investigator is new to an Institution; or
 - (iii) An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest Procedures or Management Plan.
- (f) Take reasonable steps to ensure that any Subrecipient Institutions comply with this sub-part by:
 - (i) Incorporating as part of a written agreement with the Subrecipient Institutions, terms that establish whether the FCOI Procedures of the COM or that of the Subrecipient Institutions will apply to the Subrecipient Institutions' Investigators.
 - (ii) Ensuring that if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest procedures, the subrecipient shall certify as part of the agreement referenced above that its procedures complies with this sub-part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI Procedures of the COM for disclosing significant financial interests that are directly related to the subrecipient's work for the COM.
 - (iii) Ensuring that if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest Procedures, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the COM. Such time period(s) shall be sufficient to enable the COM to provide timely FCOI reports.
 - (iv) Ensuring that if the subrecipient's Investigators must comply with FCOI Procedures of the COM, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator Disclosures of Significant Financial Interests

to the COM. Such time period(s) shall be sufficient to enable the COM to comply in a timely manner with its review, management, and reporting obligations under this subpart.

- (v) Providing FCOI reports to the COM: regarding all financial conflicts of interest of all subrecipient Investigators consistent with this sub-part, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- (g) Designate an institutional official(s) to solicit and review Disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, funded research or grant.
- (h) Require that each Investigator who is planning to participate in funded research disclose to the Institution's designated official(s), the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for funded research.
- (i) Require each Investigator who is participating in funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (h) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- (j) Require each Investigator who is participating in funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- (k) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to COM research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the funded research; or is in an entity whose financial interest could be affected by the research. COM may involve the Investigator, in the designated official(s)'s determination of whether a significant financial interest is related to the funded research. A financial conflict of interest exists when the COM, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the funded research.

- (l) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (f) of this section.
- (m) Manage identified financial conflict of interest by development and implementation of a Management Plan and, if necessary, a Retrospective Review and a mitigation report.
- (n) Provide initial and ongoing FCOI reports to the funder as required.
- (o) Maintain records relating to all Investigator Disclosures of Financial Interests and the Institution's review of, and response to, such Disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least 7 years from the date the final expenditures report is submitted to the funder.
- (p) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

5.2 PD / PI / Investigators Obligations

5.2.1 Disclosure Requirements

(a) When to Disclose

Regardless of whether an Outside Activity occurs during a University assignment or appointment, Employees engaged in research must disclose certain Outside Activities and Financial Interests which may lead to a Financial Conflict of Interest, through the designated official/s (and receive FCOI clearance through the designated College official/s) prior to commencing research. Disclosure is required under the following circumstances:

- (i) Upon research engagement in the College;
- (ii) Prior to acquiring a new Financial Interest;
- (iii) Prior to engaging in, or committing to engage in, an Outside Activity;
- (iv) Prior to accepting a position or role which could reasonably be perceived as creating a Conflict of Interest;
- (v) Prior to entering a relationship, including a familial relationship, which could reasonably be perceived as creating a Conflict of Interest; and
- (vi) At least annually, even if attesting to no change from previous disclosures.

Failure to obtain FCOI clearance prior to commencement of research, through the designated College official(s) as required herein may lead to administrative or disciplinary action. The absence of express FCOI disapproval does not constitute approval / clearance by the College.

Regarding the annual reporting obligation in section 5.2.1 (a)(vi) above, Employees must annually disclose their Financial Interests and Outside Activities existing at that time or which existed in

the previous calendar year. The College will make efforts to provide courtesy notice to Employees at least 30 days prior to their annual disclosure date. However, the failure to provide such notice or the failure of an Employee to receive such notice does not relieve an Employee of the obligation to make a timely annual disclosure.

(b) What to Disclose

The following potential Financial Conflicts of Interest and Outside Activities must be disclosed as provided below:

(i) *Management or Material Interest:* You, your spouse, children, or relatives have a management position (e.g., officer, director, partner, proprietor, Principal, Vice Principal, Dean, HOD, PI/PD), or a material (more than 5% ownership interest in the entity) financial interest in an entity that enters into any agreements or contracts with COM.

(ii) *Publicly-Traded Entity Payments/Ownership:* You, your spouse, or children receive payments or have an ownership interest of MK1,000,000 or more (including shares, partnership stake, or derivative interests such as stock options) in a publicly-traded entity where the ownership interest reasonably appears to be related to your institutional responsibilities. (Note: This does not include if the ownership interest is managed by a third party such as a mutual or retirement fund).

(iii) *Privately-Held Entity Ownership:* You, your spouse, or children have any ownership interest in a privately held entity where the ownership interest reasonably appears to be related to your institutional responsibilities.

(iv) *Public Office / Candidate:* You are a candidate for public office or you hold public office.

(v) *Outside Teaching Appointments:* You have or you are seeking approval to hold a teaching appointment with any entity other than COM.

(vi) *Outside Research:* You conduct or you are seeking approval to conduct any research at, or receive any research funding from or through, any entity other than COM.

(vii) *Classroom Works:* You require or you are seeking approval to require students to purchase works used in your classroom you or your spouse created, authored or co-authored (e.g., textbook(s), computer software, electronic or digital media) and for which you or your spouse

will receive, or anticipate receiving payment, loan, subscription, advance, deposit of money, service, or anything of value.

(viii) *Royalties / Licensing / Copyright Income*: You receive royalties, licensing fees and/or copyright income in excess of MK1,000,000 annually from an entity other than COM.

(ix) *Expert Witness/Legal Consulting*: You serve or you are seeking approval to serve as an expert witness and/or engage in consulting in a legal matter like a lawsuit or a potential lawsuit that impacts on COM.

(x) *Professional Services Related to COM Expertise*: You provide or you are seeking approval to provide paid or unpaid professional services to an outside entity and the professional services relate to your COM expertise.

(xi) *Leadership Roles*: You have a senior management, administrative, or leadership role, whether paid or unpaid, with an outside entity related to your COM expertise where you make executive business and/or financial decisions on behalf of the outside entity.

(c) How to Disclose

(i) Financial Conflict of Interest shall be reported by filling in the standard disclosure checklist and submitting to the College's FCOI reporting system within the stipulated time frame..

(d) Failure to Disclose

(i) Failure to disclose an FCOI by a respective deadline shall result in a written notification from the College, with copies to the Head of Department, Dean, Director or relevant line manager, directing the Employee to complete their disclosure within 10 business days.

(i) Failure to disclose more than 10 business days following the receipt of a written notification shall result in a written reprimand from the College, with copies to the Head of Department, Dean, Director or relevant line manager, as applicable, indicating the Employee must complete their disclosure within 10 business days.

(iii) If an Employee fails to disclose more than 10 business days following receipt of a written reprimand, the University may take administrative or disciplinary action against the Employee up to and including termination of employment.

(iv) Failure to make truthful and complete disclosure of all Reportable Outside Activities or Conflicts of Interest may subject the Employee to administrative or disciplinary action as set forth in section 7 below.

5.3 Sanctions and Management of FCOI

- (a) Where a Financial Conflict of Interest exists, COM shall, with the PI / PD / Investigator, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such conflict. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - (iv) Modification of the research plan;
 - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - (vii) Severance of relationships that create financial conflicts.

- (b) Whenever, in the course of an ongoing funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, COM shall:
 - (i) within sixty days: review the disclosure of the significant financial interest to determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.

(ii) Depending on the nature of the significant financial interest, make a determination on necessary interim measures with regard to the Investigator's participation in the funded activity between the date of disclosure and the completion of the review.

(c) Whenever a Significant Financial Interest that was not disclosed in a timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing funded research project (e.g., was not timely reviewed or reported by a subrecipient) is discovered, COM shall:

(i) within sixty days: review the significant financial interest to determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.

ii) Depending on the nature of the significant financial interest, make a determination on necessary interim measures with regard to the Investigator's participation in the funded activity between the date of disclosure and the completion of the review.

(d) Whenever a financial conflict of interest is not identified or managed in a timely manner including: failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, COM shall, within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the Investigator's activities and the funded research project to determine whether any externally-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. (See Appendix 1)

5.4 Coordination

(a) The Office of the Dean of Postgraduate Studies and Research shall be the FCOI policy holder, responsible for its implementation.

(b) The Research Support Centre, which will be the secretariat for FCOI activity and implementation. The RSC shall be responsible for:

- (i) Receiving FCOI disclosure forms
- (ii) Analysing FCOI disclosures
- (iii) Data and record management of all FCOI activities
- (iv) Coordination of FCOI awareness and training programmes
- (v) Communicating all FCOI reports
- (vi) Liaising with funding agencies

(c) The Dean of Postgraduate Studies and Research shall work closely with RSC

- (d) The Research and Publication Committee shall be responsible for:
 - (i) Issuing FCOI reports and Certificates
 - (ii) Recommending appropriate remedies where FCOI exists
 - (iii) Hearing appeals of FCOI decisions

5.5 Review and Adjudication

The Research and Publications Committee shall be responsible for receiving reports of FCOI reviews. For activities and interests disclosed through the designated College Official (s), the Research and Publications Committee will hear and determine appeals on whether a disclosed activity, interest or circumstance presents a Conflict of Interest.

5.6 Principles of Monitoring and Evaluation

- (a) As one of the key elements of the FCOI management plan, the college, through the Research and Publications Committee, shall monitor investigator compliance on an ongoing basis until completion of the investigator's funded research project. The Procedures will be periodically reviewed and evaluated as recommended by the UNIMA Council and Senate. The evaluation component will consist of:
 - (i) Outcome evaluation to determine effectiveness of the Procedures and to provide suggestions for enhancing their efficiency.
 - (ii) Process evaluation to monitor progress of the implementation, to show if revisions are necessary with the purpose of meeting the set objectives and to align the Procedures with relevant national and global developments.
- (b) The college shall, where necessary, appoint an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI. This shall however, not relieve the governing committee its responsibility of periodically reviewing the policy. The college shall also incorporate the Institutional Review Board and the Research Ethics Committee in ensuring that the ethics policy is communicated and implemented supplementary to the FCOI policy.
- (c) Staff training in FCOI
 - (i) The committee shall recommend staff training in FCOI periodically. This shall also be based on the funder's requirements on FCOI training. For NIH funded grants, an investigator and key researchers shall undergo FCOI training prior to submitting an application for funding; at least once every 4 years; whenever the Principal investigator is not in compliance with the policy and when a Principal investigator is new to the college. Investigators shall coordinate FCOI training for their project staff. At the most, staff shall be obliged to complete the NIH FCOI training tutorial on their website and submit a certificate of completion.

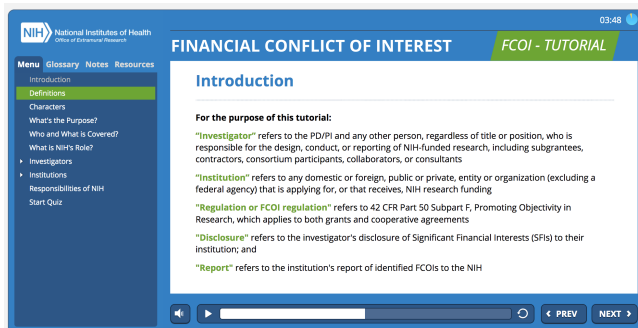
- (d) FCOI report / declaration on all grant applications
- (i) FCOI updates shall be reviewed and completed periodically and the designated institutional official shall submit a written summary of the report from the periodic review. The Research and Publications committee shall take reasonable actions to obtain regular reports from individuals and/or committees with research oversight responsibilities in line with the conflict management plans that have been set. The college shall work with its ICT department to develop an online reporting system.
- (e) Develop researcher FCOI disclosure checklist as submitted in appendix 3

5.7 Procedures Violations

The College may take administrative or disciplinary action concerning violations of these Procedures up to and including termination of employment.

6 Financial Implications

- (a) Training all Affected Faculty and investigators, both new and existing, in FCOI can have a significant cost implication. However, training in FCOI is available free of charge on the NIH website. Upon successful completion of the training, a certificate of completion is generated. This is mandatory for all investigators handling NIH funds. While an in-house FCOI tutorial may be developed to address local practice peculiarities, cost implications of doing so favour the use of the free NIH online tutorial. Developing a local training program may cost up \$100000. A screenshot and URL link for the NIH online tutorial are attached for reference.



https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

- (b) While a paper based reporting system will be utilised initially, it is envisaged that COM will develop an online FCOI reporting system. This is estimated to cost about USD 80,000 inclusive of training and rolling out.
- (c) Implementing a FCOI policy requires deliberate investment in training existing staff and engaging new staff to create a bespoke FCOI unit.. The estimated cost related to capacity building is

estimated at \$100000. In the initial stages, use of existing staff will be utilised, while capacity building efforts run concurrently.

APPENDIX 1: CONFLICT OF INTEREST GUIDELINES.

Purpose of the checklist: A conflict of interest checklist will be provided to and is to be used by all proposers to assist in screening for potential organizational or individual conflicts of interest. It will provide a checklist that one can methodically work through when faced with a situation in which one might have an actual, perceived or potential conflict.

Definition of “Proposers”: As used herein, the work “Proposer” includes both the prime contractor and all proposed subcontractors.

Conflict of Interest Checklist: The checklist is for the internal use of the Proposers. Please note that this checklist serves as a guide only, and that there may be additional potential conflict situations not covered by this checklist. If a Proposer determines a potential conflict of interest exists that is not covered by this checklist, that potential conflict must still be disclosed.

Use of the Disclosure Form: The Proposer must complete the Disclosure of Potential Financial Conflict of Interest and submit it along with the proposal. If the Proposer determines a potential conflict of interest exists, (s)he must disclose the potential conflict of interest

Material Representation: The Proposer is required to submit the attached disclosure form either declaring, to the best of its knowledge and belief, that no potential financial conflict exists, or identifying potential financial conflicts and proposing remedial measures to mitigate such conflicts. The Proposer is also responsible to update conflict information if such information changes after the submission of the proposal. Information provided on this form will constitute a material representation as to the award of this contract.

Does any member of the project team (defined as COM or non-COM personnel working under the grant) with substantive responsibility for the design, conduct, or reporting of activities under the grant, or any member of their immediate family (defined as spouse, dependent child, or registered domestic partner) have any of the following:

- Positions of management (e.g. board member, scientific advisor, director, officer, partner, trustee, employee, consultant) at a non-COM entity financing the research to be done under the grant.
- Equity interest (e.g. stock, stock options, investment, or other ownership) in a non-COM entity financing the research to be done under the grant

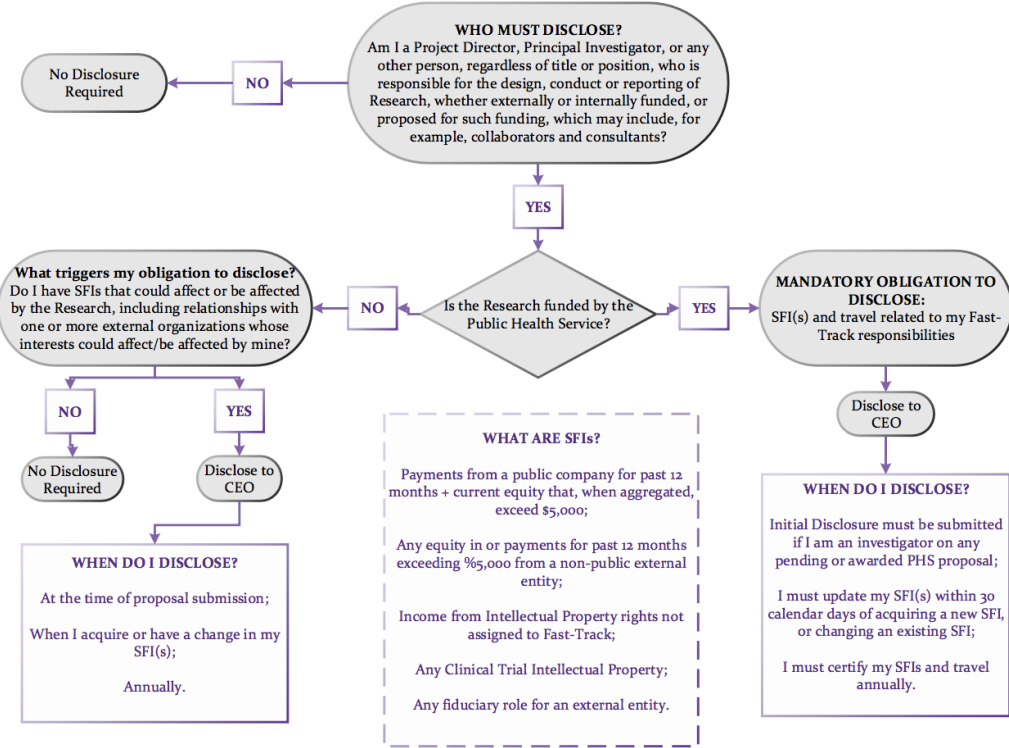
Conflict of interest may exist in any of the following cases:

- The Proposer, or its principals, own real property in a location where there may be a positive or adverse impact on the value of such property based on the recommendations, designs, or other deliverable required by the contract.
- The Proposer is providing services to another governmental or private entity and the Proposer knows or has reason to believe that the entity’s interests are, or may

be, adverse to NIH's interest with respect to the specific project covered by this contract.

- The Proposer is providing design services to a governmental or private entity, including but not limited to developers, whom the Proposer knows or has good reason to believe, have a property interest in land affected by the project covered by this contract, when the value or potential uses of such property may be affected by the Proposer's performance of work pursuant to this contract. Comment: this provision does not presume Proposers know nor have a duty to inquire as to all of the business objectives of their clients. Rather, it seeks the disclosure of information regarding cases where the Proposer has a reason to believe that its performance of work under this contract may materially affect the value or viability of a project it is performing for the other entity.
- The Proposer has a business arrangement with an NIH employee or immediate family member of such employee, including promised future employment of such person, or a subcontracting arrangement with such person, when such arrangement is contingent on the Proposer being awarded this contract. This item does not apply to pre-existing employment of current or former NIH employees, or their immediate family members. Comment: this provision is not intended to supersede any statutes or policies applicable to its own employees accepting outside employment. This provision is intended to focus on identifying situations where promises of employment have been made contingent on the outcome of this particular procurement. It is intended to avoid a situation where a Proposer may have unfair access to "inside" information.
- The Proposer has, in previous work, provided design services and such professional services that potentially provides the Proposer with an unfair advantage in preparing a proposal for this project. Comment: this provision will not, for example, necessarily disqualify a Proposer who provided other assistance for this project, however such work must be disclosed and all work products must be provided.
- The Proposer has, in previous work for NIH, performed such work as:
 - helping to create the ground rules for this solicitation, writing this solicitation, or preparing evaluation criteria or evaluation guides for this solicitation.
- The Proposer, or any of its principals, because of any current or planned business arrangement, investment interest, or ownership interest in any other business, may be unable to provide objective advice to NIH or our partners.

APPENDIX 2: GUIDANCE ON DISCLOSURE



APPENDIX 3: FINANCIAL CONFLICT OF INTEREST DISCLOSURE CHECKLIST

It is not possible to capture and document every possible situation of Financial Conflict of Interest, however the questions in this document give a guide to areas of possible conflict. It is possible that other financial interests or personal relationships have not been explicitly stated here, but you are obligated to disclose the same in order to fully and truthfully complete the questionnaire. Please read and be conversant with the College of Medicine Financial Conflict of Interest Procedures for Research, Grants and Related Activities when filling this checklist.

1. Personal or financial relationships

- Do you have a financial interest (salary, fees, dividends, stock options, royalties, compensation, sponsored travel, intellectual property, etc.) in a company or organization (foreign or domestic) that does business with (contracts, sponsors, funds, provides goods or services to) College of Medicine?
- Do you have a leadership role (CEO, owner, etc.) or serve as a board member (paid or unpaid) for an entity that does business with College of Medicine?
- Do you have a financial interest in a company or organization that is related to your professional expertise or institutional responsibilities?
- Do you have a leadership role or serve as a board member for an entity that is related to your professional expertise or institutional responsibilities?
- Do any of your immediate family members (to the fourth degree of consanguinity or affinity) have a financial interest in a company or organization that does business with College of Medicine?
- Do any of your immediate family members have a leadership role or serve as a board member for an entity that does business with College of Medicine?
- Do any of your immediate family members have a financial interest in a company or organization that is related to your professional expertise or institutional responsibilities?
- Do any of your immediate family members have a leadership role or serve as a board member for an entity that does business with College of Medicine?
- Do you engage in sponsored research, technology commercialization, or related activities on behalf of the College of Medicine?

- Do you, your spouse, or dependent children receive remuneration from and/or have equity interest in a publicly traded or privately held entity (foreign or domestic)?
- Do you, your spouse, or dependent children receive compensation for travel from a source other than College of Medicine?
- Do you, your spouse, or dependent children have intellectual property rights, income, or royalties?
- Do you, your spouse, or dependent children receive any interest from a foreign institution or government?

2. Outside employment/consulting activities

- Have you engaged in any work, paid or unpaid, other than for College of Medicine in the past 12 months or plan to in the next 12 months?
- Do you own a small business on the side or work part-time in the evenings or on weekends?
- Do you provide consulting services related to your area of expertise?
- Do you perform any other professional services for a company, organization, or government?

3. Foreign Affiliations

Do you have any of the following foreign affiliations?

- Agreements or contracts
- Research Collaborations
- Teaching or training engagements
- Consulting engagements
- Financial interests
- Intellectual property
- Visiting scholars
- Other professional affiliations

4. Immediate Family

- Does your spouse work at College of Medicine ?
- Do any of your children, stepchildren, or grandchildren (dependent or adult) work at College of Medicine?
- Do any of your siblings work at College of Medicine?
- Do any of your aunts/uncles, cousins, nieces/nephews work at College of Medicine?
- Do any of your parents or grandparents (including step) work at College of Medicine?

5. Relationships that could affect administrative decisions

- Are you on the hiring committee for a position for which your best friend is applying?
- Are you the Primary Investigator (PI) on a research grant where your relative is also on the project?
- Is your child a student in the same program or department in which you work?
- Are you close family friends with a company that does business with College of Medicine and you are involved in making purchasing or contract decisions for College of Medicine with this company?

6. Other potential conflicts or disclosures

- Do you have any former financial interests or relationships that might affect your decision making or performance of your institutional responsibilities?
- Do you serve on any other boards, commissions, or councils on a voluntary basis or that are related or unrelated to your institutional responsibilities?

7. Management Plans

- Do you have a FCOI Training Certificate?
- Do you have some other type of management plan, verbal or in writing, at the departmental level which needs to become a COM FCOI Management plan?
- Do you think you have a real or potential conflict and need an Official COM FCOI Management Plan in order to protect yourself and the university?

APPENDIX 4: EVALUATION AND MANAGEMENT

Evaluation & Management of Financial Conflict of Interest (FCOI)

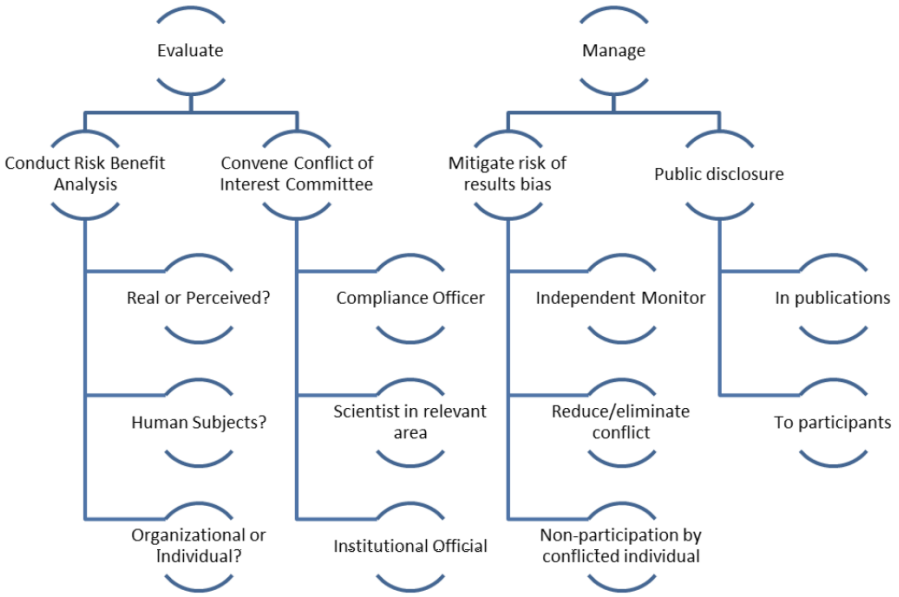


Figure 2. Components of Evaluation and Management of FCOI

APPENDIX 5: FINANCIAL CONFLICT OF INTEREST AGREEMENT FORM

Background

1. Employee's name,
2. Position,
3. Department / Faculty at College of Medicine
2. Detailed conflict description
 - a. Entity Name (with which outside interest/relationship is established)
 - b. Type of business, industry, or service
 - c. Employee's role/relationship with this entity
3. Any other relevant information on the situation as it exists and its history

Safeguards

Given the relationship between the Employee, the outside interest, and College of Medicine, there is a potential for conflict of interest/commitment. In order to assure compliance with COM policy, Employee agrees to abide by the following safeguards. Safeguards explain how the conflict will be managed and may cover such categories as:

1. Commitment
2. Transparency
3. Research Integrity
4. Use of University Resources (Including other employees or students)
5. Monitoring

Statement required on all FCOI Plans:

Iacknowledge that COM will monitor and evaluate this plan as well as policies related to it, and, at any time should COM determine, in its sole discretion, that the plan is not sufficient to guard actual or apparent conflicts of interest or is otherwise not in the interest of COM, may determine the conflicts as not capable of management and may recommend that I not to pursue the conflicting activities while an employee of COM. I further acknowledge my duty to ensure to comply with all other applicable national laws (as applicable) and that this plan is not a substitute for that responsibility.

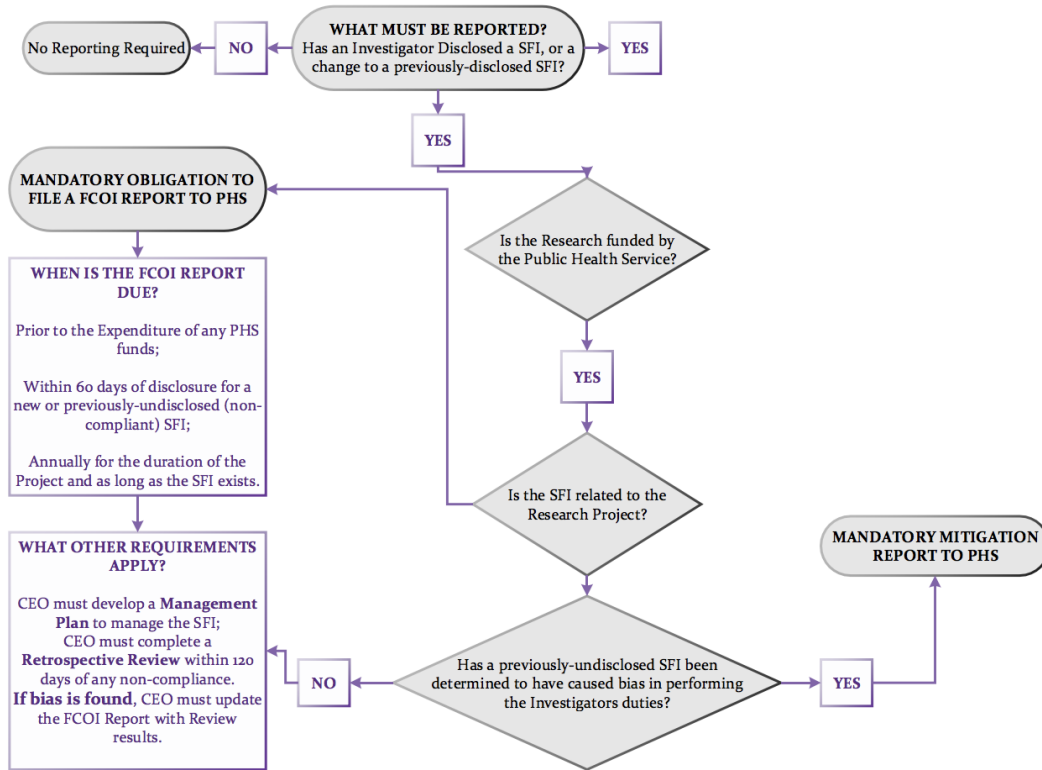
Acknowledgement and Agreement

By signing below, I,, acknowledge my agreement and intent to comply with the principles and safeguards of this Financial Conflict of Interest Management Plan.

Signature of Employee	Date
Signature of Department Head / Dean of Faculty	Date
Signature of Grants Compliance Officer	Date
Signature of Dean of Postgraduate Studies and Research	Date

APPENDIX 6: GUIDANCE ON FCOI REPORTING

B. FCOI Reporting



APPENDIX 7: RETROSPECTIVE REVIEW OF FCOI

In a Retrospective Review of FCOI, COM shall provide a comprehensive report whose documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project title;
- (2) Project number;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the Retrospective Review;
- (9) Conclusions of the Retrospective Review;
- (10) Proposed Remedies