

University of Colombo

Financial Conflict of Interest Policy

Preamble

The University of Colombo is a research-oriented State University in Sri Lanka which is governed by the Universities Act, No. 16 of 1978 and Establishment Code of the University Grants Commission and Higher Educational Institutions of 1984. One of the key strengths of the University of Colombo (UOC) is the dedicated, diverse and mature team of researchers who engage in cutting-edge research. The UOC endeavours in providing, promoting and developing higher education with a vision to become a center of global excellence in education, research and stakeholder engagement to enrich human potential for the betterment of society. Being a public funded pioneering university, the UOC has a strong commitment to research and international collaboration in line with the University Research Policy as well as Intellectual Property Policy.

Purpose

The Financial Conflict of Interest Policy (Hereinafter referred to as FCOI) of the National Institute of Health (NIH), USA establishes guidelines for disclosure of Significant Financial Interests and management of Financial Conflicts of Interests (FCOI) in research, sponsored programs, and technology transfer activities of the University¹ and to promote objectivity in research through the FCOI to ensure that the design, conduct and reporting of NIH funded research will be free from bias resulting from investigator financial conflicts of interest funded by an external sponsor.

The FCOI Policy is intended to ensure the integrity and credibility of the University, entrench academic freedom and also to cover the NIH Grants and all other Grants funded by international sources and funding agencies.² The NIH requires recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.” (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements. The FCOI requirements are aligned with 42 CFR Part 50 and the overarching goal for reporting is to promote and encourage transparency in order to avoid distorting NIH funding decisions.

The requirements laid down in this Policy are in addition to the University’s general requirements relating to conflicts of interest and as such must be addressed by investigators on any NIH proposal/project.

¹ This document was drafted by following the Financial Conflict of Interest Policy of the University of Washington, USA. Available at <https://www.washington.edu/research/compliance/financial-conflicts-of-interest-fcoi/> accessed on 28 June 2021

² The Financial Conflict of Interest Policy specifically addresses the NIH grants; however, the scope of its application is not limited to NIH grants. Thus, this policy is equally applicable to any other grants by international sources and funding agencies

Application

The requirements for Investigators/ innovators set out in this Policy apply to any person identified as senior or key personnel in a NIH grant application or progress reports who can directly or materially influence the research, or who is responsible for the design, conduct, and reporting of such research.

No research, sponsored program, or technology transfer activities occurring at the University of Colombo shall be adversely affected by the financial interests of University personnel carrying out those activities. Prior to participating in a research, sponsored program, or technology transfer activity, University personnel having a potential conflict of interest shall disclose the details to the University. An official designated by the University shall be responsible for reviewing disclosures and instituting an adequate plan for the management of any potential financial conflicts of interest. The ultimate goal of this Policy is to protect the integrity and credibility of activities related to research and technology transfer and to maintain public trust and confidence in the University and among its employees.

Persons failing to comply with this Policy shall be subject to sanctions as provided herein and by other applicable University Rules, Regulations, and Policies.

Definitions

For purposes of this Policy, the following definitions shall apply:

1. “**Compensation**”³ means any remuneration, including, without limitation, salary and payment for services not otherwise identified as salary such as consulting fees, payment of personal travel expenses, honoraria, and paid authorship. Compensation shall not include any of the following:
 - a. Salary, royalties, or other remuneration paid by the University to an Investigator or Innovator if the Investigator or Innovator is currently employed by or has an academic appointment at the University;
 - b. Payments or the entitlement to payments from the University derived from royalties and fees paid to the University by a third-party for Intellectual Property assigned by an Investigator or Innovator to the University;
 - c. Income from investment vehicles, such as mutual funds and retirement accounts, providing the Investigator or Innovator does not directly control the investment decisions made by such vehicles;

³ As per financial regulations in the State Universities in Sri Lanka, employees are only entitled to salaries and allowances.

- d. Income from seminars, lectures, or teaching engagements sponsored by the University, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of Higher Education; or
- e. Income from service on advisory committees or review panels for the University or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

2. “**Conflict Management Plan**” means a written plan instituted by the University for the management, reduction or elimination of a Financial Conflict of Interest.

3. “**Entity**” means any domestic or foreign, public or private, for profit or non-profit legal entity or organization other than the University, any agency of the Sri Lanka.

4. “**Equity**” means any interest in the profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.

5. “**Financial Conflict of Interest**” or “**FCOI**” means a Significant Financial Interest of an Investigator or Innovator that could directly and significantly affect the design, conduct, or reporting of Research or adversely affects a Technology Transfer Transaction.

6. “**Financial Interest**” means anything of monetary value, including but not limited to Compensation, Equity, Gifts, and Intellectual Property of an Investigator or Innovator or the Immediate Family Member of an Investigator or Innovator, whether or not the value is readily ascertainable.

7. “**Financial Interest Disclosure System**” means a University maintained and operated a manual system for reporting SFI Disclosures and Travel Disclosures.

8. “**Immediate Family Member**” means a person’s spouse, domestic partner, parent, grandparent, grandchild, sibling, child, or anyone who qualifies as the person’s dependent under the Sri Lankan Law.

9. “**Innovator**” means any University personnel regardless of title or position, including a University Research Employee, who has created in whole or in part any Intellectual Property in which the University has any right or interest.

10. “**Higher Educational Institutions**” means an educational institution in Sri Lanka that meets all of the following requirements:

- a. Admits as regular students only persons having qualified and registered for university education,
- b. Is legally authorized within such state to provide a program of education beyond secondary education;
- c. Provides an educational program for which the institution awards a bachelor’s degree.

d. Is a state funded public Institution; and

11. “**Institutional Official**”⁴ means one or more persons designated by the University as having responsibilities and authority under this Policy to review disclosures of significant financial interest from investigators and who oversees the process of managing and reporting on Financial Conflicts of Interest.

12. “**Institutional Responsibilities**” means any professional activity carried out by an Investigator or Innovator for which the Investigator or Innovator is compensated by the University, including: (i) sponsored activities (such as Research, training, and similar activities sponsored by external sources including central, and local governments and private businesses, corporations, foundations and organizations), (ii) non-sponsored activities (such as teaching, departmental or University supported Research, clinical work, and department and University administrative duties), and (iii) University-related public service.

13. “**Intellectual Property**” means the rights comprising a patent, industrial design, trademark, copyright, trade secret, know-how or other similar intangible property right, including but not limited to, inventor ship or authorship.

14. “**Investigator**” means any University personnel regardless of title or position, including a University Research Employee, responsible for the design, conduct, or reporting of University Research. Investigator includes, but is not limited to, the Principal Investigator, project director, co-principal investigator, and may also include other Senior/Key Personnel, a post-doctoral fellow, graduate student, trainee, staff member, collaborator, or consultant, depending on the person’s role in the Research. The primary factors to be used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to the design, conduct and reporting of the Research and the degree of independence that individual may have in performing such Research-related tasks.

15. “**Non-NIH-Funded Investigator**” means an Investigator who is neither applying for nor participating in any NIH-Funded Research.

16. “**NIH**” means the National Institute of Health U.S. Department of Health and Human Services. NIH is the steward of medical and behavioral research

17. “**NIH-Funded Investigator**” means an Investigator applying for or participating in any NIH-Funded Research. For the avoidance of doubt, NIH-Funded Investigator includes an Investigator applying for or participating in both NIH-Funded Research and non-NIH-Funded Research.

18. “**NIH-Funded Research**” means any Research or sponsored activity for which funding is available from a NIH awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

⁴Administrative and Financial officer/s assigned by the Vice Chancellor

19. “**Policy**” means this Financial Conflict of Interest Policy [FCOI].
20. “**Principal Investigator**” means any person designated by the University with the title of “Principal Investigator” of a Research or other sponsored project or otherwise having primary responsibility for the management and conduct of a Research or other sponsored project, including a project director.
21. “**Reimbursed Travel**” means travel activity for which the Travel Expenses are paid directly by the Investigator, who is then reimbursed by an Entity for such Travel Expenses. Notwithstanding the foregoing, Reimbursed Travel shall not include Travel Expenses that are reimbursed by the University, a central, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.
22. “**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) and also includes any activity for which research funding is available through a grant or cooperative agreement, research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
23. “**Senior/Key Personnel**” means the Principal Investigator and any other person identified as senior or key personnel by the University in a grant application, award, or contract or in any progress report, or any other report submitted to the NIH or other funding source.
24. “**SFI Disclosure**” means a disclosure of a Significant Financial Interest as provided in this Policy.
25. “**Significant Financial Interest**” or “**SFI**” means any of the following Financial Interests related to the Institutional Responsibilities of an Investigator or Innovator:
- a. With regard to any Entity whose Equity securities are publicly-traded, a Significant Financial Interest exists if the aggregate value of one or more of the following exceeds US\$5,000 (more than LKR 1,000,000): (i) any Compensation received during the twelve (12) months preceding the date of SFI Disclosure, (ii) any Compensation reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure, (iii) the value of any Equity interest in the Entity as of the date of SFI Disclosure;
 - b. With regard to any Entity whose Equity securities are not publicly-traded, a Significant Financial Interest exists if (i) the value of any Compensation received from the Entity in the twelve (12) months preceding the date of SFI Disclosure and/or reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure, when aggregated, exceeds US\$5,000 (more than LKR 1,000,000), or (ii) the Investigator or Innovator holds any Equity interest (e.g., stock, stock option, or other ownership interest);

c. With regard to any Entity, a Significant Financial Interest exists if the Investigator or Innovator has received income related to any Intellectual Property during the twelve (12) months preceding the date of SFI Disclosure and/or reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure which, when aggregated with other Financial Interests in the Entity, exceeds US\$5,000(more than LKR 1,000,000);or

d. With regard to any Entity, a Significant Financial Interest exists if during the twelve (12) months preceding or following the date of SFI Disclosure, the Investigator or Innovator receives or reasonably anticipates receiving one or more Gifts⁵ (including but not limited to Reimbursed Travel or Sponsored Travel meeting the definition of Gift) having an aggregate value of US\$50 (LKR 10,000.00) or more from the Entity.

26. “**Sponsored Travel**” means travel activity, the Travel Expenses for which are paid directly by an Entity on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available to the Investigator. Notwithstanding the foregoing, Sponsored Travel shall not include Travel Expenses that are paid by the University, a federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

27. “**Technology Transfer Transaction**” means a transaction through which the University conveys or transfers or negotiates to convey or transfer a University Intellectual Property right to a third-party.

28. “**Travel Disclosure**” means a disclosure of Sponsored Travel or Reimbursed Travel as provided in this Policy.

29. “**Travel Expenses**” means expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging, and related amenities.

30. “**University Research Employee**” has the same meaning as set forth in paragraph 22. For purpose of this Policy, University Research Employee shall include:

a. University faculty members and/or employees with appointments in the professorial ranks (Senior Professor, Professor, Adjunct / Visiting Professor, Vice Chancellor, Rectors, Deans, Directors in the respective Campuses, Faculties, Institutes) and, to the extent engaged in Research or Technology Transfer Transactions, other University faculty, librarians, and academic personnel;

b. University research scientists and other University employees, including professional and classified staff, who have been specifically assigned by the University to Research projects and

⁵Lack of Integrity; acceptance of gifts as per the sub section 2.2.4 of Chapter XXII of Establishment Code of the University Grants Commission and the Higher Educational Institutions

whose work contributes to the design or conduct of Research or to the analysis or reporting of Research results; and

c. Other University professional staff members who have been granted the right to apply for sponsored Research projects by the Provost or by their respective schools, Colleges or Campuses.

Procedures

A. Use of Financial Interest Disclosure System; Identification of Investigators

Investigators and Innovators shall be personally responsible for ensuring that their SFI Disclosures and Travel Disclosures required to be disclosed under this Policy are submitted in a complete and timely manner in accordance with procedures and guidelines established by the University. For all Research projects, the Principal Investigator shall be responsible for identifying all Senior / Key Personnel who are also Investigators as they become known and reporting their identity within ten (10) days thereafter.

B. Authority of Institutional Official

The Institutional Official (Administrative and Financial officer/s assigned by the Vice Chancellor) is authorized to administer and enforce this Policy. Such authorization includes the authority to (i) obtain and review SFI Disclosures and Travel Disclosures under this Policy, (ii) develop and implement Conflict Management Plans, (iii) conduct any required late or retrospective FCOI reviews, including issuance of reports of findings and conclusions and development and implementation of conflict mitigation plans, (iv) communicate with federal and other sponsors on matters pertaining to this Policy; (v) make recommendations to the University with respect to matters covered by this Policy; (vi) develop and implement reasonable and appropriate summary procedures for the disposition of matters involving compliance with this Policy; and (vii) suspend, for good cause, an ongoing Research project or pending Technology Transfer Transaction to prevent any probable or continued violations of this Policy.

C. SFI Disclosures by Investigators

All SFI Disclosures required to be disclosed by Investigators under this Policy shall be submitted in accordance with the following:

1. NIH Funded Investigators are required to disclose all SFI's within thirty (30) days of acquiring the SFI, but in no event later than submission of an application for NIH Funded Research.
2. Non-NIH-Funded Investigators are required to disclose only those SFIs that are related to their Research no later than submission of an application for the related Research.

3. Once a Research project has been funded, Investigators shall disclose, prior to participating in the project, all SFI's that have arisen since the time of application and all changes to SFI's previously disclosed.

4. With regard to ongoing Research projects –

a. all Investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI, and

b. when a new Investigator joins an ongoing Research project, the new Investigator shall submit SFI Disclosures within thirty (30) days of joining the project.

5. All Investigators shall submit an updated SFI Disclosure annually.

D. Travel Disclosures

All Travel Disclosures required by this Policy shall be submitted by Investigators in accordance with the following.

1. NIH-Funded Investigators are required to disclose all Sponsored Travel and Reimbursed Travel in accordance with the following:

a. The timing of Travel Disclosures shall be as follows:

i. At the time of application for NIH Funded Research, all Sponsored Travel and Reimbursed Travel occurring in the preceding twelve (12) months shall be disclosed,

ii. Prior to participating in the NIH Funded Research project, all Sponsored Travel and Reimbursed Travel that occurred since the time of application; and

iii. Thereafter, during the course of the Investigator's participation in NIH Funded Research –

(a) no more than thirty (30) days after the occurrence of any Sponsored Travel or Reimbursed Travel, and

(b) an updated disclosure of all Sponsored and Reimbursed Travel annually.

b. If a NIH Investigator is able to reasonably anticipate the occurrence of Sponsored Travel or Reimbursed Travel, the Investigator may elect to submit Travel Disclosures up to twelve (12) months in advance of the anticipated travel. Unless an advance Travel Disclosure becomes materially inaccurate, no further disclosure of such travel shall be required.

c. All Travel Disclosures by NIH-Funded Investigators shall include information regarding:

i. the purpose,

ii. the identity of the sponsor/organizer,

iii. the destination,

iv. the duration,

- v. the inclusion of any Immediate Family Member, and
- vi. an estimate of the approximate value of the travel.

2. Non-NIH-Funded Investigators shall submit Travel Disclosures in accordance with the following:

a. Non-NIH-Funded Investigators shall disclose Sponsored Travel and Reimbursed Travel from an Entity if –

- i. Either solely, or when aggregated, relative to the same Entity, with the value of Compensation, Equity or Intellectual Property, the total value⁶ constitutes an SFI, **and**
- ii. The SFI is related to their specific current or proposed Research project.

b. All Travel Disclosures required by this Policy for Non-NIH-Funded Investigators must include an estimate of the approximate value of the travel.

E. Disclosures by Innovators

When an Innovator has an SFI related to a Technology Transfer Transaction, the Innovator shall disclose the SFI prior to the conclusion of the Technology Transfer Transaction. All SFI Disclosures related to Technology Transfer Transactions shall be submitted by Innovators. The University Business Link (UBL), formerly Center for Commercialization, will be responsible for identifying Innovators and ensuring that Innovators who have an SFI related to the proposed Technology Transfer Transaction submit SFI Disclosures.

Disclosure of Significant Financial Interests:

All Investigators are required to disclose their outside financial interests to the NIH on an annual and ad hoc basis, as described below, using the Significant Financial Interest Disclosure Form (“Disclosure Form”), attached hereto as Attachment A and available from the Institutional Officer.

Review of Disclosure Forms:

The Institutional Official shall review all Disclosure Forms to determine (i) whether each Significant Financial Interest relates to NIH-funded research, and (ii) whether a Financial Conflict of Interest exists. This review will occur prior to the UOC’s expenditure of any funds under a NIH-funded research project, and in the course of a NIH-funded research project, within 60 days of an Investigator’s disclosure of a new Significant Financial Interest or discovery of a Significant Financial Interest that was not timely disclosed by an Investigator.

⁶ As per the Sri Lanka Treasury guidelines, Per diem will be paid for maximum of 30 days

A Significant Financial Interest is related to NIH-funded research when the Institutional Official reasonably determines that the Significant Financial Interest could be affected by the NIH-funded research or is in an entity whose financial interest could be affected by the research. A Financial Conflict of Interest exists when the Institutional Official reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project.

F. Review of Disclosures; Aggregation and Entity Rules

1. All SFI Disclosures and Travel Disclosures will be manually / digitally forwarded to the Institutional Official for review.
2. All Investigators and Innovators making SFI Disclosures or Travel Disclosures shall specify those Research projects and Technology Transfer Transactions that are related to the SFI Disclosures or Travel Disclosures. With respect to NIH-Funded Research, the Institutional Official will have the responsibility and authority to determine whether a SFI Disclosure or Travel Disclosure is related to the NIH-Funded Research and establishes an FCOI.
3. In general and except as otherwise provided in this Policy, the determination of the existence of an SFI and the requirement to disclose Financial Interests constituting an SFI will be based on the aggregation of all Financial Interests by Entity.
4. If an SFI Disclosure or Travel Disclosure is related to a Research or Technology Transfer Transaction, the Institutional Official shall review the SFI Disclosure or Travel Disclosure to determine whether the Financial Interest found an FCOI. Reviews will generally not be conducted until after a Research proposal has been funded or until after a Technology Transfer Transaction has been agreed upon in principle. Most reviews are completed within thirty (30) days following submission of all information required for the conduct of the review as determined by the Institutional Official.
5. No Investigator having an FCOI may participate in Research without prior written approval from the Institutional Official. All FCOI reviews, including any required Conflict Management Plan, must be completed before any Research activity begins or Research expenses are incurred under an award and before any Technology Transfer Transaction can be completed. In the event the Institutional Official concludes that a FCOI cannot be reduced, eliminated or managed, the Research project or Technology Transfer Transaction will not be allowed to proceed.

G. Management of Financial Conflict of Interests

1. In the event, the Institutional Official determines that an SFI Disclosure or Travel Disclosure constitutes an FCOI relating to either Research or a Technology Transfer Transaction, a Conflict Management Plan shall be developed and implemented by the Institutional Official. The FCOI review and Conflict Management Plan shall be completed prior to a conflicted Investigator

participating in the Research or prior to the completion of the Technology Transfer Transaction, as the case may be. As part of an FCOI review and development of a Conflict Management Plan, the Institutional Official shall confirm with the Investigator or Innovator that SFI Disclosures and Travel Disclosures in the Financial Interest Disclosure System are current as of the date of the review.

2. Conflict Management Plans shall consist of measures that in the reasonable judgment of the Institutional Official will reduce, eliminate, or manage the effects of the FCOI. In developing a Conflict Management Plan, the Institutional Official may conduct factual inquiries and consult with and receive recommendations from such persons as the Institutional Official deems necessary and appropriate. The terms of a Conflict Management Plan shall be consistent with all legal and regulatory requirements, the requirements of this Policy, and may include one or more of the following:

- a. Disclosure of FCOIs, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
- b. Monitoring or oversight of Research by independent co-researchers, reviewers, disinterested individuals, or committees;
- c. Maintaining copies of Research data with a neutral party;
- d. Restricting participation in activity affecting or affected by a Research project or Technology Transfer Transaction;
- e. Requiring that the SFI creating the FCOI be divested, restructured, or placed in a blind trust;
- f. Modification or severance of relationships that create or are likely to create FCOI's;
- g. Modifying the terms of written agreements relating to the Research or Technology Transfer Transaction;
- h. Reduction in University appointment;
- i. Requiring compliance with other relevant University policies, including those referenced in with Research Policy and Intellectual Policy.
- j. Requiring that participation in the recruitment or consent of subjects in human subjects Research by a conflicted Investigator be prohibited or restricted;
- k. Requiring additional disclosures or actions with respect to matters before an Ethics review committee; and
- l. Requiring that the Investigator or Innovator not participate in any business transactions between the University and parties to agreements involving sponsored Research or Technology Transfer Transactions.

3. Submission of an SFI Disclosure by an Investigator or Innovator shall not constitute approval for purposes of this policy nor be deemed to constitute compliance with any applicable provisions in Ethics Committee/Faculty of Medicine and the Research Policy of University of

Colombo. (a) the University has developed and issued a Conflict Management Plan in accordance with this policy, (b) the Conflict Management Plan covers the SFI that is the subject of the SFI Disclosure, and (c) the Investigator or Innovator has substantially complied with the terms of the Conflict Management Plan.

H. Access to SFI Disclosures and Travel Disclosures

1. The following University individuals and groups shall have access to all SFI Disclosures and Travel Disclosures submitted under this Policy:

- a. The Head of the Department or other head of the organizational unit of the Investigator or Innovator;
- b. The Dean's Office of the appropriate Faculty of the disclosing Investigator or Innovator;
- c. Office of Sponsored Program staff;
- d. Office of Research staff responsible for conflict of interest management;
- e. The Chairperson of the Faculty Research Committee and designee(s);
- f. For disclosures related to human subjects Research, the University's Faculty of Medicine Ethics Review Committee ("ERC") members; and
- g. The Institutional Official and designees.

2. Public Access for NIH Funded Research

a. If Senior/Key Personnel who are also Investigators are determined to have an FCOI related to NIH-Funded Research, the FCOI shall be posted on a publicly accessible University website and contain no less than the following information:

- i. The name of Senior/Key Personnel Investigator(s);
- ii. The title and role of the Senior/Key Personnel's Investigator(s) in the Research project;
- iii. The name of the Entity giving rise to the SFI and FCOI;
- iv. The nature of the FCOI; and
- v. The approximate dollar value⁷ of the FCOI set forth in range amounts (USD \$0-\$4,999, \$5,000-\$9,999, \$10,000 – \$19,999, amounts between \$20,000 – \$100,000 by increments of \$20,000, amounts above \$100,000 in increments of \$50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.

⁷ Conversion of USD\$ to Sri Lankan rupees should be guided by the selling rate established for similar transactions by the Central Bank of Sri Lanka on the respective date.

b. The publicly accessible website will be maintained under the direct supervision of the Research Committee, Faculty of Medicine and overseen by the Research and Development Committee (RDC) University of Colombo. The information on the website shall be updated at least annually, and in any event within sixty (60) days of the University's identification of a new FCOI of Senior/Key Personnel.

c. The FCOI information of each Senior/Key Personnel shall remain available on the University's publicly accessible website for at least three (3) years from the date the information was most recently updated.

I. Annual Update Reporting

All Investigators and Innovators who are subject to a "Conflict Management Plan" shall provide annual update reports in a form and in a manner specified by the University. In general, annual update reports shall require Investigators and Innovators to confirm there has been no material increase in the nature or amount of the Investigator's SFI and that the Investigator is complying with the terms of the Conflict Management Plan. Investigators will be restricted from submitting funding applications, expending funds, and conducting Research on projects whose annual update reports are not current.

J. Disclosure and Review of Increased SFI's and New Investigators

1. Any Investigator participating in an existing Research project who acquires a new or increased SFI that would otherwise be required to be disclosed under this Policy shall submit a new SFI Disclosure within thirty (30) days of the acquisition of the new or increased SFI. The University shall complete its review of the new or increased SFI within sixty (60) days of the submission of the SFI Disclosure.

2. Any University personnel joining an existing Research project who has an SFI that would otherwise be required to be disclosed under this Policy shall submit an SFI Disclosure prior to participating as an Investigator in the Research project and shall not participate as an Investigator in the Research project until an FCOI review has been completed.

Required Disclosures

Each Investigator is required to disclose the following Significant Financial Interests:

Any Significant Financial Interest of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirements, any University of Colombo staff, in his or her own best interest, may choose to disclose any other financial interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

The project director or principal investigator (“PD/PI”) on a proposed NIH application is responsible for obtaining a Disclosure Form from all participating Investigators. Each Investigator shall complete a Disclosure Form and attach all required supporting documentation. The completed Disclosure Form must be submitted to the Institutional Official’s office. Supporting documentation that identifies the affiliation or entity involved and the nature and amount of the interest and/or income should be submitted in a sealed envelope marked confidential and accompany the Disclosure Form.

Investigators must also disclose reimbursed or sponsored travel related to his or her institutional responsibilities, as defined above. Such disclosures must, at a minimum, include the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. Excluded from this requirement is reimbursed travel or sponsored travel by government, or local government agencies, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The Institution Official will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

K. Retrospective Reviews of NIH-Funded Research; Mitigation Plans

1. For NIH-Funded Research, if an FCOI is not identified or managed in a timely manner due to noncompliance by the Investigator or the University (including failure of an Investigator to submit SFI Disclosures or Travel Disclosures in a timely manner, a failure by the University to review an SFI or manage an FCOI in a timely manner, or a failure by an Investigator to materially comply with a Conflict Management Plan), the University shall, within one-hundred twenty (120) days from the date the non-compliance was identified, complete a retrospective review of the Investigator’s activities and the Research project and make a reasonable determination whether there was any bias in the design, conduct or reporting of the Research resulting from the FCOI.

2. The Institutional Official shall document all retrospective reviews, including NIH project number, project title, Principal Investigator, name of the Investigator with the FCOI, name of the Entity in which the Investigator has an FCOI, the reasons for the retrospective review, a detailed description of the methodology used for the retrospective review, and the findings and conclusions of the review.

3. If an FCOI is identified in the course of a retrospective review, the Institutional Official shall develop and submit a mitigation plan to the NIH funding agency. The mitigation plan shall include, at a minimum, the key elements documented in the retrospective review, a description of any impact of the bias on the Research, and the University's plan to mitigate the effect of the bias.

4. With respect to NIH-Funded Research in which a mitigation plan has been developed, the University shall submit annual FCOI reports addressing the status of the identified FCOI and any changes to the Conflict Management Plan for the duration of the NIH-Funded Research.

L. Training for Investigators Participating in NIH Funded Research

Prior to engaging in NIH-Funded Research, and no less often than every four (4) years, all NIH-Funded Investigators must complete training with respect to this Policy and the then-current NIH FCOI rules and regulations. Additionally, NIH Investigators shall complete such training whenever –

1. The University revises this Policy or related procedures in any manner that materially affects the obligations and responsibilities of NIH-Investigators;
2. A NIH-Investigator first becomes associated with the University; and
3. The University determines that a NIH-Investigator is not in compliance with this Policy or any applicable Conflict Management Plan.

M. Sanctions and Remedies for Violation of Policy

Whenever the Institutional Official determines that a person has violated this Policy, including any failure to make a required SFI Disclosure or Travel Disclosure or comply with a requirement of a Conflict Management Plan, the Institutional Official shall recommend appropriate sanctions consistent with University policies and procedures relating to faculty, employee, or other discipline. The Institutional Official is authorized to suspend, for good cause, an ongoing Research project or pending Technology Transfer Transaction to prevent any probable or continued violations of this Policy.

Violations of FCOI Policy

Whenever an Investigator has violated this policy or the terms of any resolution plan (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms) the Institutional Official shall notify the Senior Assistant Registrar (Legal and Documentation) who will impose sanctions or institute disciplinary proceedings against the violating individual, including suspension of all relevant activities and FCOI training until the matter is resolved as per the Chapter XXII of Establishment Code of the University Grants Commission and the Higher Educational Institutions.

In addition, the UOC shall follow regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

N. Record Retention

Unless some other applicable record retention law, requirement, or policy requires a longer period of retention, records created and maintained under this Policy, including SFI Disclosures, Travel Disclosures and Conflict Management Plans, shall be retained by the University for a period of no less than ten years (10) years as per the Right to Information Act, No. 12 of 2016 of Sri Lanka after the termination or completion of the Research or Technology Transfer Transaction to which they relate.

O. Sub recipient Compliance

1. Non-NIH-Funded Research. With respect to awards to the University for non-NIH-Funded Research, University subrecipients shall provide appropriate assurances to the Office of Sponsored Programs that policies and procedures no less stringent than this Policy exist and are enforced in connection with the execution of subcontracts or other sub award agreements. University officials shall confirm that all researchers employed by sub recipients, including sub-grantees, contractors, subcontractors and collaborators participating in University Research are subject to conflict-of-interest rules and procedures that are no less stringent than this Policy.

2. NIH-Funded Research. With respect to awards to the University for NIH-Funded Research, each University subrecipient shall:

- a. Provide written certification to the University that subrecipient's FCOI policy complies with all applicable NIH and federal FCOI rules and requirements, or alternatively and only if permitted by the University, that subrecipient researchers are subject to the University's policy with respect to disclosing SFI's that are directly related to the subrecipient's work for the University;
- b. If subrecipient's FCOI policy applies, specification of the time periods for the subrecipient to report all identified subrecipient research FCOI's to the University, which shall be sufficient to enable the University to provide timely reports to NIH under this Policy; and
- c. If the University allows subrecipient researchers to comply with the University's FCOI policy, specification of the time periods for the subrecipient to submit subrecipient researcher SFI Disclosures to the University, which shall be adequate to enable the University to perform the review, management and reporting required by this Policy.

P. Federal Reporting⁸

The Office of Sponsored Programs is responsible for reporting matters involving FCOI disclosures in accordance with applicable federal requirements.

1. Prior to the expenditure of any funds under a NIH-Funded Research project, the University shall provide to the NIH awarding component an FCOI report regarding any Investigator's SFI or Travel Disclosure determined by the University to constitute an FCOI and ensure that the University has implemented an appropriate Conflict Management Plan.

2. In the event the University identifies a previously unreported FCOI related to an ongoing NIH-Funded Research project, the University shall provide the NIH awarding component an FCOI report regarding any Investigator's SFI found by the University to be an FCOI and ensure that the University has implemented an appropriate Conflict Management Plan within sixty (60) days of identifying this interest.

3. All FCOI reports to NIH awarding components shall include sufficient information to enable the NIH awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the University's Conflict Management Plan. Elements of the FCOI report shall include no less than the following and may include such additional information that the Institutional Official or the NIH awarding component may request:

a. Project Number;

b. Principal Investigator;

c. Name of the Investigator with the FCOI;

d. Name of the Entity with which the Investigator has an FCOI;

e. Nature of the Financial Interest (e.g., Compensation, Equity, Intellectual Property, consulting fees, Sponsored Travel, Reimbursed Travel);

f. Value of the Financial Interest (dollar ranges are acceptable);

g. Description of how the FCOI relates to the NIH-Funded Research and the basis for the University's determination that it is an FCOI; and

h. Description of the key elements of the University's Conflict Management Plan, including –

i. Role and principal duties of the conflicted Investigator;

ii. Conditions of the Conflict Management Plan;

iii. How the Conflict Management Plan is designed to safeguard objectivity in the Research project;

⁸ Not applicable in Sri Lanka

National Audit Act 2018 Sri Lanka has empowered Auditor General (AG) to conduct comprehensive audit over the Public Enterprises and Empowering Committee on Public Enterprises (COPE) to review performance account are under the Public Accounts Committee

- iv. How the Conflict Management Plan will be monitored to ensure Investigator/Innovator compliance; and
- v. Other information as needed, including information regarding the FCOIs of all subrecipient Investigators consistent with the requirements of the 2011 NIH rule.

Q. Auditing and Oversight Monitoring.

Office of Research and Development Committee shall take such actions that it deems reasonable to audit and/or monitor compliance with Conflict Management Plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with Conflict Management Plans.

R. Timing

All Significant Financial Interests must be disclosed prior to the time a proposal for NIH-funded research is submitted. All Disclosure Forms must be updated by Investigators during the period of the award on an annual basis and within 30 days of discovering or acquiring (through, e.g., marriage, or inheritance) a new Significant Financial Interest. Individuals who intend to contribute as an Investigator to an ongoing NIH-funded project must submit a Disclosure Form prior to contributing to the NIH-funded project.

Other Relevant Policies and Procedures

The resolution shall be incorporated into a Memorandum of Understanding between UoC and the Investigator that details the conditions or restrictions imposed on the individual.

The Memorandum of Understanding shall be signed by the individual and, on behalf of the Faculty/Institute, the Dean/Director of the Faculty/Institute the Vice Chancellor overseeing Finance and Administration, as appropriate. Actual or potential conflicts of interest will be satisfactorily managed, reduced or eliminated in accordance with these guidelines and prior to accepting any award they will be disclosed to the sponsoring agency for action.

Additional policies may be related to the management of Significant Financial Interests and may be referenced in any Conflict Management Plan developed under this Policy. This policy shall be interpreted and applied consistent with other applicable University policies, including, but not limited to, the following:

National:

[The 1978 Constitution of the Democratic Socialist Republic of Sri Lanka](#)

[National Audit Act, No. 19 of 2018](#)
[Right to Information Act, No 12 of 2016 of Sri Lanka](#)
[Government Establishment Code](#)
[Sri Lankan Government Gazettes](#)
[Public Administrative Circulars](#)
[Ministry of Finance Circulars](#)
[Financial Regulation](#)
[Finance Act No. 38 of 1971](#)
[Intellectual Property Act, No. 36 of 2003](#)
[Sri Lanka Public Accounting Standards](#)
[Procurement Guideline and Manual 2006](#)

State Universities in Sri Lanka:

[Universities Act No. 16 of 1978 as amended](#)
[Establishment Code of the University Grants Commission and the Higher Educational Institutions of 1984](#)
[University Grants Commission Circulars](#)
[Finance Circular letters](#)
[Establishment Circular lettershttps://www.ugc.ac.lk/](https://www.ugc.ac.lk/)
[Other Circular letters](#)
[Orders and Ordinance](#)

University of Colombo

[University By-Laws](#)
[University Policies](#)
[Social Media Guidelines](#)
[Standard Operating Procedure \(SOP\)](#)
[Memorandum of Understanding \(MoU\)](#)
[Research Policy Guidelines of the University of Colombo](#)
[Intellectual Property Policy of University of Colombo](#)