

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

Christian Medical College, Vellore (CMC) is committed to ensuring its faculty an open and productive environment in which to conduct teaching, patient care, and research. CMC's concern with financial conflict of interest (FCOI) reflects the ever-increasing complexity of our society, our various relations with each other and with outside institutions including industry and funding agencies along with the heightened national and governmental sensitivity to such matters. Here FCOI is defined as "significant financial interest (SFI) that could directly or indirectly and significantly affect the design, conduct or reporting of externally funded research" and includes anything of monetary value. Additionally, faculty members' external financial relationships may compromise the integrity of decisions they make as teachers and providers of patient care.

Significant Financial Interests

The following comprise a potential SFI and is applicable to the faculty member (either as a principal investigator, co-investigator or their immediate family members and must be reported.

- A) Financial interests (equity or other ownership interests) in the assets or liabilities of any company that may benefit from the research activity held during conduct of research or for 3 years after completion of the study.
- B) Payments (salary, consultation fees or honoraria) from any company that may benefit from the research activity during conduct of research or for 3 years after completion of the study. Cost of conducting the study or other studies which are under a contractual arrangement with a company as well as miscellaneous payments that would be controlled by the institutional finance and accounts department are excluded.
- C) Employment or executive relationships or compensation arrangements with any company that may benefit from the research activity.
- D) Intellectual property rights or proprietary interests (patents, copyrights and royalties from such rights) related to the research.

In response to these concerns, CMC, Vellore has adopted the following statements of FCOI policy:

1. Awareness and Training

It is the policy of Christian Medical College, Vellore that its faculty have an obligation to avoid unacceptable financial conflicts of interest and to ensure that their activities and interests do not conflict with their obligations to the institution or its welfare. To achieve this, the following will be undertaken:

- A) The FCOI policy will be readily available on the institutional research website (<https://www.cmch-vellore.edu/SITES/research/Index.html>) along with a FCOI disclosure form (Appendix 1).
- B) The FCOI disclosure form will be required to be submitted by the faculty and other investigators on receiving funding from external sources including grant agencies and PHS funds.

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

- C) Faculty and study team members will be trained on current FCOI policy prior to engaging in research or when they have newly join the institution.
- D) Faculty and study team members shall receive revision in training every 4 years along with other research training modules (GCP module) or whenever there is a change in policy or when they are determined to be non-compliant.

2. Disclosure, Review and Monitoring Requirements

Disclosure of significant financial interest by faculty engaging in research to the institution is a requirement.

- A) Faculty should submit the FCOI disclosure form to the research office i) on submitting a grant application ii) annually if funded when submitting reports to the grant agency and iii) within 30 days of discovering or acquiring a new SFI.
- B) The submitted FCOI forms are reviewed by the 3 institutional officials monthly and report provided to the faculty member.
- C) The Vice Principal (Research) in consultation with the Principal and Director (or their pre-determined representatives) comprise the Institutional Review Committee (IRC) determines whether that the faculty members disclosure form presents a serious FCOI that must be resolved.
- D) Consultation on monetary value and whether the disclosure constitutes a significant FCOI can be sought with the finance and accounts departments at CMC and with the faculty member concerned with all consultations recorded in writing.
- E) Activities and interests that are unlikely to lead to SFI require no consultation. These include examiner fees, clinical consultation fees or honoraria for publications or lectures. These are returned to the institution as per institutional rules.
- F) If no FCOI is determined, the faculty member is provided a written report by the IRC and is required to continue to submit disclosure forms as required for the duration of funding (as given in point 2.A above).
- E) If an FCOI is determined, a management plan is instituted in writing by the IRC to manage the FCOI and to be implemented prior to expenditure of funding. This could include i) public disclosure of FCOI prior to publishing or presenting results ii) disclosure of FCOI directly to study participants iii) appointment of an independent monitor iv) modification of the research plan to avoid the FCOI v) change of personnel or personnel responsibilities to avoid the FCOI vi) reduction or elimination of the financial interest and vii) severance of the relationship leading to the FCOI. The faculty member can be consulted about the appropriate resolution and management of the FCOI.
- F) If the faculty member disagrees with the FCOI or management plan developed by the IRC, they may pursue the matter with the Director.

3. Reporting Requirements to Funding Agencies

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

FCOI reports will be provided by the research office to external grant agencies both Indian (ICMR, DBT, DST and others) and international (NIH, UKRI, EU and others) as requested.

- A) The FCOI reports will be sent based on the grant agencies guidelines including i) prior to expenditure of funds ii) within 30-60 days of a new FCOI identified iii) annually and iv) retrospectively if needed.
- B) In case of any FCOI identified, subsequent to a management plan being instituted and complied with, a mitigation report documenting the SFI, impact on research and institutional activities and management plan will be sent to the grant agency as required.
- C) In case a faculty member does not comply with the institutional FCOI management plan within the stipulated time, the grant agency will be informed, and the complete institutional report (FCOI form, management plan and mitigation report) submitted.

4. Maintenance of Records

All FCOI records for each faculty members grants will be retained at the research office for a duration of 5 years following submission of the final expenditure reports.

5. Enforcement, Continuing Review and Non- Compliance

The following steps will be undertaken at Christian Medical College, Vellore to ensure compliance with the FCOI and management plan in case of any SFI identified.

- A) Faculty member will comply with the management plan in case an SFI is identified within the stipulated time or face sanctions from the IRC including freezing of all research accounts and departmental funds.
- B) Subsequently, continuing review is conducted annually with submission of FCOI forms along with the annual report.
- B) A retrospective review of the faculty members activities will be conducted in case of non-compliance of an SFI or non-timely declaration or improper management within 120 days and determine impact on the study.
- C) In case of research involving interventions such as drugs, medical devices, treatment regimens or procedures, if the FCOI was not identified, reported or managed, the SFI must be declared at every public presentation of the research outcomes and an addendum added to any prior publications or presentations.

6. Subrecipient Requirements

The Christian Medical College may conduct research with other research organizations by providing sub-recipient grants as long as the sub-recipient complies with the institutional policies. This is not applicable to grants received from outside the country as per national regulations no subrecipient grants can be awarded with foreign funds.

7. Public Accessibility Requirements

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

The institutional FCOI policy will be made available on Christian Medical College Research Website as mentioned in 1.A. In addition, for individual FCOI, the following steps will be undertaken:

- A) Updated information on FCOI held by faculty members will be made available by the research office on request within 5 working days during the conduct of a study and for 3 years after completion of the project.
- B) Be made publicly available on the project website if available and updated annually or within 60 days whenever any change or new FCOI is identified.
- C) This will include information on the faculty members name, title or designation, role in a given project or study, name of the entity with SFI is held, nature of the SFI, an approximate value (USD and INR) or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

Appendix 1: FCOI Disclosure Form

The primary purpose of this Financial Conflict of Interest Disclosure Form (FCOI-D) is to prevent bias in the design, conduct, or reporting of research projects. The FCOI-D Form should be completed prior to expenditure of funds (initial disclosure), annually or within 30 days if there are any changes or newly identified FCOI by each faculty member of a study receiving external funding in their role as principal investigator or co-investigator participating in research. FCOI are as defined in the institutional FCOI policy.

1. Study Name:

2. IRB Reference Number:

3. IRB Approval Date:

4. Type of FCOI (check whichever is applicable):

- Initial Disclosure
- Annual Disclosure
- Newly identified FCOI
- Amended FCOI Disclosure (after management plan)
- Retrospective Disclosure

5. Date of FCOI Disclosure Form Submission:

6. Study Investigators (add more rows as needed):

Name	Designation and Department	Role in the Study	Contact Details (Phone and Email)

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

7. For EACH investigator listed above, complete and attach the form below:
 (Please check a box (Yes/Nil) for each point below. Add more pages as needed)

I declare that	Yes	Nil
<p>In the past 12 months, I and/or my immediate family have received compensation/payments by a commercial sponsor(s) of research study(s) in which the value of compensation could be affected by study(s) outcome(s).</p>	<p><input type="checkbox"/> Please describe <i>the financial interest and your plan to manage the conflicting interest.</i></p>	<p><input type="checkbox"/></p>
<p>In the past 12 months, I and/or my immediate family had received proprietary interest in tested product(s) including, but not limited to, a patent, trademark, copyright or licensing agreement.</p>	<p><input type="checkbox"/> Please describe <i>the financial interest and your plan to manage the conflicting interest.</i></p>	<p><input type="checkbox"/></p>
<p>In the past 12 months, I and/or my immediate family had received equity interest from a commercial sponsor of my research study(s), i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices.*</p>	<p><input type="checkbox"/> Please describe <i>the financial interest and your plan to manage the conflicting interest</i></p>	<p><input type="checkbox"/></p>
<p>In the past 12 months, I and/or my immediate family had received equity interest from a commercial sponsor of my research study(s). The commercial sponsor is a publicly held company and the interest exceeds \$10,000 in value or 10% of the voting stocks or controlling interest of the commercial sponsor, whichever is lower. *</p>	<p><input type="checkbox"/> Please describe <i>the financial interest and your plan to manage the conflicting interest.</i></p>	<p><input type="checkbox"/></p>

Christian Medical College, Vellore

Financial Conflict of Interest Disclosure Policy - January 2021

*This requirement applies to interests held during the time the investigator or study team member is carrying out research and for 3 years following completion of the study(s).

Declaration

- I confirm that I have read through the latest institutional Financial Conflict of Interest Disclosure Policy.
- I confirm that the information submitted in this Disclosure Form is true and accurate on the date of declaration.

Signature: _____ *Date:* _____

Full Name:

Note:

1. Please ensure that all fields are filled in.
2. This form is valid until the next disclosure cycle (on or before 31 Dec of each year).
3. Please submit an updated FCOI Disclosure Form as soon as possible but not later than 30 calendar days if any of the circumstances relevant described herein change during the conduct of the research.
4. If any changes to the FCOI Disclosure Form is required as a result of the management plan please submit an amended form.