CancerCare Manitoba
ActionCancerManitoba

GOVERNING DOCUMENTS

Policy and Procedure

Title:	**Financial Conflict of Interest for National Institutes of Health (NIH) Reporting and Assessment**	
Policy Number:	01.018	Section: Administration
Effective Date:	November 5, 2014	
Revised Date:	October 3, 2019	
Approving Body:	President and CEO	
Authority:	CancerCare Manitoba Act	
Responsible Officer:	President and CEO	
Delegate:		
Contact:	Manager, Clinical Trials Unit	
Applicable to:	All CCMB Staff and Physicians	

1.0 BACKGROUND:

All investigators who are applying for and/or receiving NIH funding or who are participating in an NIH-funded research project, whether directly or through a subcontract must comply with this policy, in addition to compliance with CancerCare Manitoba's (CCMB's) Conflict of Interest Policy.

2.0 PURPOSE:

2.1 To clarify requirements regarding reporting of Significant Financial Interests (SFIs) by persons at CCMB.

2.2 To outline the process by which a designated official determines whether the SFI is connected to an investigator's institutional responsibilities and assesses whether it is a Financial Conflict of Interest ("FCOI") for an NIH-funded project.

2.3 To outline the responsibilities of the Designated Official and CCMB in managing and reporting FCOIs to NIH.

2.4 To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from investigator FCOIs.

2.5 To comply with Public Health Services (PHS) regulations (US regulations: 42 CFR Part 50 Subpart F and 45 CFR Part 94).

3.0 DEFINITIONS:

3.1 **Designated Official:** Director of Finance or designate at CCMB.

3.2 **Disclose:** an investigator's disclosure of a Significant Financial Interest to CCMB.

3.3 **Employee:** all persons employed or contracted by CCMB as well as members of the medical staff, research investigators, board members, volunteers, and students/trainees.

3.4 **FCOI or Financial Conflict of Interest:** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

3.5 **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.

3.6 **Institutional Responsibilities:** includes duties such as:

a. participation in research (defined for purposes of this FCOI Procedure as including the preparation or performance of creative works and reflective inquiry) and the dissemination of the results of research by means appropriate to the discipline;

b. clinical service, if identified in the Employee's job description;

c. participation in training, instruction or teaching programs, including classroom teaching, supervision of graduate students and personal interactions with and advising students;

d. provision of service to the Employee's discipline; participation in the governance of CCMB and any of its Departments; and dissemination of knowledge to the general public by making available the Employee's expertise and knowledge of the discipline, all of which shall be carried out according to the standards of professional conduct expected of that Employee; and

e. any other responsibility outlined in the Employee's job description, employment agreement or appointment letter with CCMB, in a post-doctoral fellow's appointment letter with CCMB, or in policies applicable to the post-doctoral fellows.

3.7 **Investigator:** 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 funded by the NIH or proposed for such funding, which may include, for example, collaborators or consultants. "Investigator" also includes senior/key personnel identified as such by CCMB in the grant application, progress report, or any other report submitted to the NIH by or on behalf of CCMB under this FCOI Policy and Procedure.

3.8 **Manage:** taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

3.9 **NIH:** the National Institutes of Health ("NIH") and other US Public Health Service ("PHS") funding sources, within the Department of Health and Human Services ("HHS"), and any other research funding source which has adopted the HHS Final Rule at 42 CFR Part 50 Subpart F and 45 CFR Part 94, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

and Responsible Prospective Contractors," respectively. Other funding sources which have adopted the aforementioned HHS Final Rule include those listed by the US Federal Demonstration Partnership. Reporting requirements under the Final Rule are administered by the National Institutes of Health.

3.10 **Significant Financial Interest or SFI:**

3.10.1 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:

a. 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 $5,000. 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); and "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

b. with regard to any non-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, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

c. intellectual property rights and interests (e.g., patents regardless of filing status, copyrights), upon receipt of income regarding those rights and interests in excess of $5,000 per year per entity (payor).

3.10.2 Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities when the annual aggregated amount paid to the specific Investigator, exceeds $5,000 per entity; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a US federal, state, or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education. This disclosure will include, at a minimum:

a. the purpose of the trip,
b. the identity of the sponsor/organizer,
c. the destination, and

d. the duration.

The institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the NIH-funded research.

3.10.3 If an Investigator receives more than $5,000 per year from one entity in total payments for multiple SFIs (as defined in 3.10.1 and 3.10.2 above), then the details of each such SFI must be disclosed.

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

a. salary, royalties, or other remuneration paid by CCMB to the Investigator if the Investigator is currently employed or otherwise appointed by CCMB, including intellectual property rights assigned to CCMB and agreements to share in royalties related to such rights;

b. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or the Investigators family does not directly control the investment decisions made in these vehicles;

c. income from seminars, lectures, teaching engagements or service on advisory or review panels sponsored by a US federal, state, or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education; similar income from non-US equivalents of these entities where the annual aggregated amount paid to the specific Investigator does not exceed $5,000 per entity; or

d. income from service on advisory committees or review panels for a US federal, state, or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education; similar income from non-US equivalents of these entities where the annual aggregated amount paid to the specific Investigator does not exceed $5,000 per entity.

4.0 **POLICY:**

4.1 Investigators must report and disclose any potential financial conflict of interest as outlined in the Procedure.

4.2 The Designated Official is responsible for the assessment and record keeping of

financial conflicts of interest as outlined in the Procedure.

4.3 The Designated Official is responsible for the management and reporting of financial conflicts of interest as outlined in the Procedure.

4.4 The department responsible for conducting the trial at CCMB is responsible for the training of Investigators related to this Policy and its requirements, as outlined in the Procedure.

4.5 The Communications Department at CCMB is responsible for posting and maintaining this policy on the CCMB public website.

5.0 **PROCEDURE:**

5.1 **Reporting by Investigators**

5.1.1 Who Must Disclose:

All Investigators who are:

- applying for and/or receiving NIH funding, or
- who are working on an NIH-funded research project;

whether directly or through subcontract, must Disclose, in writing to the Designated Official at CCMB, all SFIs (and those of the Investigator's spouse and dependent children) at the following times:

a. Initial disclosure:

i. Initial disclosure must be made at least 30 days before the time of application for NIH-funded research;
ii. The initial disclosure must include all SFIs in the 12 months preceding the disclosure;

b. Ongoing disclosure:

i. Within 30 days of discovering or acquiring (including but not limited to a purchase, marriage, inheritance, etc.) a new SFI, and
ii. On an annual basis during the term of the NIH-funded research, disclosure of:
    - All SFIs received in the 12 months preceding the disclosure that were not previously reported; and
    - Updated information regarding any previously disclosed SFI.

c. New to CCMB:

i. All Investigators who are new to CCMB and are applying for

and/or receiving NIH funding or who are participating in an NIH-funded research project must make the initial disclosure and ongoing disclosures as noted above.

5.1.2 Steps to Disclose SFIs to CCMB

a. The Investigator must complete the Financial Interests Report attached to this FCOI Policy and return it to the Designated Official.

b. The Designated Official, in conjunction with the responsible department managing the trial, will determine whether the third party entity(ies) or individual(s) named in the Significant Financial Interest(s) Disclosed by an Investigator (or spouse and/or dependent child[ren]) should be informed of the disclosure and the fact that the disclosed information may be made available to the NIH or, in the case of a Financial Conflict of Interest, to the public. The Designated Official will provide the informed third party entity or individual with the opportunity to indicate any concern with such access to the SFI information and may obtain consent using an Informed Consent Form from Third Party for Disclosure of Personal Information.

5.2 **Assessment and Record-Keeping by Designated Official**

5.2.1 The Designated Official must review all disclosures of SFIs from Investigators, including sub-recipient Investigators, within the timeframes noted below in 5.2.2, and determine whether:

a. the disclosures related to NIH funding; and

i. an Investigator's SFI is related to NIH research when the Designated Official reasonably determines that the SFI:
- could be affected by the NIH-funded research; or
- is an entity whose financial interest could be affected by the research.

The Designated Official may involve the Investigator in the Designated Official's determination of whether an SFI is related to the NIH-funded research.

b. whether each SFI is an FCOI

i. An FCOI exists when CCMB, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

5.2.2 The review and determination noted in 5.2.1 above must be conducted by the Designated Official at the following times:

a. prior to CCMB's expenditure of any funds under an NIH-funded research project;

b. within sixty (60) days whenever, in the course of an ongoing NIH-funded project, an Investigator or sub-recipient Investigator who is new to participating in the project discloses an SFI or an existing Investigator or sub-recipient Investigator discloses a new SFI to CCMB; and

c. within sixty (60) days whenever CCMB identifies an SFI that:

i. was not previously disclosed in a timely manner by an Investigator or sub-recipient Investigator; or
ii. for whatever reason, was not previously reviewed by CCMB during an ongoing NIH-funded research project.

5.2.3 Record-keeping - The Designated Official, on behalf of CCMB, must maintain records relating to all Investigator disclosures of SFIs and CCMB's review of, and response to, such disclosures (whether or not a disclosure resulted in CCMB's determination of an FCOI) and all actions under CCMB's policies (including this FCOI Policy) or retrospective review related to the SFI and/or the FCOI, if applicable, for at least three (3) years from the date the final expenditures report is submitted to NIH, the date of final payment or, where applicable, for other time periods specified.

5.2.4 NIH may inquire at any time (before, during, after award) into any Investigator's disclosure of Financial Interests and CCMB's review of, and response to, such disclosure, whether or not the disclosure resulted in CCMB's determination of an FCOI. This includes situations in which an Investigator moves from one institution to another.

5.2.5 CCMB is required to submit to NIH, or permit NIH on site to review, all records pertinent to compliance with this FCOI Procedure.

5.3 Management and Reporting of FCOIs

5.3.1 If the Designated Official determines through his or her review pursuant to 5.2.1 above that there is an FCOI, the Designated Official must prepare an FCOI management plan to manage the FCOI. Key elements of the management plan include:

- role and principal duties of the conflicted Investigator in the research project;
- conditions of the management plan;
- how the management plan is designed to safeguard objectivity in the research project;
- confirmation of the Investigator's agreement to the management plan;
- how the management plan will be monitored to ensure Investigator

compliance; and
- other information as needed.

Examples of conditions or restrictions that might be imposed to manage an FCOI:
- public disclosure of the FCOI (e.g., when presenting or publishing research);
- for research projects involving humans, disclosure of the FCOI directly to the participants;
- appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from an FCOI;
- modification of the research plan;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- reduction or elimination of the Financial Interest (e.g., sale of an equity interest), or
- severance of relationships that create Financial Conflicts of Interest.

5.3.2 The Investigator is required to comply with the management plan prescribed by the Designated Official.

5.3.3 On behalf of CCMB, the Designated Official must monitor compliance with the management plan on an ongoing basis until the completion of the project.

5.3.4 Reporting Requirements to NIH

CCMB, through its Designated Official, must provide initial and ongoing FCOI reports to NIH as applicable:

a. after the award is granted but prior to CCMB's expenditure of any funds under an NIH-funded research project;

b. annually at the same time as the annual progress report is due:

For any FCOI previously reported by CCMB, the report must address the status of the FCOI and any changes to the management plan for the duration of the NIH-funded research project. The annual FCOI report must specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

c. in the time and manner specified by NIH for any other FCOI reports for the duration of project period (including extensions with or without funds).

d. Sub-recipients: CCMB must provide FCOI reports to NIH regarding all FCOIs of all sub-recipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

FCOI reports by CCMB must include sufficient information to enable NIH to understand the nature and extent of the FCOI, and to assess the appropriateness of CCMB's management plan. Each FCOI report prepared by the Designated Official on behalf of CCMB must contain:

- grant number;
- project director/principal Investigator or contact project director/principal Investigator if a multiple project director/principal Investigator model is used;
- name of Investigator with the FCOI;
- name of the entity with which the Investigator has an FCOI;
- nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- value of the Financial Interest per year:
    - $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 by increments of $50,000; or
    - a statement that a value cannot be readily determined
- a description of how the Financial Interest relates to NIH-funded research and the basis for CCMB's determination that the Financial Interest conflicts with such research; and
- key elements of CCMB's management plan.

5.4 Other CCMB and Investigator Responsibilities: Training, Subcontracting and Public Accessibility of Information

5.4.1 Training:

The department responsible for conducting the trial at CCMB must provide the following mandatory training, as prescribed in the NIH regulations, to its Investigators:

a. inform each Investigator of CCMB's policy on FCOIs

b. inform each Investigator of the Investigator's responsibilities regarding the disclosure of SFIs and the NIH regulations

c. require each Investigator to complete training regarding CCMB's policy on FCOIs and the Investigator's responsibilities:

i. prior to engaging in NIH-funded research,
ii. at least every four years, and
iii. immediately when any of the following circumstances apply:
    - CCMB revises this FCOI Policy or any other financial conflict of interest policies or procedures
    - an Investigator is new to CCMB

- CCMB finds that an Investigator is not in compliance with this FCOI Policy or any other CCMB's financial conflict of interest policy or procedures or with any management plan.

The Investigator must undertake such training from CCMB through the department responsible for conducting the trial.

The department responsible for conducting the trial is responsible for maintenance of the required training package for Investigators.

5.4.2 Subcontracting:

If CCMB carries out the NIH-funded research through a sub-recipient, CCMB must take reasonable steps to ensure that any sub-recipient Investigator complies with this procedure:

a. incorporate as part of written agreement with sub-recipient, terms that establish whether this FCOI Policy or the sub-recipient's policy/procedure will apply to the sub-recipient's Investigators.

b. if the sub-recipient's Investigators must comply with the sub-recipient's financial conflicts of interest policy/procedure, CCMB shall obtain from the sub-recipient as part of the written agreement referenced above a certification that its policy/procedure complies with the NIH regulations, specifically 42 CFR Part 50 Subpart F or 45 CFR Part 94. The agreement shall also specify the time periods for the sub-recipient to report all identified Financial Conflicts of Interest to CCMB. Such time periods shall be sufficient to enable CCMB to provide timely FCOI reports, as necessary, to the NIH as required by this FCOI Policy.

c. if the sub-recipient's Investigators must comply with this FCOI Policy, CCMB must obtain a written agreement specifying time periods for the sub-recipient to submit all Investigator disclosures of Significant Financial Interests to CCMB. Such time periods shall be sufficient to enable CCMB to comply in a timely fashion with its review, management and reporting obligations under this FCOI Procedure.

5.4.3 Public Accessibility of Information

a. CCMB shall maintain an up-to-date, written, enforced policy and procedure on Financial Conflicts of Interest, that complies with NIH regulations and make such policy available via a publicly accessible website.

b. after an award has been granted, but prior to CCMB's expenditure of any funds under a NIH- funded research project, CCMB shall make available in writing within five (5) business days of any request, the

information listed in 5.4.3 (c) concerning any SFI that meets the following criteria:

i. SFI was disclosed and is still held by the Investigator who has been identified by CCMB as senior/key personnel for the NIH-funded research project in the grant application, contract proposal, contract, progress report, or other required report submitted to the NIH;
ii. CCMB determines that the SFI is related to the NIH-funded research; and
iii. CCMB determines that the SFI is an FCOI.

c. CCMB must make available in response to written requests the following minimum information:

i. investigator's name,
ii. investigator's position with respect to the research project,
iii. nature of the SFI,
iv. approximate dollar value of the SFI:
- $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 by increments of $50,000
- a statement that a value cannot be readily determined;

v. the entity with which the Investigator has an FCOI, to enhance transparency and accountability.

d. CCMB shall update the above-noted information within 60 days when there are changes to the information and, at a minimum, shall update the above-noted information annually.

e. the above-noted information, as updated, shall remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

5.5 Non-Compliance Constitutes Misconduct

5.5.1 Non-compliance constitutes misconduct. In the event of non-compliance, CCMB may initiate actions under applicable collective and other agreements or applicable CCMB Policy.

5.5.2 Retrospective Review and Mitigation: Whenever CCMB identifies an SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by CCMB during an ongoing NIH-funded project (including but not limited to when the SFI was not reviewed in a timely fashion or reported by a subrecipient):

Step 1: the Designated Official shall, within sixty (60) days determine whether:

i. the disclosures relate to NIH funding; and

- an Investigator's SFI is related to NIH-funded research when the Designated Official reasonably determines that the SFI:
  - could be affected by the NIH-funded research; or
  - is an entity whose Financial Interest could be affected by the research.

The Designated Official may involve the Investigator in the Designated Official's determination of whether an SFI is related to the NIH-funded research.

ii. each SFI is an FCOI

- An FCOI exists when CCMB, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

Step 2: If the Designated Official determines that an FCOI exists, the Designated Official must 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 FCOI going forward.

Step 3: Within 120 days of CCMB's determination of non-compliance, CCMB shall complete a retrospective review of the Investigator's activities and the NIH-funded project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research.

Step 4: CCMB is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- project number;
- project title;
- Principal Investigator or contact Principal Investigator if a multiple Principal Investigator model is used;
- name of the Investigator with the FCOI;
- name of the entity with which the Investigator has an FCOI;
- reason(s) for the retrospective review;
- detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- findings of the review; and
- conclusions of the review.

Step 5: Based on the results of the retrospective review, if appropriate, CCMB shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, CCMB is required to notify NIH promptly and submit a mitigation report to NIH. The mitigation report must include, at a minimum, the key elements cited in Step 4 above and a description of the impact of the bias on the project and CCMB's plan of action or actions taken to eliminate or mitigate the effect of the bias (including, but not limited to: impact on the project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the project is salvageable).

CCMB will, thereafter, submit FCOI reports annually as specific in 5.3 of this FCOI Policy.

5.5.3 In any case in which the HHS determines that an NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by CCMB as required by the regulations, CCMB must not only require the Investigator involved to disclose the FCOI in each public presentation of the results of the research, but also to request an addendum to previously published presentations.

5.5.4 On the basis of its review of records or other information that may be available, NIH may decide that a particular FCOI will bias the objectivity of the NIH-funded project to such an extent that further corrective action is needed or that CCMB has not managed the FCOI in accordance with this FCOI Policy, the NIH may determine that issuance of a Stop Work Order by the contracting officer or other enforcement action is necessary until the matter is resolved.

6.0 REFERENCES:

6.1 Appendix A - Financial Interests Report

6.2 Conflict of Interest, CCMB Policy No. 01.001.

6.3 Conflict of Interest Policy and Procedure, University of Manitoba, June 16, 2009.

6.4 Financial Conflict of Interest for National Institutes of Health (NIH) and Other Applicable Research Funding Sources Reporting and Assessment Procedure, University of Alberta, October 1, 2013.

6.5 NIH Financial Conflict of Interest homepage http://grants.nih.gov/grants/policy/coi/

6.6 NIH FCOI training tutorial
http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

Department of Health and Human Services: 42 CFR Part 50 and 45 CFR Part 94 (United States Government)

Policy Contact: All enquiries relating to this policy should be directed to:	
Name:	
Title/Position:	Manager, Clinical Trials Unit
Phone:	
E-mail:	
Address: (if required):	

DOCUMENTATION	
Policy Location: This policy is located (hard and e-copy formats):	
1.	The original signed and approved policy is on file in the Executive Office, CCMB
2.	The e-copy is on file in the CCMB Governing Documents Library, SharePoint
3.	

Revision History:

Date	Version	Status	Author	Summary of Changes
dd/mm/yyyy	#	Initial, Draft Final Minor/Major revision		
05/11/2014	1	Initial	CCMB Legal Counsel, CIO, CCMB Sr Mgmt, Policy Committee	New policy at CCMB; aligns with NIH regulations and University of Manitoba policy.
19/03/2015	2	Final	CCMB Policy Committee, CIO	Final review and minor revisions.
26/03/2018	2	Minor revision	S.Friedenberger	Formatted to new template
03/10/2019	3	Revision	KDyck, KKwong	Minor revisions

Approvals Record:
This Policy requires approval by:

Approval		
Date	**Name / Title**	**Signature**
	Not required.	

FINAL APPROVAL:

Date	**Name / Title**	**Signature**
Oct 3 2019	Dr. Sri Navaratnam President and CEO CancerCare Manitoba	*Approved by* *Dr. S. Navaratnam*