

accordingly. For clarity, this means that Members must disclose their conflicts of interest to each institution separately, unless and until directed otherwise.

3. The following individuals are excluded from the application of this Policy:
 - a. all students and trainees, including those who are registered at the University (the latter being “Learners”). Students and trainees who are not registered at the University will be expected to comply with the conflict of interest reporting requirements of their home institution;
 - b. volunteers; and,
 - c. individuals sitting on the OHRI Board of Directors, or a committee of the Board of Directors. These individuals shall continue to be subject to the Board of Directors Conflict of Interest policy.
4. Learners shall be required to follow the University’s policy(ies) on Conflict of Interest and shall make all required disclosures to the University in accordance with said policy(ies).

DEFINITIONS

5. For the purpose of this Policy:

“Conflict of Interest” includes any situation in which a Member or Related Party has an External Appointment or other personal or professional relationship with, or a Financial Interest in an Outside Entity that may affect or compromise, or appear to affect or compromise the Member’s objectivity, judgement or actions in carrying out his or her Research Activity and/or other OHRI duties. A conflict of interest can be real, potential or perceived in nature.

“Disclosure Report” means a report through which a Member discloses to OHRI specific information relevant to deciding whether such individual is in a Conflict of Interest, the form of which report is approved by OHRI and may be amended from time to time.

“External Appointment” shall refer to a position or appointment held outside of OHRI, the Hospital or the University where the individual is a corporate board director, officer or trustee or has a similar duty in a for-profit or not-for-profit organization, lobby group or industry organization. Members may or may not derive any financial benefit and/or enjoy any ownership interest as a result of their holding these positions (for example, positions at other academic institutions, on peer group review panels, on advisory boards, or on editorial boards).

“Financial Interest” means an opportunity to receive anything of monetary value, e.g. salary or other payments, royalties, consulting fees or honoraria, work-in-kind, gifts, equity interests (for example stocks, stock options or other ownership interests, including dividends or distributions) or Intellectual Property rights. This definition shall expressly exclude the following:

- (i) salary and any other fees and payments received from or through OHRI (including any payments made under the OHRI policy on “Clinician Remuneration from Industry-Based Clinical Trials”), the Hospital or the University, including approved practice plan earnings and the distribution of those earnings that may be established by departmental or other similar agreements (provided that those agreements and the departmental or divisional group plans have been approved by the appropriate authority);
- (ii) salary and any other fees and payments (including for the conduct of seminars or lectures) received from any individual source other than the OHRI, the Hospital or the University that, when aggregated for the Member and his or her Related Parties over the next twelve months, are not expected to exceed \$5,000;
- (iii) interests of any amount in publicly traded, diversified mutual funds or managed funds;
- (iv) funds received by OHRI on behalf of the Member from any for-profit or not-for-profit organization for the purpose of supporting said Member’s Research Activities, including but not limited to grant funds;
- (v) any Gifts, as defined in and governed by The Ottawa Hospital’s Gift Policy. For greater clarity, all Members must comply with TOH’s Gift Policy, including the required disclosures as prescribed therein.

“Intellectual Property” includes, without limitation, inventions, technology (including computer software), technical information, trademarks, official marks, designs, drawings, information, literary and artistic works, formulae, processes, materials (including cell lines and antibodies) and know how, whether or not such Intellectual Property may be protected through the registration of any patent, trade-mark, industrial design, copyright or integrated circuit topography or other form of legal protection.

“Related Party” means (i) a Member’s immediate family member (for example, spouse, child, parent or sibling), or other person living in the same household; (ii) a professional corporation beneficially owned or controlled by a Member; or, (iii) any other party that reasonably could be perceived to influence the discharge of the Member’s duties to OHRI.

“Research Activity(ies)” means any activity conducted under the auspices of OHRI that results in the creation and/or public dissemination of knowledge, including without limitation scholarly activities in basic research, research in clinical epidemiology and human subject research.

“Outside Entity” means any individual, corporation, partnership, sole proprietorship or other legal entity (for profit or otherwise) other than OHRI or a Related Party.

POLICY

6. In the discharge of their Research Activities and OHRI duties, Members shall:
 - (a) act with honesty and integrity, in good faith and in the best interests of the OHRI; and,
 - (b) not allow past or existing financial, business, professional, family or social relationships or responsibilities to influence their conduct or judgment.
7. Each Member is responsible for ensuring his or her own compliance with this Policy and shall disclose to OHRI the nature and extent of all Conflicts of Interest of which he or she is aware in accordance with the procedures identified hereunder.
8. Members are responsible for being aware of and complying with the policies and guidelines of the agencies and companies that support their Research Activities, including but not limited to those policies and guidelines related to conflict of interest. For greater specificity, Members conducting research that is funded by the Canadian Institutes of Health Research must comply with the *Tri-Agency Framework: Responsible Conduct of Research*. Members conducting research that is funded or proposed for funding by the Public Health Service of the United States Department of Health and Human Services, including the National Institute of Health, must comply with the terms set out in *Appendix A – Public Health Services (PHS) Funded Research*.
9. A Conflict of Interest may be permitted by the OHRI where the OHRI determines, in its sole discretion, that a Conflict of Interest can be managed in such a manner that is compliant with legislation and other regulatory or contractual requirements, protects the integrity, reputation and interests of the OHRI and withstands the test of reasonable and independent scrutiny.
10. All information disclosed by a Member under this Policy will be held in confidence by OHRI except for essential purposes (e.g. under compulsion of statute or judicial process). In the event the Member holds an appointment at the Hospital and/or the University, some or all of the disclosed information may be shared on a confidential basis with selected representatives of those institutions as needed to properly manage the Conflict of Interest.
11. Members must disclose relevant Conflict(s) of Interest in research ethics board applications for projects with which they are affiliated, as required by the applicable research ethics board(s) of record (including but not limited to OHSN-REB). Disclosures made under this Policy do not replace the requirement to disclose such Conflict of Interest(s) to the applicable research ethics board(s) of record. Notwithstanding the foregoing, OHRI reserves the right to share information disclosed by a Member under this Policy with OHSN-REB, strictly on a confidential and need-to-know basis. OHSN-REB may act to constrain those research activities of the Member that are pertinent to the Conflict of Interest, for

example the Member's role in a research project, the consent process, and in the selection of research participants, as it deems appropriate.

12. A Member who fails to comply with this Policy, including by failing to disclose a Conflict of Interest or to follow a management plan, shall be subject to appropriate disciplinary action up to and including termination of employment, placement, appointment or contract with OHRI, or a suspension or revocation of privileges (where applicable). In addition to any disciplinary actions taken, the Finance Office may be directed to freeze the Member's research cost centre(s), until further notice, and the Member may be required to reimburse to the originating source the monetary value of any benefit received directly or indirectly arising out of such non-compliance. A serious breach of this policy may be required to be reported to the Member's professional body, if applicable. All sanctions will be commensurate with the seriousness of the violation.

PROCEDURES

13. Members shall complete a Disclosure Report at least annually. The annual disclosure process shall be initiated by OHRI at a time and through a reporting mechanism determined by OHRI.
14. Members shall disclose any Conflict of Interest arising outside of the annual disclosure process on a transactional basis. To the extent possible, Members shall complete a Disclosure Report prior to entering into any relationship or engaging in any activity or service that may give rise to a Conflict of Interest. In all circumstances, Members shall disclose any new Conflict of Interest within thirty (30) days of its acquisition or discovery.
15. OHRI Human Resources will receive and conduct an initial review of the completed Disclosure Reports. The Disclosure Reports shall then be referred to the Conflict of Interest Working Group ("Working Group") for assessment. The Terms of Reference for the Working Group may be found **here**. The Member disclosing the Conflict of Interest may be asked to provide additional information to the Working Group.
16. Conflict of Interest disclosures are evaluated in accordance with risk-based assessment and escalation criteria approved by the Relationship Management Committee of the Board of Directors ("Committee"), as may be amended from time to time. If the Conflict of Interest disclosure is determined by the Working Group to meet certain of these criteria, it shall be referred to the Committee for further review. The Terms of Reference for the Committee may be found **here**. The emphasis of both the Working Group and the Committee shall be on the disclosure and management of Conflicts of Interest, where possible.
17. If the Working Group or Committee (as applicable) determines that a disclosed Conflict of Interest can be managed so as to allow the relationship or activity to proceed, a management plan shall be implemented. The disclosing Member will

be provided an opportunity to provide input to the Working Group or Committee on the development of an appropriate management plan. To ensure consistency and efficiency, the Committee will develop standard management plans to address commonly disclosed types of Conflict of Interest.

18. Decisions of the Working Group or Committee shall be communicated in writing to the individual making the disclosure and to his or her immediate supervisor, if applicable. The disclosing Member will be required to sign a copy of any management plan implemented in a response to the disclosure to acknowledge his or her agreement to comply with its terms.
19. In the event that a Member disagrees with a decision of the Working Group or Committee, he or she may proceed as follows:
 - (a) In the case of a decision issued by the Working Group, the Member may appeal to the Committee for a reconsideration. The appeal must be received in writing by the OHRI Chief Operating Officer within 20 business days of the communication of the decision to the individual making the disclosure.
 - (b) In the case of a decision issued by the Committee, the Member may appeal to the OHRI Board of Directors for a reconsideration. The appeal must be received in writing by the OHRI Chief Operating Officer or the OHRI Chief Executive Officer and Scientific Director within 20 business days of the communication of the decision to the individual making the disclosure. The decision of the OHRI Board of Directors is final and binding.

REVIEW

20. The OHRI Board of Directors will review this Policy at least every three (3) years.

EXCEPTION

21. No exception may be made to this Policy without the written consent of the Board of Directors.

REFERENCES

The Ottawa Hospital's Conflict of Interest Policy
Sick Kids' Relationship Disclosure and Management Policy
Tri-Agency Framework: Responsible Conduct of Research (2016)

APPENDIX A: Public Health Service (PHS) Funded Research

*** Any terms not expressly defined within this Appendix A shall have the same meaning as that established in the policy outlined above*

PURPOSE

1. This Appendix A to the Conflict of Interest Policy (“Appendix A”) implements the requirements of the federal (US) regulations set forth in 42 CFR Part 50 and 45 CFR Part 94 governing the responsibility of researchers to promote objectivity in PHS-funded research. It sets out the internal processes for ensuring that research conducted at or under the auspices of OHRI with funding from PHS is free from bias resulting from Financial Conflicts of Interest. This Appendix A shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

APPLICATION

2. This Appendix A applies to Investigators who are planning to participate in, or are participating in any PHS-Funded Research conducted under the auspices of OHRI.

DEFINITIONS

3. For the purposes of this Appendix A:
 - (a) **“Designated Official(s)”** means the person(s) designated by OHRI to oversee the solicitation process and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or who is participating in PHS-Funded Research.
 - (b) **“Financial Conflict of Interest”** means a Significant Financial Interest that stands to *directly and significantly* affect the design, conduct, or reporting of the PHS-Funded Research.
 - (c) **“FCOI Report”** means a report concerning a Financial Conflict of Interest to PHS.
 - (d) **“Investigator(s)”** means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-Funded Research, which may include, for example, collaborators or consultants.
 - (e) **“PHS-Funded Research”** means research funded by or proposed to be funded by the United States Public Health Service or any of its organizational units, including without limitation the National Institute of Health (collectively, “PHS”).

- (f) **“Significant Financial Interest”** means a financial interest consisting of one or more of the following interests of an Investigator (including, for the purpose of this definition, those of his or her spouse and dependent children) that reasonably appears to be related to his or her OHRI responsibilities:
- i. With regard to any publicly traded entity, remuneration which has an aggregate value in the twelve months preceding the disclosure of over \$5,000USD.
 - ii. With regard to any non-publicly traded entity, remuneration which has an aggregate value in the twelve months preceding the disclosure of over \$5,000USD, or when the Investigator holds any equity interest in such entity;
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), solely upon receipt of income related to such rights and interests that exceeds \$5,000USD;
 - iv. Reimbursed or sponsored travel received in the preceding twelve months that is related to an Investigator’s OHRI responsibilities. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Exceptions: “Significant Financial Interest” does not include:

- i. salary, royalties, or other remuneration paid by OHRI to the Investigator if the Investigator is currently employed or otherwise appointed by OHRI,
- ii. intellectual property rights assigned to OHRI and agreements to share in royalties related to such rights;
- iii. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- iv. income from seminars, lectures, teaching engagements, service on advisory committees or review panels or travel expenses sponsored by 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.

REQUIREMENTS

4. Each Investigator shall be required complete training regarding this Appendix A that is offered by PHS (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html), and/or that is organized or otherwise provided by OHRI:
 - (a) prior to engaging in any PHS-Funded Research;
 - (b) upon his or her arrival at OHRI and at least every four (4) years thereafter; and,
 - (c) immediately upon the occurrence of any of the following circumstances:
 - i. any revision of this Appendix A which affects the requirements of Investigators; or,

- ii. the identification of non-compliance with this Appendix A or any management plan implemented by OHRI in response to his or her Financial Conflict(s) of Interest.
5. Each Investigator shall disclose in writing to OHRI a list of his or her Significant Financial Interests (and those of his or her spouse and dependent children):
 - (a) no later than the time of application or submission of the formal proposal for funding; **and**,
 - (b) during the period of the award, either on an annual basis or within thirty (30) days of his or her acquiring or discovering a new reportable Significant Financial Interest.
6. The Grants Office shall solicit the disclosures of Significant Financial Interests and refer them to the Designated Official(s) for review and assessment.

MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

7. Prior to the disbursement of any funds for PHS-Funded Research or within sixty (60) days of the identification of a new or previously undisclosed Significant Financial Interest, the Designated Official shall:
 - (a) review the Investigator's Significant Financial Interest disclosure(s); and,
 - (b) (i) determine whether the Significant Financial Interest is related to the PHS-Funded Research and, if it is, (ii) identify whether the Significant Financial Interest is a Financial Conflict of Interest.

For clarity, an Investigator's Significant Financial Interest is related to the PHS-Funded Research when it could be affected by the PHS-Funded Research or is in an entity whose financial interest could be affected by the PHS-Funded Research.

8. When a Financial Conflict of Interest is not identified or managed in compliance with the timelines set out above, OHRI shall - within 120 days - complete a retrospective review of the Investigator's activities to determine whether the design, conduct or reporting of the PHS-Funded Research was biased during the time period of the noncompliance.
9. If the Designated Official identifies a Financial Conflict of Interest, he or she shall refer the Investigator's Significant Financial Interest disclosure to the Working Group. The Financial Conflict of Interest shall be reviewed and assessed in accordance with the procedures identified in the Conflict of Interest Policy, and the Working Group or the Committee shall develop and implement a management plan that specifies the actions that have been, and shall be taken to manage, reduce or eliminate such Financial Conflict of Interest.
10. The Designated Official(s), the Working Group or the Committee may request additional information from the Investigator in connection with his/her/its review of any disclosure of a Significant Financial Interest.

11. Investigators shall comply with the review process identified hereunder, and any action taken by OHRI that it decides is necessary to manage, reduce or eliminate a Financial Conflict of Interest, including any management plan.

REPORTING OF FINANCIAL CONFLICTS OF INTEREST

12. OHRI shall provide FCOI Reports regarding any Investigator's Financial Conflict(s) of Interest to PHS in accordance with s50.605(b) (i.e. prior to the disbursement of funds, within sixty (60) days of any subsequently identified Financial Conflict of Interest or annually, as applicable). Where any such FCOI Report involves a Significant Financial Interest that was not timely disclosed by an Investigator or was not previously reviewed or managed by OHRI, OHRI shall further complete a retrospective review to determine whether the design, conduct or reporting of the PHS-Funded Research prior to the identification and management of the Financial Conflict of Interest was biased. If OHRI identifies any bias, it shall promptly notify PHS and submit a mitigation report.

13. For clarity, any information disclosed to OHRI under this Appendix A or related to its implementation and/or enforcement may be shared with PHS, strictly on a need-to-know basis and to support OHRI compliance with the federal regulations.

REMEDIES

14. Non-compliance with this Appendix A or any management plan implemented by OHRI in response to a Financial Conflict of Interest will be addressed in accordance with the Conflict of Interest Policy.

15. OHRI shall promptly notify PHS if the failure of an Investigator to comply with this Appendix A or a management plan implemented by OHRI appears to have biased the design, conduct, or reporting of the PHS-Funded Research, and of the corrective action taken or to be taken.

16. In any case in which PHS determines that PHS-Funded 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 a Financial Conflict of Interest that was not managed or reported by OHRI as required by the federal regulations, OHRI shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the PHS-Funded Research and to request an addendum to previously published presentations.