

# University Health Network Policy & Procedure Manual Research: Conflict of Interest of Research Personnel

## Policy

In keeping with its commitment to maintaining public confidence in research, University Health Network (UHN) addresses additional requirements that relate specifically to [conflicts of interest](#) (COIs) of [research personnel](#).

Research personnel will not conduct research or any actions involving the expenditure of research funds with a known and unmanaged COI. All research personnel must disclose, in writing, all actual, apparent, perceived and potential [COI situations](#). It is essential that research personnel maintain the highest standard of public trust and integrity.

All conflicts of interest will be disclosed and managed, approved or rejected in accordance with the process for [disclosure](#) as described herein.

In addition to their obligations regarding their individual COI situations, all research personnel have the obligation to report [institutional COI](#) situations to the executive vice-president (EVP) Science & Research.

This policy applies to all research personnel. Failure to adhere to this policy may result in disciplinary action up to and including termination of employment, engagement, appointment, or contract with UHN.

The UHN Research Ethics Board's review and determination regarding conflicts of interest is separate from the process in this policy.

## Disclosure

[Research personnel](#) will make a written disclosure to the EVP Science & Research or [designate](#) of all actual, apparent, perceived and potential [COI situations](#) in advance, or as the COI situations arise and/or become known. Disclosures will include sufficient information to allow the EVP Science & Research or designate to accept, reject or require management of a COI situation. The disclosure must also include notification of any additional reporting obligations related to the COI situation. (See [Conflict of Interest and Confidentiality Agreement Online](#).)

For [COIs](#) involving the leadership positions identified below, disclosure will be made, in writing, as follows:

- department/[division head](#) to EVP Science & Research
- EVP Science & Research to chief executive officer (CEO)

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Section	<b>Professional Practice</b>	Revision Dates	<b>12/10; 05/13; 10/16</b>
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- CEO to UHN Board of Trustees

## Annual Declaration

All [research personnel](#) are required, on an annual basis, to complete and submit a written declaration to the EVP Science & Research or designate, confirming that they have disclosed all [COIs](#) throughout that particular year as required by this policy, and that they are in compliance with the policy.

## Approval Process

[COI situations](#) are not permitted prior to review by the EVP Science & Research or designate. The EVP Science & Research or designate agrees to render decisions about managing COI situations in a timely fashion and in writing. In any review of a COI situation, the EVP Science & Research or designate may attach such terms and conditions as the EVP Science & Research or designate considers appropriate or necessary to manage the COI situation.

The [designate](#) will provide an annual report to the EVP Science & Research, summarizing all COI disclosures made to the designate, along with the management plans for managing the COI situation regarding the disclosures.

The designate may request that the EVP Science & Research review the COI situation according to the process for disclosures of [significant financial interest](#).

## Significant Financial Interest

The EVP Science & Research will review all disclosures involving [significant financial interest](#). The [research personnel](#) will provide sufficient information to allow the EVP Science & Research, to manage the [COI situation](#) involving the significant financial interest, including, but not limited to, the completion of a COI disclosure form. (See [Conflict of Interest and Confidentiality Agreement Online](#).) The EVP Science & Research may consult with other senior management (including the chair of the Research Ethics Board, if the research involves human subjects) as needed.

## U.S. Federal Funding

UHN [research personnel](#) participating in research funded by the U.S. Public Health Service (PHS), which includes National Institutes of Health (NIH), must also comply with PHS regulations [Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought](#) and [Responsible Prospective Contractors](#). (Refer to the [NIH Financial Conflict of Interest](#) webpage.) Investigators (including sub-investigators) applying for and receiving U.S. federal funding must:

- Complete and submit a UHN COI Disclosure and/or Annual Declaration prior to applying for funding, and continue to follow this policy throughout the period of the award.

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- Complete the UHN COI training module prior to starting the research and renew the training not less than every four years.
- Ensure that they have completed and submitted the required financial [conflict of interest](#) reports to the funding agency, both prior to the start of the research and annually throughout the award period.

## Management of COI Situations

[Research personnel](#) should propose a plan to manage their [COI situation](#) at the time of making the disclosure. The EVP Science & Research or [designate](#) has the discretion to assess adequacy and impose additional requirements that must be incorporated into the management plan.

The following conditions or restrictions could be proposed by the research personnel to manage COI situations (though others may also be included, depending on the nature and kind of the COI situation):

- ensuring no direct reporting relationship with research personnel's [immediate family](#)
- monitoring of the research by independent reviewers
- modification of the research plan, patient recruitment, or sites
- independent data collection or data analysis
- an independent data monitoring committee
- disqualification from participation in all or a portion of the research
- divestiture of financial interests
- non-acceptance of the gift, goods, or expenses
- severance of relationships that create the COI situation

## Confidentiality of COI Disclosures

The disclosure information will not be divulged without the written consent of the [research personnel](#), except:

- internally by UHN for the purposes of complying with policies, including this policy
- for the purposes of complying with applicable laws
- to cooperate with procedures being undertaken to address allegations of research misconduct
- where the research team involves other institutions, the institution administering the funds will copy the disclosure to other relevant institutions if a [significant financial interest](#) is involved or may be involved

UHN will share disclosures with funding agencies as required. If the research is to be conducted at more than one institution, the institution administering the grant funds will make the required disclosure to the funder (subject to the funder's direction).

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## Appeals Process

[Research personnel](#) may appeal a negative decision to the CEO or, in the case of research personnel covered by the Medical Staff By-laws, following procedures outlined in the Medical Staff By-laws.

## Responsibilities

### Research Personnel

- Review and maintain familiarity with current related UHN policies.
- Provide written disclosure to the EVP Science & Research or [designate](#) of all actual, apparent, perceived and potential [COI situations](#), in advance or as the COI situations arise and/or become known.
- Provide sufficient information to allow the EVP Science & Research to manage the COI situation by completing the COI disclosure form. (See [Conflict of Interest and Confidentiality Agreement Online.](#))
- Propose a plan to manage the COI situation at the time of making the disclosure.
- Report [institutional COI situations](#) related to research to the EVP Science & Research.

### EVP Science & Research/Designate

- Review and maintain familiarity with current related UHN policies.
- Review all disclosures and render decisions regarding managing [COI situations](#) in a timely fashion and in writing.
- Assess adequacy of management plan submitted and impose additional requirements, if required.
- Maintain confidentiality of disclosures according to this policy.
- [Designate](#) will provide annual report to the EVP Science & Research, including disclosures and management plan received and decisions made
- EVP Science & Research will review all disclosures involving [significant financial interest](#).
- EVP Science & Research, will review annual summary report from designates.

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## Definitions

**Conflict of interest (COI):** Activities or situations that place a person or institution in a real, perceived, or potential conflict between their duties or responsibilities related to research and their personal, institutional or other interests. A COI may include a [significant financial interest](#).

**COI situations:** [Conflicts of interest](#) that may occur when individuals' or institutions' judgements and actions in relation to research are, or could be, affected by personal, institutional or other interests, including, but not limited to, business, commercial, or financial interests, whether of individuals, their [immediate families](#), their friends, or their former, current or prospective professional associations or of the institution itself.

**Designate:** A department/[division head](#) designated by the EVP Science & Research, to receive and review disclosures of [COI situations](#) in accordance with this policy.

**Division head (or equivalent):** Heads of a clinical/research division, including the Cancer Clinical Research Unit (CCRU) at the Princess Margaret Cancer Centre.

**Immediate family:** Grandparents, uncles, aunts, cousins, parents, brothers, sisters, spouse, father-in-law, mother-in-law, brother-in-law, sister-in-law, nephews, nieces, children and grandchildren.

**Institutional conflicts of interest:** Those that may occur when UHN, any of its senior management or trustees, or a department, centre or other sub-unit, or an affiliated foundation or organization is in a real, perceived, or potential conflict between their duties or responsibilities related to research and their personal, institutional or other interests.

**Research personnel:** All personnel, paid by UHN, or by other sources, involved in the conduct of research. This includes, but is not limited to, those personnel working in laboratory, administrative, clinical or support areas.

**Significant financial interest:** Includes significant financial interests in the specific research (or in the specific research program) of the individual and means anything of monetary value, including, but not limited to, salary or other payments for service (e.g. consulting fees or honoraria), equity interests excluding mutual funds (e.g. stocks, stock options of other ownership interests) and intellectual property rights (e.g. patents, copyrights and royalties from such rights) where:

- such payments to the individual exceed \$10,000 annually, or
- the individual's equity interest exceeds five percent ownership or a value of \$10,000 (whichever is greater) at fair market value, or
- royalty payments received by the individual exceed \$10,000 annually

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## Related UHN Policies

1. [Intellectual Property Protection & Commercialization](#) policy 1.20.013
2. [Research Authorship](#) policy 40.60.001
3. [Conflict of Interest](#) policy 2.50.002
4. [News Releases](#) policy 1.50.003

## References

1. Granting Agency Policies: Tri-Council Memorandum of Understanding, Schedule 14 (CIHR) & U.S. Regulations 42 C.F.R. 50 Subpart F (NIH).
2. Toronto Academic Health Sciences Network (TAHSN) Statement: "Policy Requirements for a Research Financial Conflicts of Interest (FCOI) Policy", adopted May 2006.

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