



**THE QUEEN'S
MEDICAL CENTER**

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Owner Dawn Tani: Mgr,
Sponsored
Programs
Area Research
Applicability QMC + QMCW
AG

Investigator Significant Financial Interest Disclosure Policy, 610-21-177-B

1. POLICY

1. No individual shall use a position with The Queen's Medical Center (QMC), or confidential information acquired as a result of his or her position, to permit an actual, potential or implied conflict to arise between QMC's interests and such individual's personal interests.
2. Individuals shall not directly or indirectly accept any compensation or benefit (regardless of monetary amount) which, in any way, might tend to influence their judgment or actions concerning the best interests of QMC.
3. This policy is enacted to comply with relevant Federal regulations including Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought* and 45 CFR Part 94 *Responsible Prospective Contractors*. Investigators participating in PHS research at or under the auspices of QMC are required to follow the above mentioned CFRs along with this policy.

2. DEFINITIONS

1. **Associated Entity:** Associated entity of the Investigator means any trust, organization or enterprise other than QMC over which an Investigator exercises management control.
2. **Business:** Business means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or estate trust, any other legal entity organized for profit or nonprofit purposes, and any affiliated entity thereof, but excluding QMC or any other entity controlled by, controlling or under common control with QMC.
3. **Conflict of Interest:** A potential conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations such that an

independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. For purposes of this policy, *a conflict of interest exists when QMC, through procedures described herein, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of projects.*

4. **Financial Conflict of Interest (FCOI):** As defined in 42 CFR Part 50 Subpart F "means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research."
5. **Institutional Responsibilities:** As defined in Title 42 CFR Part 50 Subpart F means an Investigator's professional responsibilities on behalf of the Institution, which may include: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. This will be determined per job descriptions, contracts, and other available information.
6. **Investigator:** Investigator means the principal investigator/project director, co-principal investigators, sub-investigator, collaborating investigator, and/or any other person regardless of title or position, who is responsible for the design, conduct, or reporting of research activities funded by the Public Health Service (PHS), or proposed for funding, which may also include consultants. In this context, the term "Investigator" includes the investigator's family (including spouse, dependent children or stepchildren) or Associated Entity.
7. **Manage:** As defined in Title 42 CFR Part 50 Subpart F "means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias."
8. **PHS Awarding Component:** PHS is a division of the U.S. Department of Health and Human Services. Its awarding component is the organizational unit of the PHS that funds the research that is subject to this policy. The agencies include but are not limited to the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control (CDC), Food Drug and Administration (FDA), U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Healthcare Information System (HIS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).
9. **Research:** As defined in Title 42 CFR, research means "the systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award."
10. **Significant Financial Interest (SFI):** As defined in Title 42 CFR Part 50 Subpart F means "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 or stepchildren) that reasonably appears to be related to the Investigator's institutional responsibilities", but not limited to:

1. salary or other payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship and fees for serving on boards/advisors), which individually or in the aggregate, exceeds \$5000 in the twelve months preceding the disclosure;
2. equity interest (e.g., stocks, dividends, stock options or other ownership interests but excluding any interest arising solely by reason of investment in such business by a mutual fund, pension fund, other institutional investment fund or publicly traded stock over which the Investigator(s) does not exercise management control) which when valued as of the date of disclosure individually or in the aggregate, exceeds \$5000, including any equity interest in non-publicly traded entities;
3. intellectual property rights and interests (e.g., patents, copyright proceeds and technology transfer royalties and licensing fees), upon receipt of income related to such rights and interests; and/or
4. other items of value (e.g., bond interests, real or personal property, forgiveness of debt, loans, or gifts), which, individually or in the aggregate, total in excess of Five Thousand Dollars (\$5,000) in any one business, or represent more than Five Percent (5%) ownership interest in any one business.
5. 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. The disclosure will include at a minimum the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Further information may be requested including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
6. The term SFI does not include:
 1. salary, royalties, or other remuneration from QMC or QHS (The Queen's Health Systems) including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 2. income from seminars, lectures, teaching engagements, and travel (including reimbursement by the entities mentioned below) sponsored by a Federal, state, or local government agency, an institution of higher learning as defined at 20 U.S.C 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
 3. income from service on advisory committees or review panels for public or nonprofit entities;
 4. an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than five percent ownership in any single entity; or
 5. salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children over the

next twelve months, are not expected to exceed \$5,000; or

6. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decision made in these vehicles.

3. PURPOSE

1. This policy and procedure defines the steps to identify and manage Investigator's FCOI in relationship to PHS-funded research projects and their institutional responsibilities.
2. The purpose is to protect the credibility and integrity of QMC's researchers and staff so that public trust and confidence in QMC is ensured. Objectivity in research is preserved by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.
3. In accordance with federal regulations, QMC has a responsibility to manage, reduce or eliminate any actual or potential FCOI that may be presented by the financial interests of an Investigator.
4. Thus, QMC requires that Investigators disclose any significant financial interests (SFIs) that would reasonably appear to be affected by PHS-funded research or is in an entity whose financial interest could be affected by the research.

4. PROCEDURE

1. Each Investigator is required to disclose the following SFIs:
 1. any SFI of the Investigator (including spouse and dependent children), that meets the minimum requirements as defined in section 2.10 that reasonably appears to be related to the Investigator's institutional responsibilities.
2. Regardless of the above minimum requirements, a researcher or staff member, in his or her own best interest, may choose to disclose any other financial or related 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.
3. As required by Federal regulation, each Investigator must complete Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under any of the following circumstances: 1) QMC's SFI policies or procedures change in a manner that affects Investigator requirements; 2) an Investigator is new to QMC; 3) QMC finds an Investigator noncompliant with this policy.
 1. Training will be coordinated by ORD and the subsequent records will also be maintained within ORD to ensure compliance under this policy.
4. Each Investigator shall complete a Financial Disclosure Form (see attached Form 4) PRIOR to participating in a PHS-funded project and attach all required supporting documentation.
 1. The completed disclosure form must be submitted to the Office of Research and Development (ORD) before submission of the research proposal to the [to]PHS

Agencies using normal QMC procedures.

2. If an Investigator is new to a PHS-funded research project then disclosure shall be made prior to expenditure of funds as applicable, or Investigator's involvement in the project. In cases in which QMC identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, an FCOI report to the PHS Awarding Component is not required.
3. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted to ORD in a sealed envelope, marked confidential, and accompany the disclosure form. Additional information may be requested so that an appropriate determination can be made.
4. All disclosures must be updated by investigators at least annually during the period of the award or within thirty days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) new SFIs. Such disclosure should include any information that was not disclosed initially to the Institution, or in a subsequent disclosure of SFIs (e.g., any FCOI identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
5. The Director of the ORD at QMC, or official designee, shall conduct an initial review of all financial disclosures.
 1. If the initial determination is made that there exists an SFI as defined under this policy, then the disclosure packet will be referred to the appropriate QMC official.
 2. The Official then determines whether the SFI meets the definition of an FCOI. QMC may involve the Investigator in the determination of whether an SFI is related to the PHS-funded research.
 1. If the SFI is not determined to be an FCOI per this policy, then a report to the PHS Awarding component does not apply, and management, reduction, or elimination of the COI (if necessary), will be handled on a case by case basis.
 2. If the SFI is determined to be an FCOI, then the Official will take such actions as necessary to develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage the FCOI. The necessary details will be outlined in an agreement between QMC and the researcher. An initial report will be submitted to the appropriate PHS Awarding component. For any SFI that QMC identifies as conflicting subsequent to the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), QMC shall provide to the PHS Awarding Component, within sixty days, an FCOI report and ensure that it has implemented a management plan. Any FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the conflict and to assess the suitability of QMC's management plan. The FCOI report should include but are not limited to the following:
 - Project number;

- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded research and the basis for QMC's determination that the financial interest conflicts with such research;

A description of the key elements of QMC's management plan including: (i) Role and principal duties of the conflicted Investigator in the research project; (ii) Conditions of the management plan; (iii) How the management plan is designed to safeguard objectivity in the research project; (iv) Confirmation of the Investigator's agreement to the management plan (v) How the management plan will be monitored to ensure Investigator compliance; and (vi) Other information as needed.

3. Whenever QMC implements a management plan related to PHS-funded research, QMC shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project and submit the corresponding FCOI reports annually. The annual FCOI report should address the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project including extensions with or without funds.
4. Whenever an investigator has violated the terms of the agreement, the Official shall recommend disciplinary actions (see Section 5.2) or termination of the research project.
5. In addition, QMC shall follow federal regulations regarding the prompt notification of the sponsoring agency (if appropriate) of the corrective action taken or to be taken in the event an investigator has failed to comply with this policy, or if the FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.
 1. If such FCOI report involves a SFI without timely disclosure by an Investigator or, for whatever reason, was not previously reviewed or managed by QMC (e.g., without timely review or report by a subrecipient), the Institution has 60 days to make a determination, ensure the implementation of a management plan, and file the FCOI with the appropriate agency.
 2. A retrospective review is also required to be completed within 120 days of the noncompliance, to determine whether any PHS-funded research, or

portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. Retrospective review documentation shall include the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Reason(s) for the retrospective review
- Detailed methodology used for the review such as review process, methodology, review panel composition, and documents reviewed
- Review findings;
- Review conclusions.

If appropriate, QMC shall update the previously submitted FCOI report based on the results of the retrospective review and specify the actions that will be taken to manage the FCOI going forward. Additionally, if bias is found, QMC is required to notify the PHS Awarding Component promptly and submit a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, QMC will submit FCOI reports annually. Depending on the nature of the FCOI, QMC may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of QMC's retrospective review.

6. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.
7. In situations in which DHHS determines that a PHS-funded clinical research project 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 FCOI that was not managed or reported by QMC as required, QMC shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations. In addition, Investigators may also be subject to the retrospective review and

mitigation plan procedures described in 4.5.5.2.

6. Records of Investigator financial disclosures, reviews of, response to and all actions taken under QMC's policy or retrospective review, to manage actual or potential conflicts of interest (whether or not a disclosure resulted in the Institution's determination of an FCOI), shall be retained by the ORD until three years after the later of the termination or completion of the award to which they relate or other applicable dates as specified in 45 CFR 75.361.
 1. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and QMC's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the determination of an FCOI. QMC is required to submit, or permit on site review of, all records pertinent to compliance with Title 42 CFR Part 50, Subpart F and 45 CFR Part 94.
 2. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that QMC has not managed the FCOI in accordance with this subpart. The PHS Awarding Component may determine that imposition of special award conditions, or suspension of funding or other enforcement action, is necessary until the matter is resolved.
7. Collaborators/sub recipients/subcontractors/consortium partners from other not for profit or academic institutions must either comply with this policy or provide a certification from their institutions that they are in compliance with Title 42 CFR Part 50, Subpart F or 45 CFR Part 94 regarding SFI disclosure and that their portion of the project is in compliance with their Institutional policies.
 1. Whether the subrecipient's Investigators agree to comply with the subrecipient's FCOI policy or QMC's policy, the agreement shall specify time period(s) for the subrecipient to report all identified FCOIs to QMC. Such time period(s) shall be sufficient to enable QMC to provide timely FCOI reports to the PHS as required. In addition, if the subrecipient complies with QMC's policy then the disclosure shall be within a time period sufficient to enable QMC to solicit and review subrecipient Investigator disclosures in order that QMC may identify, manage, and report identified FCOIs in a timely manner.
 2. QMC is required to submit FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
 3. Subcontractors from commercial firms need not make a certification, except when the prime award is from the Public Health Service (PHS).
 1. The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with federal policies regarding SFI disclosure and that its portion of the project is in compliance with company policies.
 4. Each Investigator and other key personnel on studies where QMC is the institution of record must comply with the requirements of The Queen's Health Systems Code of

Conduct and Conflict of Interest Policy. Subrecipients are allowed to follow their own SFI policy as long as the subcontract specifies this term.

5. GUIDELINES TO ASSIST REVIEWERS TO MANAGE ACTUAL OR POTENTIAL FINANCIAL CONFLICTS OF INTEREST

1. Examples of conditions or restrictions that might be imposed to FCOIs include, but are not limited to:
 1. public disclosure of FCOIs when presenting or publishing the research including addendums to previously published research;
 2. monitoring of research by independent reviewers capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 3. modification of research plans;
 4. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 5. divestiture of SFI; and/or
 6. severance of the relationship that creates actual or potential conflicts.
2. Example of sanctions
 1. In the event the Official determines that a key individual has failed to comply with this policy and such noncompliance has, or has the appearance of biasing his/her professional activities, sanctions may include but are not limited to the following:
 1. provide written notification of the business in which the key individual has a significant financial interest in each public presentation of the conduct of results of the key individual's professional activities;
 2. require disclosure of the SFI in each public presentation of the conduct of results of the key individual's professional activities;
 3. potential suspension of funding of the key individual's professional activities related to FCOI; and/or
 4. such other disciplinary action as the Official or Sponsor deems appropriate.

6. NON-COMPLIANCE

1. The Official will complete a retrospective review as specified in 4.5.5 in cases of Investigator non-compliance with this Policy. QMC will notify the PHS Awarding Component promptly and submit a report in cases where bias is found. The report will address the impact of the bias on the research project and the actions QMC has taken, or will take, to eliminate or mitigate the effect of the bias.

7. PUBLIC ACCESSIBILITY

1. Prior to QMC's expenditure of funds under a PHS-funded research project, QMC shall ensure public accessibility via written response to any requestor within five business days of when the request was received concerning any significant financial interest disclosed to QMC that meets the following three criteria:
 - The significant financial interest was disclosed and is still held by the Senior/Key Personnel;
 - QMC determines that the significant financial interest is related to the PHS-funded research; and
 - QMC determines that the significant financial interest is a FCOI.

The information will include, at a minimum, the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. Any response to a written request will include current information as of the date of the correspondence. Information is subject to at least annual updates and within 60 days of a newly identified FCOI but the updated information must be requested under separate cover and will be available for three years from the date the information was most recently updated. PHS-funded research conducted by a subrecipient Investigator complying with their own FCOI policy will have the responsibility of making such information publicly accessible.

If you have any questions, please call the Office of Research and Development at 691-4843.

Attachments

 [Form 4 - Financial Disclosure Form](#)

Approval Signatures

Step Description

Approver

Date

Applicability

Queen's Medical Center, Queen's Medical Center West Oahu