



**Queen's implementation of the  
National Institutes of Health (NIH), Human and Health Services (HHS) and Public Health Service (PHS)  
Financial Conflicts of Interest  
Regulation 42 CFR Part 50 and 45 CFR Part 94**

<b>Queen's Office of Administrative Responsibility</b>	University Research Services ( <b>URS</b> ) under the purview of the Office of the Vice Principal (Research)
<b>Designated Official</b>	Executive Director, URS (or designate)
<b>Scope &amp; Purpose</b>	Applicable to all Investigators applying for and/or receiving funding from the Agency or working on a project funded by the Agency so as to promote objectivity in research and to ensure research is free from bias, as required under US Regulations <i>42 CFR Part 50 and 45 CFR Part 90</i>

**Overview**

The Agency has implemented a new Financial Conflict of Interest Policy (**the Regulation**). All grant applications and awards dated on or after 24 Aug 2012 are subject to the Regulation. Some sub awards granted prior to 24 Aug 2012 will be subject to the Regulation if the Prime Recipient elects to apply the Regulation retroactively. Queen's will not apply the Regulation retroactively to any award for which it is the prime recipient.

In certain circumstances, such as the determination of a Financial Conflict of Interest or a failure to disclose a Significant Financial Interest, the Agency may require some form of public reporting. Accordingly if you elect to

receive the Agency's award and comply with the Regulation then you will be asked to sign and return the attached disclosure and consent form. This form will allow Queen's to provide the reports required by the Regulation to the NIH and, if applicable, make the information publicly available. Please read the disclosure and consent form carefully and see parts 3 & 4 below for more information regarding this.

You may opt out of complying with the Regulation however this will mean that the award must be returned to the Agency (if already received), or you must relinquish the grant if the award has not yet been received. The Agency requires compliance by all recipients as a condition of any award and Queen's has no ability to remove this condition from the terms of the award.

The requirements of the Regulation only apply to funding applications / awards from the Agency and are in addition to any Queen's established policies and procedures or collective agreement provisions regarding conflicts of interest.

### **Purpose of this Information Memorandum**

- (a)** To clarify the Agency's reporting requirements regarding reporting of significant financial interests (**SFI**) by Investigators at Queen's;
- (b)** To outline the Agency's process by which the Designated Official confirms whether the SFI is connected to an Investigator's institutional responsibilities, and assesses whether it is a financial conflict of interest (**FCOI**) for a project funded by the Agency; and
- (c)** To outline the Agency's expectations of the Designated Official, Queen's and the Investigator in managing and reporting FCOI's to the Agency, in order to comply with the Regulation.

### **Procedure**

1. Reporting by Investigators
2. Assessment and record-keeping by the Designated Official
3. Agency Requirements Regarding Management and Reporting of a FCOI
4. Agency Requirements Regarding Training, Sub Contracting and Public Accessibility of Information
5. Non-Compliance
6. Definitions
7. Declaration by Investigator
8. Disclosure & Consent by Investigator

#### **1. REPORTING BY INVESTIGATORS**

##### **1.1 Who Must Disclose:** All Investigators who are:

- applying for and/or receiving funding from the Agency; or
- working on a project funded by the Agency,

whether directly or through a subcontract, must disclose any SFI in writing to the Designated Official. See the Definitions section at part 6 to assist you in understanding what the Agency considers to be a SFI.

The Agency requires disclosure of any SFI (including any SFI held by the Investigator's spouse or dependent children) to be made at the following times:

##### **(a) Initial Disclosure:** the initial disclosure must:

- (i)** be made at least 30 days before the time of the application to the Agency; and
- (ii)** include all SFI's in the 12 months preceding the application to the Agency.

- (b) Ongoing Disclosure:** the Agency requires ongoing disclosure at the following periods:
  - (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 Agency funded research. This includes providing updated information on a previously disclosed SFI.
  
- (c) New to Queen's:** All Investigators who are new to Queen's and are applying for and/or receiving funding from the Agency, or who are participating in an Agency-funded research project, must make the initial disclosure and ongoing disclosures noted above.

**1.2 Steps to Disclose a Significant Financial Interest:** To disclose a SFI to Queen's:

- (a)** the Investigator, on behalf of themselves; their spouse; or dependent children must complete the Disclosure and Consent Form for Significant Financial Interests attached to this Information Memorandum and return it to the Designated Official.
  
- (b)** the entity or individual in which the Investigator, his/her spouse or his/her dependent children has a SFI must complete the Informed Consent by Third Parties for Disclosure of Personal Information Form attached to this Information Memorandum. The entity or individual must return that Consent Form to the Investigator. The Investigator must return the Consent Form to the Designated Official.

As discussed in the Overview above the disclosure and consent form(s) attached to this Information Memorandum include the right for Queen's to notify the Agency, and provide to the Agency any reports it may require pursuant to the provisions of the Regulation. Additionally, the disclosure and consent form(s) will allow Queen's to make certain information publicly available, as required by the Regulation.

**2. AGENCY REQUIREMENTS REGARDING ASSESSMENT AND RECORD-KEEPING BY DESIGNATED OFFICIAL**

**2.1** The Agency requires that the Designated Official must review all disclosures of SFI's from Investigators, including sub recipient Investigators, within the timeframes noted below and to determine whether or not:

- (a)** the disclosure is related to the Agency funding

The Agency's policy is that the SFI is related to Agency funded research when the Designated Official may reasonably determine that the SFI:

- (i)** could be affected by the Agency-funded research; or
- (ii)** 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 or not a SFI is related to Agency-funded research.

- (b)** each SFI is a FCOI

According to Agency policy a FCOI exists when Queen's, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Agency-funded research.

- 2.2** The review and determination noted above must be conducted by the Designated Official at the following times:
- (a)** prior to Queen’s expenditure of any funds under an Agency-funded research project. This means that your research account may not be authorized until after the Agency’s requirements on disclosure and assessment have taken place.
  - (b)** within 60 days whenever, in the course of an ongoing Agency-funded project, an Investigator or sub recipient Investigator who is new to participating in the project, discloses a SFI or an existing Investigator or sub recipient Investigator discloses a new SFI to Queen’s; and
  - (c)** within 60 days whenever Queen’s identifies a SFI that:
    - (i)** was not disclosed in a timely manner by an Investigator or sub recipient Investigator; or
    - (ii)** for whatever reason, was not previously reviewed by the Designated Official during an ongoing Agency-funded project.
- 2.3 Record Keeping:** the Designated Official must maintain records relating to all Investigator disclosures of SFI’s and Queen’s review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI) and all actions under the Agency’s Regulation; the Agency’s policy; or any retrospective review related to the SFI and/or FCOI (if applicable). Pursuant to the Agency’s requirements the records must be kept for at least 3 years from the date the final expenditures report is submitted to the Agency, the date of final payment; or where applicable, for other time periods specified.
- 2.4** The Agency may inquire at any time (before, during or after an award) into any Investigator disclosure of financial interests and Queen’s review of, and response to, such disclosure, whether or not the disclosure resulted in Queen’s determination of a FCOI. This includes situations in which an Investigator moves from one university to another.
- 2.5** Queen’s is required to submit to the Agency, or permit the Agency on site to review, all records pertinent to compliance with the Regulation.

### **3. AGENCY REQUIREMENTS REGARDING MANAGEMENT AND REPORTING OF FCOI**

- 3.1** If the Designated Official determines that there is a FCOI, the Agency requires the Designated Official to prepare a FCOI management plan to manage the FCOI. The Agency specifies that the key elements of the management plan should include:
- role and principal duties of the conflicted Investigator;
  - 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;
  - other information as needed.

Agency examples of conditions or restrictions that might be imposed to manage a FCOI:

- public disclosure of FCOI (e.g., when presenting or publishing research);
- for research projects involving humans, disclosure of 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 a 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.

### 3.2 Other Agency Requirements

- (a) the Investigator is required to comply with the management plan prescribed by the Designated Official;
- (b) on behalf of Queen's, the Designated Official must monitor compliance with the management plan on an ongoing basis until the completion of the Project.

### 3.3 Agency Reporting Requirements: Queen's, through its Designated Official, must provide initial and ongoing FCOI reports to the Agency as applicable:

- (a) after the award is granted but prior to any expenditure of any funds;
- (b) annually at the same time as the annual progress report is due:

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

- (c) in the time and manner specified by the Agency for any other FCOI reports for the duration of the project period (including extensions with or without funds).
- (d) sub recipients: Queen's must provide FCOI reports to the Agency regarding all FCOI's of all sub recipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

FCOI reports must include sufficient information to enable the Agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of Queen's management plan. Each FCOI report prepared by the Designated Official must contain:

- the 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 FCOI;
- name of the entity with which the Investigator has a 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 and \$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.
- a description of how the financial interest relates to Agency-funded research and the basis for Queen's determination that the financial interest conflicts with such research; and
- key elements of Queen's management plan.

#### **4. AGENCY REQUIREMENTS: TRAINING, SUB CONTRACTING AND PUBLIC ACCESSIBILITY OF INFORMATION**

**4.1 Training:** The Agency requires Queen's to provide the following mandatory training to Investigators, as prescribed in the Regulation:

- (a) inform each Investigator of the Agency's requirements on FCOI's and Queen's implementation of those requirements;
- (b) inform each Investigator of the Agency's requirements regarding disclosure of SFI's and the Regulation; and
- (c) require each Investigator to complete training regarding the implementation of the Agency's Regulation at Queen's and the Investigator's responsibilities pursuant to the Regulation. The training periods set down by the Agency are:
  - (i) prior to engaging in Agency-funded research;
  - (ii) at least every 4 years; and
  - (iii) immediately when any of the following circumstances apply:
    - there are revisions to the Regulation and resulting policies;
    - an Investigator is new to Queen's;
    - Queen's finds that an Investigator is not in compliance with the Agency's Regulation or with an agreed upon management plan.

The Investigator must undertake such training from Queen's.

The NIH has provided an informative online tutorial to supplement the training offered by Queen's. The tutorial takes approximately 30 minutes to complete and you may print a certificate of completion at the end of the tutorial. We ask that you undertake the tutorial and provide us with a copy of your certificate of completion when you return the signed disclosure and consent form(s) to us. The tutorial is found at: <http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm>

**4.2 Sub Contracting:** if Queen's carries out Agency-funded research through a sub recipient, then Queen's must take reasonable steps to ensure that any sub recipient Investigator complies with the Regulation by:

- (a) incorporating, as part of the written agreement with sub recipient, terms that establish whether the Regulation as implemented at Queen's will apply, or whether the sub recipient has its own FCOI policy that will apply to the sub recipient's Investigators;
- (b) incorporating a provision whereby the sub recipient warrants that its FCOI policy complies with the Regulation, specifically 42 CFR Part 50 or 45 CFR Party 94 if the sub recipient elects to follow its own FCOI policy; or

- (c) incorporating a provision whereby the sub recipient Investigators must comply with the implementation of the Regulation at Queen's. If this is agreed between the parties then Queen's must obtain a written agreement specifying time periods for the sub recipient to submit all Investigator disclosures of SFI's to Queen's. Such time periods must be sufficient to enable Queen's to comply in a timely fashion with its review, management and reporting obligations under the Regulation.

**4.3 Public Accessibility of Information:** pursuant to the Regulation the Agency requires that Queen's must:

- (a) maintain an up-to-date, written, enforced policy (and associated procedures) on financial conflicts of interest that comply with the Agency's regulations and make such policy available via a publicly accessible website. This Information Memorandum is part of Queen's compliance with the Agency's requirements.
- (b) Make available, via publicly accessible website or in writing within 5 business days of any request, the information listed in part 4.3(c) below concerning any SFI that meets the criteria below. Note that Queen's must do this prior to the expenditure of any award funds:
- SFI was disclosed and is still held by the Investigator who has been identified by Queen's as senior/key personnel for the Agency-funded research project in the grant application, contact proposal, contract, progress report, or other required report submitted to the Agency;
  - Queen's determines that the SFI is related to Agency-funded research; and
  - Queen's determines that the SFI is a FCOI.
- (c) post on the publicly accessible website, or make available in response to written requests, the following minimum information:
- Investigator's name;
  - Investigator's position with respect to the research project;
  - nature of the SFI;
  - approximate dollar value of the SFI;
    - \$0 - \$4,999;
    - \$5,000 - \$9,999;
    - \$10,000 - \$19,999;
    - amounts between \$20,000 and \$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,
  - the entity with which the Investigator has a FCOI,
- to enhance transparency and accountability in accordance with the Agency's requirements.
- (d) Queen's is required to update the above-noted information within 60 days when there are changes to the information and, at a minimum, shall update the information annually.
- (e) the above-noted information, as updated, shall remain available for responses to written requests or for posting via Queen's publicly accessible website for at least 3 years from the date that the information was most recently updated.

## 5. NON-COMPLIANCE

The Agency considers that non-compliance with the Regulation constitutes misconduct in relation to the Agency-funded research. The Agency requires Queen's to follow the Regulation regarding any event of non-compliance with Agency-funded projects. Queen's is obliged to follow the Agency's requirements and recommendations if there is Investigator non-compliance. The Agency's requirements are set out in this section. Queen's may also review any non-compliance in accordance with relevant collective agreement(s); policies and regulations applicable to research at Queen's.

**5.1 Retrospective Review and Mitigation:** whenever Queen's identifies a SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing Agency-funded project (including but not limited to when the SFI was not reviewed in a timely fashion or reported by a sub recipient):

**(a) Determination:** the Designated Official must, within 60 days, determine whether:

- (i)** the disclosures relate to Agency-funded research; and
- (ii)** an Investigator's SFI is related to Agency-funded research when the Designated Official reasonably determines that the SFI;
  - could be affected by the Agency-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 a SFI is related to the Agency-funded research.

The Agency has determined that each SFI is a FCOI if the Designated Official at Queen's reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the Agency-funded research.

**(b) Management Plan:** if the Designated Official determines that a 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 the FCOI going forward.

**(c) Retrospective Review:** within 120 days of a determination of non-compliance, Queen's must complete a retrospective review of the Investigator's activities in relation to the Agency funded project to determine whether any Agency-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.

**(d) Documentation:** Queen's is required to document the retrospective review, such documentation must 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 a 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.

**(e) Report:** based on the results of the retrospective review, if appropriate, Queen’s must update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found then Queen’s is required to notify the Agency promptly and submit a mitigation report to the Agency. The mitigation report must include, at a minimum, the key elements cited in part 5.1 (d) above and a description of the impact of the bias on the project and Queen’s plan of action(s) 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).

**(f) Annual Reports:** Queen’s must, thereafter, submit FCOI reports annually as specified in part 3.3 of this Information Memorandum.

**5.2 PHS Funded Clinical Research:** in any case in which the HHS determines that a PHS-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 a FCOI that was not managed or reported by Queen’s as required by the Regulation, Queen’s must not only require the Investigator involved to disclose the FCOI in each public presentation of the results of the research, but also request an addendum to previously published presentations.

**5.3 Agency Rights Regarding Determination of Bias:** on the basis of its review of records or other information that may be available, the Agency reserves the right to decide: that a particular FCOI will bias the objectivity of the Agency-funded project to such an extent that further corrective action is needed; or that Queen’s has not managed the FCOI in accordance with the Regulation. The Agency 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. DEFINITIONS

The following is a synopsis of the Agency’s definitions:

<p><b>Investigator</b></p>	<p>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 Agency or proposed for such funding, which may include, for example, collaborators or consultants. Investigator also includes senior / key personnel identified as such by Queen’s or Prime Recipient in the grant application, progress report, or any other report submitted to the Agency by Queen’s or Prime Recipient under the Regulation.</p>
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**Significant Financial Interest (SFI)**

- (1) **(financial interests)** 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) **(publicly traded entity)** With regard to any publicly traded entity, a SFI 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); 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) **(non-publicly traded entity)** With regard to any non-publicly traded entity, a SFI 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)** Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests or upon the filing of a patent application, whichever is earlier.
- (2) **(sponsored travel)** 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; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by an US federal, state, or local government agency, an US institution of higher education, or an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an 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 a FCOI with the Agency-funded research.

- (3) **(exclusions)** The term SFI does not include the following types of financial

	<p>interests:</p> <ul style="list-style-type: none"> <li>(a) <b>(salary or other remuneration paid by Queen’s)</b> salary, royalties, or other remuneration paid by Queen’s to the Investigator if the Investigator is currently employed or otherwise appointed by Queen’s, including intellectual property rights assigned by Queen’s and agreements to share in royalties related to such rights;</li> <li>(b) <b>(investments out of Investigator’s direct control)</b> 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;</li> <li>(c) <b>(teaching / lecture income affiliated with certain US entities)</b> income from seminars, lectures, or teaching engagements sponsored by a US federal, state, or local government agency, and US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education; or</li> <li>(d) <b>(service or advisory income affiliated with certain US entities)</b> income from service on advisory committees or review panels for an US federal, state, or local government agency, an US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education.</li> </ul>
<p><b>Designated Official</b></p>	<p>The individual appointed to this position at Queen’s, currently, the Director of the Office of Research Services and under the purview of the Vice Principal (Research).</p>
<p><b>Institutional Responsibilities</b></p>	<p>Queen’s obligations to the Agency on submission of a grant application or receipt of award funds include duties such as:</p> <ul style="list-style-type: none"> <li>(a) participation in teaching programs;</li> <li>(b) participation in research and dissemination of the results of research by means appropriate to the discipline;</li> <li>(c) provision of service to the discipline of the staff member; participation in the governance of Queen’s, the Faculty and the Department; and dissemination of knowledge to the general public by making available the staff member’s expertise and knowledge of the discipline all of which shall be carried out according to the standards of professional conduct expected of a staff member;</li> <li>(d) clinical service, in conjunction with one of Queen’s affiliated hospitals, if identified in the staff member’s job description; and</li> <li>(e) any other responsibility outlined in the staff member’s job description, employment agreement or appointment letter with Queen’s, in a post-doctoral fellow’s appointment letter with Queen’s; in applicable policies; or as identified Queen’s Calendar as a responsibility of a student to Queen’s (as applicable).</li> </ul>

<b>Financial Conflict of Interest (FCOI)</b>	A SFI that could directly and significantly affect the design, conduct, or reporting of Agency-funded research.
<b>Disclose</b>	An Investigator's disclosure of SFI's to Queen's.
<b>Financial Interest</b>	Anything of monetary value, whether or not the value is readily ascertainable.
<b>Manage</b>	Taking action to address a FCOI, which may 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.

## 7. DECLARATION

I have read and understood this Information Memorandum entitled "Information Memorandum National Institutes of Health (NIH), Public Health Service (PHS) and Health and Human Services (HHS) Financial Conflict of Interest (FCOI) Regulation 42 CFR Part 50 and 45 CFR Part 54".

I make the following declaration (check all statements that apply):

- If I am the Principal Investigator and I wish to opt out of compliance with the Agency's Regulation. I hereby authorize Queen's to advise the Agency / Prime Recipient that I am unable to accept the award and or to negotiate with the Agency to replace Queen's Principal Investigator with a suitably qualified Investigator who is in a position to comply with the Agency's Regulation.
- If I am not the Principal Investigator and I wish to opt out of compliance with the Agency's Regulation, I hereby authorize Queen's Designated Official to advise the Queen's Principal Investigator that I cannot take part in the Agency-funded research project and I understand the full ramifications of this choice.
- I agree to comply with the Agency's Regulation and will complete /have completed the following disclosure and consent form(s):
  - Disclosure & Consent Form on behalf of myself; my spouse and/or dependent child(ren);
  - Third Party Disclosure & Consent Form
- I understand and acknowledge that in addition to my obligations to the Agency, Queen's University also has obligations to the Agency as set out in this document in relation to the Agency Award for which I am the Investigator.
- I have completed the NIH FCOI online tutorial and attach a copy of my certificate of completion for Queen's records.
- If I am the Principal Investigator under the Award (for Agency-funded research conducted at Queen's) I advise I have provided a copy of this Information Memorandum to the following Investigators / Senior or Key Personnel (as those terms are defined by the Agency) involved in the Agency-funded research. Additionally, I confirm that I have instructed each Investigator / Senior or Key Personnel to return their signed documentation directly to Queen's Designated Official.

I understand this is an ongoing requirement and the Information Memorandum must be provided to any new Investigator / Senior or Key Personnel during the term of the Agency-funded research project.

Date:

\_\_\_\_\_  
Investigator Name:

Title:

Institution (if other than Queen's):