ORE 101 Appendix B:

UNIVERSITY OF WATERLOO

Conflict of Interest Disclosure Form
(pursuant to Policy 69)

and

Researcher Declaration of Conflict of Interest

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<th>Name:</th>
<th>Department:</th>
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<td>Title and Rank:</td>
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<td>Study Title:</td>
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<td>Investigator(s):</td>
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<td>ORE #:</td>
<td>Academic Year:</td>
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This form is intended to answer the requirements for declarations of conflict of interest pursuant to University of Waterloo Policy 69, “Conflicts of Interest,” and pursuant to the requirements of the Tri-Council Policy Statement, 2nd ed. (TCPS 2).

Part I of this form relates to the Policy 69 requirement. Please refer to Policy 69 for additional explanation of its requirements.

Part II relates to the TCPS 2 requirement. Appropriate excerpts from the TCPS 2 are repeated in Part II below to explain its requirements.

Once identified, conflicts of interest are to be managed according to the terms of Policy 69 and in a manner satisfactory to the REB.

**PART I - POLICY 69 CONFLICT OF INTEREST DISCLOSURE**

1. Compensated External Professional Activity (consulting, board memberships, teaching, etc.)

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<th>Company or Organization</th>
<th>Description of Relationship, Form of Compensation, and Conflict or Potential Conflict of Interest</th>
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Approved: Secretariat, April 23, 2013. Revised April 1, 2014; December 22, 2015
2. Business Interests and Relationships (personal, family or other)

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3. Other External Activities

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PART II - TCPS 2 CONFLICT OF INTEREST DISCLOSURE

Part II of this form should be used to ensure that any real or perceived conflicts of interest are fully disclosed by all members of the research team as part of the ethical review process and that appropriate steps are taken to minimize or manage the conflict.

“Researchers and research students hold trust relationships, either directly or indirectly, with participants, research sponsors, institutions, their professional bodies and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty. Although the potential for such conflicts has always existed, pressures on researchers (e.g., to delay or withhold dissemination of research outcomes or to use inappropriate recruitment strategies) heighten concerns that conflicts of interest may affect ethical behaviour.” (TCPS 2, p. 91)

“Researchers’ conflicts of interest may arise from interpersonal relationships (e.g., family or community relationships), financial partnerships, other economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm), academic interests (e.g., dual role as researcher and instructor) or any other incentives that may compromise integrity or respect for the core principles of this Policy. Conflicts may arise from an individual’s involvement in dual and multiple roles within or outside an institution. While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.” (TCPS 2, p. 91)

For each specific conflict of interest identified below (i.e., a “yes” response), a brief description of the nature of the conflict must be provided. Additionally, if a conflict of interest is identified, the mitigation mechanism section must be completed.

The existence of a conflict of interest, whether real or perceived, does not imply wrongdoing on anyone’s part.
**Financial Conflicts of Interest:**

Does the principal investigator or any other member of the research team (e.g., co-investigators, collaborators), and/or their partners/spouses or dependents:

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<tr>
<td><strong>1.</strong> Have a proprietary interest(s) or potential proprietary interest, in the product under study or the outcome of the research including, but not limited to, patents, trademarks, copyrights and licensing agreements?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td><strong>2.</strong> Within the last 12 months, have a financial, equity or other interest in the sponsor of the study, or a competitor of the sponsor, including, but not limited to, ownership interest, stock options or other financial interest?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td><strong>3.</strong> Receive financial arrangements whereby the value of the compensation could be influenced by the outcome of the study? For example, personal remuneration that is significantly greater for a favourable outcome, or compensation to the investigator in the form of equity interest in the sponsor or a competitor of the sponsor, or compensation tied to sales of product such as royalty interest.</td>
<td>Yes [ ] No [ ]</td>
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4. Within the last 12, receive any payment(s) of other sorts from the sponsor or a competitive company? For example, grants to fund ongoing research, compensation in the form of equipment, travel funds, honoraria, or publication planning services? **Disclose any amount in excess of $5000 and state the amount.**

If **yes**, please describe:

| Yes [ ] No [ ] |

5. Are there any other financial conflicts of interest which may affect this research?

If **yes**, please describe:

| Yes [ ] No [ ] |

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**Mitigation Mechanisms for Financial Conflicts of Interest:**

Please indicate which of the relevant mitigation mechanisms listed below will be used to minimize or manage the real, potential or perceived financial conflicts of interest specified above. At minimum, all conflicts of interest are to be fully disclosed to participants during the information and consent process, preferably in writing in an information and consent letter. The disclosure should also mention the additional mitigation mechanisms, if any, which will be implemented.

1. The researcher(s) will disclose financial interests during the information and consent process, preferably in writing in an information and consent letter.

   ___ Yes
   ___ Not Applicable. Please explain:
2. The researcher(s) will disclose conflicts of commitment during the information and consent process, preferably in writing in an information and consent letter (e.g., researcher who is an owner or senior manager in the sponsoring firm, researcher who has a personal relationship with member(s) of the sponsoring firm, researcher with a previous affiliation with the sponsoring firm).

___ Yes
___ Not Applicable. Please explain:

3. The researcher(s) will divest financial interests (e.g., put shares into a blind trust).

___ Yes
___ Not Applicable. Please explain:

4. The researcher(s) will arrange to have the study monitored by independent reviewers (e.g., a data safety management board for a Health Canada regulated clinical trial).

___ Yes
___ Not Applicable. Please explain:

5. Other optional mitigation mechanisms:

□ Provide a detailed study budget to the Office of Research for independent review.
□ Members of research team have completed training on conflict of interest (e.g., CITI Canada, NIH).

6. Additional mechanisms the researcher(s) will put in place (list below):

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
**Non-financial Conflicts of Interest:**

1. Are there any other conflicts of interest of a non-financial nature (e.g., interpersonal relationships, academic interests, other incentives) that may affect or influence study participants and impede voluntary participation, restrict participant autonomy or prevent informed choices being made?  
   If yes, please describe:  
   Yes [ ] No [ ]

2. Is there any other non-financial conflict of interest which may affect the conduct of the research or its scholarly integrity or scientific merit?  
   If yes, please describe:  
   Yes [ ] No [ ]

**Mitigation Mechanisms for Non-financial Conflicts of Interest:**

Please indicate which of the relevant mitigation mechanisms listed below will be used to minimize or manage the real, potential or perceived conflicts of interest specified above. At minimum, all conflicts of interest should be fully disclosed to participants during the information and consent process, preferably in writing in an information and consent letter. The disclosure should also mention the additional mitigation mechanisms, if any, which will be implemented.

1. The researcher(s) will disclose conflicts of commitment during the information and consent process, preferably in writing in an information and consent letter (e.g., researcher or collaborator recruiting people over whom they have a position of influence/authority).
   ___ Yes  
   ___ Not Applicable. Please explain:
2. The researcher(s) will arrange to have the study monitored by independent reviewers (e.g., a data safety management board for a Health Canada regulated clinical trial).

___ Yes
___ Not Applicable. Please explain:

3. Other optional mitigation mechanisms:
   □ Members of research team have completed training on conflict of interest (e.g., CITI Canada, NIH).

4. Additional mechanisms the researcher(s) will put in place (list below):
   __________________________________________
   __________________________________________
   __________________________________________

Declarations:

□ I have completed this form and I am satisfied I have fully describe all real, potential or perceived conflicts of interest associated with this research. I am also satisfied that the proposed mitigation mechanisms will address the conflict of interest issues described.

□ If the research is a clinical trial as defined by the University of Waterloo guideline, I will register the study on clinicaltrials.gov. All clinical research should be registered, even if not a clinical trial.

□ I will report all research results, and avoid selective reporting of results which are favourable to the sponsor’s objectives or a participating or collaborating individual, organization or community.

□ I will not exert undue pressure on or coerce potential participants, nor incorrectly apply exclusion or inclusion criteria, in order to meet the sponsor’s site recruitment targets or those of a participating or collaborating individual, organization or community.

Name of Principal Investigator: __________________________
Signature of Principal Investigator: ______________________
Date: ____________
Name of any additional research team member with conflict: _________________________
Signature: ______________________
Date: ___________

Name of any additional research team member with conflict: _________________________
Signature: ______________________
Date: ___________