# UNIVERSITY OF WESTERN ONTARIO INVESTIGATOR PROCEDURES

## FOR COMPLIANCE WITH THE U.S. PUBLIC HEALTH SERVICE FINANCIACONFLICT OF INTEREST REGULATION

#### I. INTRODUCTION AND APPLICATION OF INVESSIGATOR OCEDURES:

ThesenvestigatorProcedures are made under the University of Western Ontario Policy on <u>Academic Integrity in Research Activities, MAP</u>,Perff@ctive date September 24, 2013, and are supported by the <u>UWOFA Collective Agreement 262/8622</u>, Article Academic Responsibilities of Members

The University of Western Ontario ("Westerni") committed to ensuring the highest standards of must ensure that in research their conduct meets University standards and best practices professional and disciplinary standards, applicable laws and regulations, and the integrity standards of any entities sponsoring any component of research work.

Where research is funded by the U.S. Public Health Service (PHS), which includes the N Institutes of Health (NIḤ) he following U.S. regulationegarding Financial Cobicts of Interest (FCOI) applies

42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in

Together, thenvestigator

intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. Western's PHSCOI Investigator rocedures apply those that meet the Investigator definition, which includes, but is not limited the DP/PIs.

- f Senior/keyPersonnel:Theprincipal Investigatoor projectdirector, and anyother person identified assenior/keypersonnel by Westernin the grant application, progress report, or anyother report submitted to the PHS by Westernunder the Regulation (or, in the case of a research contract for the U.S. government anyother personidentified assenior/keypersonnel in the contract proposal and contract).
- f Significant Financial Interest (SFI): A Financial Interest that reasonably appears to be related to the Investigator's Professional Responsibilities:
  - 1. with regard to a publicly traded entity, the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure exceeds,000USD
  - 2. with regard to a norpublicly tradedentity:
    - a) the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosureeds
      - 2. von7.2 (t)-4.3 (7.5 ( d)2.9 (i)-3.2 (n)-0.8 (g p)7.6 (t)-6 ((o)-9

### a) What to Disclose

Investigators must disclose their Significant Financial Interests (including Sponsored Travel). If an Investigator is not sure whether a particular Financial Interest is significant should be disclosed, the hould disclose it.

Parts IV and V below seut the actions Westerand the PHS will take to ensure

The decisin of the Designated Official final.

#### 4) Management of FCOIs and Managementans

Where an FCOI is found to exist, Westwith take such actions as are necessary to manage the FCOI, including developing and implementing a management plan and, where required, conducting a redispective review (see section below).

The principal Investgator and the Chair and Deanof the Investigator's academic unit (or delegate) will develop a management plan, in consultation as appropriate with the Investigator determined to have an FCOI. The management plan must specify the actions that have been and will be taken to manage the FCOI, including a mechanism for monitoring compliance with the management plan until the completion of the subject research project, and will be subject the approval of the Designated Official. The management plan will specify who is responsible for implementing the management plan and monitoring Investigator compliance until completion of the research. This will ordinarily (but not always) be the Chair or Deanthe Investigator's academic unitor delegate).

In addition, where an FCOI was not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined to be an FCOI or to comply with an FCOrhanagement plan), Westerwill, within 120 days of determination of non-compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in its design, conduct or reporting.

6)

- iii. the nature and approximate dollar value of that.
- 8) Other Obligations of the University

In addition to the specific obligations set outabove, Westerrwill comply with all other institutional obligations mandated by the FC@egulation(and set out in the Institutional Procedures), including, but not limited to, the following:

i. posting these Investigator rocedures and the Institutional Procedures on the publicly accessible website of the Virtuesident, Research (Westerstate964rch)e10.7 (w)-6.4 (e)-693 (t)-5.9 (e)-0.02-plnh)

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#### Financial Administration

- f Western Financial Services JS Federal Award Requirements
- f Western Financial Services/Procurement Services Procurement Practices
- f <u>UWO Procurement Code of Eth</u>ics

(Last revised: May, 2021)