

## CONFLICT OF INTEREST DISCLOSURE FORM PACKET

### Guidance on Conflicts of Interest (COI) in Research

#### Purpose

This guidance ensures transparency and integrity in research by defining key terms, outlining disclosure requirements, and illustrating common COI scenarios for Covered Individuals (faculty, staff, postdocs, and others responsible for research design, conduct, or reporting).

#### Operating Definitions

**Covered Individual:** Anyone responsible for the design, conduct, or reporting of research, including PIs, co-investigators, and project directors.

**Family Member:** Includes spouse, dependent children, and any person financially dependent on the Covered Individual or sharing joint financial interests.

**Conflict of Interest (COI):** Any situation that could bias—or appear to bias—research decisions. COIs may be financial or non-financial.

**Financial Conflict of Interest (FCOI):** A financial interest that could directly and significantly affect the design, conduct, or reporting of research.

**Institutional Responsibilities:** All professional duties performed on behalf of WesternU, including research, teaching, clinical practice, and committee service.

**Research:** Any systematic investigation intended to contribute to generalizable knowledge, including basic and applied research and product development.

#### Disclosure Requirements

Disclose within 30 days of employment, annually, and within 30 days of acquiring a new interest.

Significant Financial Interests ( $\geq$  \$5,000) include payments, equity, IP rights, royalties, sponsored travel, gifts > \$500, fiduciary roles, in-kind support, and outside research activities. Exclusions: internal salary, government/academic income, advisory service income, investment vehicles without direct control, government-sponsored travel.

#### Examples of COI Scenarios

- A PI owns stock in a company sponsoring their research project.
- A faculty member receives consulting fees from a pharmaceutical company whose drug is being tested in their lab.
- A researcher holds a patent on a device being evaluated in a clinical trial they oversee.

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- A Covered Individual participates in a foreign talent program and receives lab space abroad without disclosure.
- A biotech company provides free reagents and equipment for a WesternU lab without a formal agreement.
- A faculty member serves on the board of a start-up that funds their research.
- A researcher's spouse works for a company that manufactures a product being studied in the researcher's project

### Key Points:

Disclose equity >\$5,000 or >5% ownership.

Disclose consulting fees >\$5,000.

Disclose sponsored travel (except by government or higher education).

### Examples:

Own \$10,000 stock in biotech company → Disclose.

Lecture at state university, \$1,000 honorarium → Do NOT disclose.

### When to Disclose:

At initial employment (within 30 days).

Annually.

Within 30 days of acquiring a new interest.

### How to Complete the Form:

Fill Section A for personal details. If you have any SFI, complete Section B with entity name, nature of interest, and approximate value. Questions about disclosure contact [ORRA](#).

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**Western University of Health Sciences**

**CONFLICT OF INTEREST in RESEARCH DISCLOSURE FORM**

*To be completed and filed by all Covered Individuals (Faculty [regular, auxiliary and emeritus], postdoctoral scholars, and staff. before submitting proposals to federal agencies requiring financial disclosures. Submit completed form to the [Office of Research Regulatory Affairs](#). See page four of this form for the definition of investigator and other terms per federal regulations. For policy details please refer to the Conflicts of Interest in Research policy.*

**Section A**

Investigator Name \_\_\_\_\_ University Address \_\_\_\_\_

Title \_\_\_\_\_ Role on Project \_\_\_\_\_

Office Telephone \_\_\_\_\_ E-Mail Address \_\_\_\_\_

- Have you completed the required Financial Conflict of Interest Training \_\_\_\_ YES \_\_\_\_ NO

If YES, include a copy of your Certificate of Training to Sponsored Research.

If NO, contact ORRA for assistance.

- Do you, your spouse, any dependent children, and/or any Associated Corpus in aggregate have Significant Financial Interests (1) that would reasonably appear to be affected by any of your Institutional Responsibilities including but not limited to activities funded or proposed for funding by the National Institutes of Health, National Science Foundation or Public Health Service; or (2) in Entities not controlled by the University whose financial interests would reasonably appear to be affected by such activities?

YES \_\_\_\_ Complete Section B below. Submit a separate disclosure form for each entity with which you have a significant financial interest.

NO \_\_\_\_ Sign below to certify (1) that you have fully and to the best of your ability completed this disclosure form and (2) that you will update your disclosure form promptly if relevant circumstances change. Do not complete Section B.

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Signature \_\_\_\_\_ Date \_\_\_\_\_

**Section B** *(To be completed only if answer is yes to Question 2)*

Name of Entity \_\_\_\_\_

Activity or product of entity related to current or prospective university-based research or educational activities:

\_\_\_\_\_

Nature of the Significant Financial Interest to you or your family:

\_\_\_\_\_ Participation as employee(s)

\_\_\_\_\_ Equity interest in Non-Publicly traded entities

\_\_\_\_\_ Consulting or occasional lecturing

\_\_\_\_\_ Honoraria

\_\_\_\_\_ Travel Reimbursement

\_\_\_\_\_ Service on Advisory or Directors' Boards

\_\_\_\_\_ Writing commissioned papers or reports

\_\_\_\_\_ Payments, through Western's distribution plan, of royalties on patents and copyrights, etc.

\_\_\_\_\_ Payments, not through Western's royalty distribution plan, for intellectual property rights

\_\_\_\_\_ Other (\_\_\_\_\_)

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Approximate dollar value of the interest: \$\_\_\_\_\_

\*For amounts greater than \$150,000, estimate the amount to the nearest increment of \$50,000.

\_\_\_ The interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Elaboration of answers to previous questions and description of steps already taken, or being taken, to oversee and/or manage potential conflicts of interest (*Attach additional pages if necessary*):

Sign below to certify (1) that you have fully and to the best of your ability completed this disclosure form and (2) that you will update your disclosure form promptly if relevant circumstances change.

Signature \_\_\_\_\_ Date \_\_\_\_\_

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**OPERATING DEFINITIONS**

According to the National Institutes of Health (NIH), National Science Foundation (NSF) and Public Health Service (PHS) regulations:

**Significant financial interest** (SFI) signifies anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). All SFI related to the Investigator's institutional responsibilities must be disclosed.

The term does **not** include:

- Salary, royalties or other remuneration from Western University of Health Sciences;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities including a federal state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or research institution that is affiliated with an institution of higher education;
- Income from service on advisory committees or review panels for public or nonprofit entities including a federal state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or research institution that is affiliated with an institution of higher education;
- 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 a 5% ownership interest in any single entity; or
- 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 reasonably expected to exceed \$5,000.
- 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.

**Investigator** signifies "the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NIH, NSF or PHS."

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**Associated corpus** signifies any trust, organization or enterprise other than the University over which investigators, singly or collectively with members of their households, and/or immediate family, exercise a controlling interest.

**Entity** signifies any legal body created for profit or charitable purposes.

**Travel reimbursements and sponsored travel:**

Disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional Responsibilities (including purpose of trip, sponsor/organizer, destination and duration). It is NOT REQUIRED to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of Higher education 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. The University will determine if any travel requires further investigation, including determination or disclosure of the monetary value.