



# FINANCIAL CONFLICT OF INTEREST (FCOI) TRAINING

WESTERN NEW ENGLAND UNIVERSITY OFFICE OF THE GENERAL COUNSEL



## POLICY PURPOSE

- The purpose of the WNEU Financial Conflict of Interest Policy is to prevent financial conflicts of interest and to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, reporting of research funded under grants or cooperative agreements will be free from bias resulting from FCOIs of an Investigator.

# POLICY SUMMARY

- WNEU's Financial Conflict of Interest Policy describes its commitment to manage conflicts of interest in sponsored projects where the sponsor may be any external sponsor or the University itself. The purpose of the policy is to protect the credibility and integrity of the University's faculty and staff so that public trust and confidence in the University's sponsored projects is ensured.
- **Full Policy**
  - <https://www1.wne.edu/academic-affairs/Financial%20Conflict%20of%20Interest%20Policy%20Revised%20March%202021.pdf>

# DEFINITIONS

- Investigator means 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 funded research, or proposed for such funding, which may include, for example, collaborators or consultants.
- Institutional Responsibilities means the Investigator's professional responsibilities on behalf of the University, which are defined by the University and may include responsibilities related to teaching, professional development, research, scholarship, advising, and University governance and service.
- Institutional Official: the individual within the University who is responsible for the solicitation and review of disclosures of significantly financial interests including those of the Investigator's family related to the Investigator's institutional responsibilities. For the purposes of this policy the Institutional Official is Vice President of Finance and Administration, or their designee.

# DEFINITIONS

- Significant Financial Interest: anything of monetary value that appears to be related to the Investigator's institutional responsibilities, including, but not limited to:
  - Salary or other payments for services (e.g., consulting fees or honoraria) as defined as the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000;
  - Equity interests (e.g., stocks, stock options or other ownership interests) as defined as the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000;
  - Intellectual property rights (e.g., patents, copyrights and royalties from such rights) not reimbursed through the University.

# WHAT IS A SIGNIFICANT FINANCIAL INTEREST?

- An SFI constitutes financial interests of the Investigator (and those of the Investigator's spouse and dependent children) exceeding a defined threshold that:
  - Reasonably appears to be related to the Investigator's Institutional Responsibilities; and/or
  - Could reasonably affect or be affected by the outcome of the sponsored project, and has been/will be processed and/or received during a twelve-month period prior to and/or after the disclosure
- Defined Threshold:
  - A \$5000 aggregate amount, on an entity-by-entity basis, for each of the following categories:
    - 1) Income from and equity in a publicly traded entity;
    - 2) income from a non-publicly traded entity;
    - 3) income from any intellectual property rights and interests; and
    - 4) reimbursed or sponsored travel.
  - A \$0 aggregate amount, on an entity-by-entity basis, for:
    - 1) equity in a non-publicly traded entity; and
    - 2) income from managerial interest.

## SIGNIFICANT FINANCIAL INTERESTS EXCLUDE:

- Salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- 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;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency (Government Agency), an Institution of higher education as defined at 20 U.S.C. 1001(a) (Higher Education Institution), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- Income from service on advisory committees or review panels for a Government Agency, a Higher Education Institution, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- Travel reimbursed or sponsored by a Government Agency, a Higher Education institution, an academic teaching hospital, a medical center, or a research institute that is affiliated with a Higher Education Institution; and
- Grants and contracts administered through the University

# EXAMPLES OF POSSIBLE SIGNIFICANT FINANCIAL INTERESTS

- Sponsored or reimbursed travel
  - All travel that is related to Investigator Institutional Responsibilities and is deemed an SFI must be disclosed
- Gifts
- Favors for services that result in financial gain
- Vested or non-vested stock or stock options
- Ownership interest in publicly traded or non-publicly traded entities
- Intellectual property rights, such as patents
- Income from Honoraria or Consulting Fees
- Loans



# REQUIRED TRAINING

- **Why?**
  - Investigators must complete this training presentation to:
    - Understand Investigator Institutional Responsibilities; and
    - Be compliant with the WNEU's Financial Conflict of Interest Policy
- **When?**
  - Prior to proposal submission or the expenditure of funds, whichever is applicable (initial training);
  - At least every four years after initial training; and
  - Within a reasonable period of time when:
    - WNEU's Financial Conflict of Interest Policy changes such that it affects Investigator responsibilities;
    - Investigators are new to WNEU; or
    - Investigators are not in compliance with WNEU's Financial Conflict of Interest Policy

# SUBMISSION OF SIGNIFICANT FINANCIAL INTEREST (SFI) DISCLOSURES

- **By whom?**
  - All Investigators whom the Principal Investigator deems responsible for the design, conduct, or reporting of the project; or
  - All Investigators whom the Principal Investigator deems as "Senior" or "Key" personnel
- **Which forms?**
  - Citation will be inserted when available.
- **To whom?**
  - Submit to Western New England University's Vice President of Finance and Administration, or their designee
- **When?**
  - Prior to proposal submission or the expenditure of funds, whichever is applicable
    - For sponsored projects involving human or animal subjects, when the project is being designed for implementation
  - Within thirty days from the date that a new SFI arises in an active sponsored project
  - On an annual basis for each active sponsored project

# RESPONSIBILITIES PRIOR TO SUBMISSION

- Prior to submitting disclosure of Significant Financial Interests, or after a new Significant Financial Interest has been discovered or acquired, the Investigator should discuss proposed measures that will be taken to manage, reduce, or eliminate any actual or potential; conflict of interest with appropriate University officials, including:
  - Public disclosure of significant financial interests;
  - Review of research protocol by independent reviewers;
  - Monitoring of research by independent reviewers;
  - Modification of research plan;

## SUBRECIPIENTS (SUBS) ON SPONSORED PROJECTS:

- Subs will work with the Investigator to ensure that relationships are created in compliance with Western New England University's Financial Conflict of Interest Policy
  - For Subs with compliant policies:
    - Ensure that the Sub has disclosed to WNEU all identified FCOIs within forty-five days from the date of identifying the FCOI and/or prior to the expenditure of funds.
    - Ensure that the certification of Sub's policy compliance is incorporated into the written subcontract agreement.
  - For Subs without compliant policies:
    - Collect all of the Sub's SFI disclosures that directly relate to the Sub's work for the University using the SFI disclosure forms and submit the forms prior to executing the agreement and/or in compliance with Western New England University's Financial Conflict of Interest Policy.
    - Work with the Vice President of Finance and Administration to ensure that the appropriate Sub language is incorporated into the written subcontract agreement.

## PUBLIC ACCESSIBILITY REQUIREMENT FOR SPONSORED PROJECTS:

- WNEU is required to make the information below publicly accessible on the University's Academic Affairs webpage, if:
  - An SFI is determined to be an FCOI;
  - Investigators are designated as "Senior" or "Key" personnel; and
  - Investigators still hold the SFI:
- Publicly accessible information:
  - Investigator's name
  - Investigator's title
  - Investigator's role with respect to the project
  - Name of the entity in which the SFI is held
  - Nature of the SFI
  - Approximate value of the SFI

# VICE PRESIDENT OF FINANCE AND ADMINISTRATION SFI DISCLOSURE REVIEW PROCESS

- The Vice President of Finance and Administration:
  - Receives SFI disclosure forms from Investigators
  - Performs initial review of the form(s) for potential financial conflicts of interest (FCOIs); and
  - For projects that require Disclosure on Form 2
    - Records the initial determination;
    - Drafts an FCOI Memorandum of Understanding detailing a management plan, if necessary, that may impose the following:
      - Modification of the research plan;
      - Disqualification from participation in all or a portion of the research funded;
      - Divestiture of significant financial interests; or
      - Severance of relationships that create actual or potential conflicts; and

# RETROSPECTIVE REVIEW PROCESS

- If the Vice President of Finance and Administration determines that an FCOI was not identified or managed in a timely manner, they will 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 the design, conduct or reporting of the research.
- Documentation of the retrospective review shall include:
  - The project number,
  - Project title
  - Principal Investigator
  - Name of Investigator with the FCOI
  - Name of the entity with which the Investigator has the FCOI
  - Reason(s) for the retrospective review
  - Detailed methodology used for the retrospective review; and
  - Findings and conclusions of the review.
- This review shall take place within 120 days of the Institution's determination of non-disclosure.
- The Vice President of Finance and Administration will update any previously submitted reports, specifying the actions that will be taken to manage the FCOI going forward.

# VIOLATION PROCESS

- If bias is found, the report from the retrospective review process will include a mitigation report, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.
- Sanctions or institute disciplinary proceedings against the violating individual, including suspension of all relevant activities until the matter is resolved.
- In addition, the University shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.



IF YOU HAVE ANY QUESTIONS/COMMENTS, PLEASE CONTACT:

- **Vice President for Finance and Administration**

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