**Marymount University**

**Office of Sponsored Programs**

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**Marymount University**

# PHS Financial Conflict of Interest (FCOI) Disclosure Form

**For all Investigators and Senior/Key Personnel involved with PHS-Funded Research\***

|  |  |
| --- | --- |
| Investigator Name: | Rank/Title: |
| Dean or Division/Area Head: | Role:  PI  Senior/Key Personnel  Consultant  Partner/Collaborator PI  Other |
| School (Academic) or Division (non-Academic): | Department: |
| Email: | Campus Phone: |
| List the PHS Awarding Agency/Agencies you are submitting a sponsored program or already have one from: | |
| Institution (if Subrecipient or subcontractor on a MU sponsored award and following MU PHS FCOI Policies and Procedures): | |

I am reporting on activities:  **Initial Disclosure**, on Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Annual Disclosure** for the year **\_\_\_\_\_\_**

**Updated Disclosure** as an addendum to most recent PHS FCOI Disclosure Form

Refer to Marymount University’s PHS FCOI Policy and Procedures for guidance in filling out this Disclosure Form.

|  |
| --- |
| **A. Disclosure of Significant Financial Interests (\*\* See Definitions and exclusions on the last page)** |

Please indicate whether **you and/or your Family (your spouse or domestic partner, and/or your dependent children)** have any of the following financial interests that may be reasonably related to your *Institutional Responsibilities[[1]](#footnote-1)*:

|  |  |  |
| --- | --- | --- |
| Yes | No | 1. ***Remuneration and Equity Interest:*** Have you and/or a member of your Family received: (a) salary/compensation or any payment for other services (such as consulting fees, honoraria, paid authorship, expert witness fees, advisory board membership fees) from a *Publicly Traded Entity* in the past 12 months that when combined with (b) the value of any equity interest in such an entity (including any stock, stock option, or other ownership interest) has a value greater than $5,000? (Do not include ‘indirect’ equity interest or ownership, such as mutual funds.) |
| Yes | No | 2. ***Remuneration***. Have you and/or a member of your Family received salary/compensation or any payment for other services (such as consulting fees, honoraria, paid authorship, expert witness fees, advisory board membership fees) from a *Non-Publicly Traded Entity* in the past 12 months that when combined has a value greater than $5,000? |
| Yes | No | 2. ***Equity Interest****.* In the past 12 months, did you and/or a member of your Family own *any* equity interest in a *Non-Publicly Traded Entity* (including any stock, stock option, or other ownership interest? (Do not include ‘indirect’ equity interest or ownership, such as mutual funds.) |
| Yes | No | 3. ***Equity Interest***. In the past 12 months, did you and/or a member of your Family own any stock or hold stock options in a *Privately- Held Entity* of which the *combined* value is greater than $5,000? (Do not include ‘indirect’ equity interest or ownership, such as mutual funds.) |
| Yes | No | 4. ***Intellectual Property***. In the past 12 months, did you and/or a member of your Family receive royalties or other income related to intellectual property rights and interests (including, patents, copyrights, and trademarks? (Exclude intellectual property rights of academic or scholarly works at MU) |

For **yourself** ONLY:

|  |  |  |
| --- | --- | --- |
| Yes | No | 5. ***Sponsored Travel***. In the past 12 months, did you receive any reimbursed travel or sponsored travel (i.e., paid on your behalf and not reimbursed directly to you) that is related to your Institutional Responsibilities from an individual or Entity other than a federal, state, or local government agency, an institution of higher education[[2]](#footnote-2), academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education that, when combined, values more than $5,000 per individual or Entity? |

**If you responded “YES” to any of the questions above, you must also complete the PHS FCOI Disclosure Attachment Sheet.**

**B. Investigator Certification & Signature Page**

I certify that I have read and understand the Marymount PHS Financial Conflict of Interest (FCOI) Policy and related Procedures. To the best of my knowledge, I have made all required financial disclosures and the information provided in this document is complete and true. I acknowledge that I am responsible for updating information **annually** or within **30** days of acquiring any new *Significant Financial Interest* (e.g. through purchase, inheritance or marriage). I will promptly correct any incomplete or inaccurate information. If required, I will comply with conditions or restrictions imposed by the University to manage real or perceived FCOIs. If I am unable to comply, I understand that the University may decline the PHS-funded sponsored award or terminate the PHS-funded research program.

Check if your Disclosure Form includes any required Attachment Sheets and they are provided with this submission.

Investigator’s Signature Printed Name Date

**Administration only:**

No Financial Conflict of Interest appears to exist.

A complex Financial Conflict of Interest appears to exist and review is needed by the Sponsored Program COI Committee.

FOR PROPOSALS: A Financial Conflict of Interest may exist. The proposal may be submitted, but if the sponsored research is awarded, no expenditures are allowed until an approved Management Plan is in place and PHS has been notified.

FOR UPDATED FCOI DISCLOSURES: A Financial Conflict of Interest may exist. No research or expenditures may go forward until an approved Management Plan is in place and PHS has been notified.

IO Signature Printed Name Date

AOR Signature Printed Name Date

**PHS Financial Conflict of Interest(FCOI) Disclosure Form ATTACHMENT SHEET**

**Replicate this Sheet as needed to document any real or possible conflicts of interests with entities**

|  |  |  |
| --- | --- | --- |
| **Complete this section if you answered “YES” on any question in the PHS Financial Conflict of Interest (FCOI) Disclosure Form covering the present and the preceding 12 months.** | | |
| Investigator Name: | | Date Form Completed: |
| Reporting for  Self and/or  Immediate Family | For Family Member:  Spouse or Domestic partner  Dependent child | |

# Remuneration\*\*

|  |  |  |  |
| --- | --- | --- | --- |
| **Type (consulting fees,**  **salary, etc.)** | **Entity name and address** | **Amount of compensation**  **or Financial interest** | **Services Provided** |
|  |  | $ |  |
|  |  | $ |  |
|  |  | $ |  |

1. **Travel\*\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Sponsor name and address** | **Destination** | **Duration** | **Purpose** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Equity Interest\*\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Equity type (stock, stock**  **options, etc.)** | **Market value** | **Entity name stock/options are in** | **Percent of ownership** |
|  | $ |  |  |
|  | $ |  |  |
|  | $ |  |  |

# Intellectual Property (IP)

|  |  |  |  |
| --- | --- | --- | --- |
| **Type (patent, trademark, copyright)** | **Total royalties or other**  **income in past 12 mos.** | **Owner/inventor** | **Subject matter of IP**  **(description)** |
|  | $ |  |  |
|  | $ |  |  |
|  | $ |  |  |

# Marymount PHS FCOI Disclosure Form Definitions and Exclusions

Investigators who are planning to participate in PHS-funded research must disclose their *Significant Financial Interests* (SFIs) over the previous twelve-month (12) period to Marymount University no later than at the time of application for PHS-funded research and definitely before any expenditures (or continued expenditures) of funding on an active PHS-funded research project. Annual disclosure (and updated disclosure for changes in *Financial Interest* during the year) is required after a PHS-funded sponsored award is granted. See the Marymount University PHS FCOI Policy and Procedures for more detailed information governing this Form.

**Remuneration** – Any salary or payment for services (e.g., consulting fees, authorship fees, honoraria) that reasonably appears to be related to your Institutional Responsibilities, whether or not it is related to the PHS-funded research.

Exclusions: You do not have to disclose:

1. Salary or royalties paid by Marymount if the recipient is currently employed or otherwise appointed by Marymount.
2. Income from lectures, seminars, teaching engagements or service on advisory committees or review panels sponsored by federal, state or local government agency, an institution of higher education, a research institute that is affiliated with an institution of higher education, or academic teaching hospital or medical center.
3. If remuneration is from a *Publicly-Traded E*ntity and, aggregated with equity interest (see below) from a Publicly Traded Entity, is less than $5,000.

**Reimbursed or Sponsored Trave**l – Travel related to your Institutional Responsibilities paid on your behalf (or on behalf a Family member) and not reimbursed so that the monetary value may not be readily available.

Exclusions: You do not have to disclose:

1. Travel expenses that are reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, a research institute that is affiliated with an institution of higher education, a medical center or an academic teaching hospital.
2. Travel expenses that are less than $5,000 aggregated per Entity.

**Equity Interests** – Stock, stock options or other ownership interests in any *Publicly* o*r Non-Publicly* traded Entities that reasonably appear to be related to your Institutional Responsibilities, whether related to the PHS-funded research or not.

Exclusions: You do not have to disclose:

1. Interests in a *Publicly-Traded* Entity that have an aggregated total with remunerations (see above) in the past 12 months less than $5,000, based on public prices or other fair market value.
2. Income from investment vehicles, such as mutual funds and retirement accounts, when you or your *Family* does not directly control the investment decisions in these vehicles.

**Royalties and Income related to Intellectual Property** – Royalties or other income related to Intellectual Property and interests (e.g., patents, copyrights).

Exclusions: You do not have to disclose:

1. Intellectual property rights assigned to Marymount and agreements to share in royalties related to such rights (e.g., royalties received under the relevant Marymount Patent Policy).
2. If any of the following are less than $5,000: (i.) Interests in licensed intellectual property rights (e.g. patents, copyright), (ii.) royalties from such rights, and (iii) agreements to share in royalties related to licensed intellectual property rights.

**Other Significant Definitions**

**Entity** – Any domestic or foreign, public or non-public (private) organization from which an Investigator (and his/her Family) receives remuneration or in which they have an ownership or equity interest.

**Family –** The Investigator and his or her: his/her spouse, parents, parents-in-law, children, children-in-law, siblings, uncles, aunts, first cousins, step-relations, grandparents, nieces, and nephews, or any other person residing in the same household as the Investigator. Note: Marymount’s definition of Family is more expansive than federal regulations and by law, the University’s definition prevails for meeting compliance with PHS FCOI Regulations.

**Financial Conflict of Interest (FCOI)** – A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research (42 CFR § 50.603).

**Financial Interest** – Anything of monetary value, whether or not the value is readily ascertainable (42 CFR § 50.603).

**Institutional Responsibilities** – Refers to an Investigator's professional responsibilities on behalf of the University, including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (42 CFR § 50.603)

**Investigator** – 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 PHS, or proposed for such funding, which includes Senior/Key Personnel, and may include partners/collaborators through subawards or consultants through subcontracts (42 CFR § 50.603)

**Senior/Key Personnel** – The Project Director/Principal Investigator (PD/PI) and any other person identified as Senior/Key Personnel by the University in a sponsored program application, progress report, or any other report submitted to PHS by the University as required by regulation (42 CFR § 50.603).

**Significant Financial Interest** – A “Financial Interest” consisting of one or more of the following interests of the Investigator (and the Investigator's Family) or any reimbursed or sponsored travel that reasonably appears to be related to the Investigator's “Institutional Responsibilities” (42 CFR § 50.603).

Publicly Traded-Entities – Regarding any publicly traded Entity, a “Significant Financial Interest” exists if the value of any remuneration received from the “Entity” in the twelve (12) 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 (42 CFR § 50.603);

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 (42 CFR § 50.603);

Non-Publicly Traded Entity – Regarding any non-publicly traded “Entity,” a “Significant Financial Interest” exists if the value of any remuneration received from the Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's Family) holds **any** equity interest (e.g., stock, stock option, or other ownership interest) (42 CFR § 50.603);

Intellectual Property – Intellectual property rights and interests (e.g., patents, copyrights), upon **receipt** of income related to such rights and interests (42 CFR § 50.603);

Travel Reimbursement – Investigators 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; in the 12 months preceding the disclosure; provided, however, that this does not apply to 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 (42 CFR § 50.603).

The term “Significant Financial Interest” **does not** include the following types of Financial Interests:

* 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 University and agreements to share in royalties related to such rights;
* Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
* 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, an Institution of Higher Education (IHE) 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 IHE; or
* Income from service on advisory committees or review panels for a federal, state, or local government agency, an IHE 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 IHE (42 CFR §50.603).

**“NEW” Significant Financial Interest** – Is a different type or nature of Significant Financial Interest (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. Additional, a “new” one occurs even if it is to be the same type or nature of Significant Financial Interest (e.g., royalty payment), but from a different source (e.g., company A versus company B).

1. Refers to an Investigator's professional responsibilities on behalf of the University, performed in the course of and within the scope of your appointment or employment by MU, which includes activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards. [↑](#footnote-ref-1)
2. As defined at 20 USC § 1001(a) [↑](#footnote-ref-2)