**Interest Disclosure Form (IDF) for Investigators** **Not Affiliated with the University of Miami**

You are being asked to complete this disclosure because you have been identified as an external researcher engaged in the conduct of a human subject research project under the oversight of the University of Miami (UM). This information is required in order for UM to meet its regulatory obligations to ensure that an investigator’s related activities, financial and obligatory interests are assessed for conflict of interest and, if needed, appropriate conflict management is implemented.

**Terms are defined and examples given in an Appendix attached to this document.** If you have any questions about UM’s [Conflict of Interest (COI) in Research](https://www.research.miami.edu/_assets/pdf/policies-and-guidelines/conflict-of-interest--conflict-of-commitment--foreign-influence--and-institutional-conflict-of-interest-policy_policystat-002.pdf) policy or this form, please email UM’s Disclosures & Scholarly Activities Management (DSAM) at [DSAM@miami.edu](mailto:DSAM@miami.edu). Please provide complete typed responses to the requested information below.

**I. Research Identifying Information** *(This section to be completed by UM PI or designee)*

University of Miami eProst number:

Title:

Sponsoring Agency and Award # (if applicable):

Is this research funded by a Public Health Service (PHS) agency? ***Circle one:*** Yes / No (A full list of agencies can be found on UM’s website: <https://www.research.miami.edu/about/admin-areas/raa/udisclose/glossary-and-acronyms/index.html>)

**II. Non-Affiliated Investigator Contact Information**

Last Name, First Name:

Mailing Address:

Office Telephone #:

Email Address:

Employer Name:

Employer Address:

Title or position:

**III. Role on Research**

Please describe *in detail* the role(s) or duties you will perform on this research:

**IV. Related Activities, Financial or Obligatory Interests**

In the table below, please provide information about any related or possibly related activities, financial and obligatory interests that you, as well as your spouse or dependents, may have performed or held in the past 12 months that are **related to the above named project**.

A sample table and a list of examples is in the Appendix.

**Disclosure Table Instructions**

If you do not have any related activity, financial or obligatory interests put N/A in the first box of the Disclosure Table and go to section VI. Make an entry in each column as follows (add another sheet if needed):

**If you have a related activity, financial or obligatory interests:**

**Entity**: Provide the *full legal name* of the company or other organization. In most cases, there will be one name per line. An example of an exception to that could be a royalty interest where one entity owns the intellectual property (IP) and another has licensed it. For example, if USA University owns IP that you invented and licensed it to Big Pharma, Inc., you would enter USA University/Big Pharma, Inc.

**Activity, Financial or Obligatory Interests***:* Include all the activities or interests (irrespective of compensation) that apply for the named entity. If the interest is that of a family member rather than yourself, so indicate (e.g., Spouse is Consultant).

* Activity examples: consultant, manager, partner, board of directors, scientific advisory board member
* Financial Interest examples: salary, stock, stock options, licensed IP, royalties, loan, ***sponsored or reimbursed*** ***travel expenses***
  + Note: Do not include stocks/stock options that are in mutual funds of diversified holdings which are professionally managed.
* Obligatory Interest examples: uncompensated advisory board membership, consulting, unlicensed IP
  + Note: if you have unlicensed IP related to the study, list “IP” as the entity name and indicate $0 for compensation

**Value or Compensation:** If you have more than one activity/interest for a single entity, you may need multiple entries in this column. If you list more than one, specify the activity/interest to which it applies (see sample table in Appendix).

For values less than $100,000 use the ranges below. If the value is $100,000 or more, you must enter the specific amount (e.g., $283,400). For equity/stock in a non-public company where value cannot be readily determined by public price or fair market value, enter “Equity Value Unknown.”

|  |  |  |
| --- | --- | --- |
| * + $0 (None)   + $1 - $4,999   + $5,000 - $9,999 | * + $10,000 - $19,999   + $20,000 - $39,999   + $40,000 - $59,999 | * + $60,000 - $79,999   + $80,000 - $99,999 |

**Relationship to the Research**: Describe the way in which the activity/interest is related to the research.

|  |  |  |  |
| --- | --- | --- | --- |
| **Entity** | **Activity, Financial or Obligatory Interests** | **Value or Compensation** | **Relationship to the Research** |
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**V. Travel Expenses**

If you included travel expenses for any of the entities above *and* the above named research is sponsored by a federal agency or other organization that requires the Public Health Service (PHS) COI regulations be followed (e.g., NIH--click here of a full list of agencies: <https://www.uresearch.miami.edu/uresearch-services/udisclose/glossary-and-acronyms/index.html>), you must list reimbursed travel or travel that was paid on your behalf. DO NOT list travel that was paid or reimbursed by your employer, by the University of Miami in connection with this research. Also exempt are income from activities (seminars, lectures, teaching engagements,  service on advisory committees or review panels) for, or sponsored by a United States 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. If you need additional space, please attach a separate sheet.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Travel sponsor** | **Travel purpose** | **Travel destination** | **# of Trips** | **Total # days** |
|  |  |  |  |  |
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**VI. Certification**

Please check the box to affirm:

I certify that I have read and understand UM’s training document (PDF that accompanied this form).

By submitting this IDF, I certify that the above information is complete and true to the best of my knowledge. I acknowledge that should my activities, financial or obligatory interests, or those of my family members, change in a way that results in different answers to any of the questions asked in this disclosure, *I will submit updated information within 30 days*. I will comply with these and any other disclosure requirements imposed by the University of Miami. I understand that should the University determine a conflict management plan is needed that I must agree to that plan in order to participate in the research.

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

If you have any questions regarding completion of this form or UM’s COI policy, please email [DSAM@miami.edu](mailto:DSAM@miami.edu). Once complete, submit this form to the UM PI (or designee) of the study.

**APPENDIX**

**Sample Disclosure Table**

|  |  |  |  |
| --- | --- | --- | --- |
| **Entity** | **Activity/Interest** | **Value or Compensation** | **Relationship to the Research** |
| Big Pharma, Inc. | Wife is a Consultant | $5,000 - $9,999 | Big Pharma, Inc. makes one of the compounds tested in this research. She consults with them about this product. |
| Little Company, LLC | Stocks (about 2%)  Royalties | Equity Value Unknown  $1 - $4,999 | I am a research scientist. Our company owns IP rights on the other compound tested in this research. I am the inventor but have not received in royalties or other payments. I receive royalties for a different invention, one that is not involved in this project. |
| General Stuff | Stock (3000 shares) | $60,000 - $79,999 | We use GS software in this research. The research is not testing the software which has been on the market for more than a decade. |
| Not for Profit Foundation | Travel reimbursement | $1 - $4,999 | I am an uncompensated member of the board of directors of this 501c3 organization, and traveled to the annual meeting in Big City. The foundation paid for my plane ticket, hotel room and food during the trip. |

**Definitions**

***Activity, Financial*** or ***Obligatory Interests*** include:

* An ***Activity*** is the role(s) in which you provide a service such as membership on the governing board of an entity, service on its board of directors, service on a scientific advisory board, work as a consultant, or having a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, or partner.
* A ***Financial interest*** means anything of monetary value, whether or not the quantitative value is readily ascertainable (e.g. stock options), inclusive of sponsored or reimbursed travel expenses.
* An ***Obligatory Interest*** is a relationship (regardless of compensation) that involves a responsibility or commitment to an external entity (e.g. uncompensated Advisory Board membership).

***Equity Interest:*** Ownership interests or securities, including but not limited to shares of stock or securities; stock options; warrants or any other rights to purchase stock or securities; debt instruments; partnership interests in a general or limited partnership; or membership interests in a limited liability company.

***External researchers***: An investigator who is not a UM employee, faculty member, student or agents who is engaged in human subject research. For example:

* researchers at a non-UM facility who are working under the direction of a UM PI;
* researchers in multisite research studies where UM is the IRB of record for an external site that does not have a COI review process;
* Researchers at a non-UM facility where UM is not the IRB of record who request to undergo UM’s COI review process.

***Family Member:*** An investigator’s spouse or dependent child.

***Intellectual Property Interest*** means the filing of a thought or idea that could be protected.

***Investigator***means the project director (PD), principal investigator(s) (PIs), co-investigators, and any other person substantively contributing to the design, conduct, or reporting of on a research project under the oversight the University of Miami (UM).

***Related***: A financial or obligatory interest can be called “related” to a research project if it involves the same or similar focus (disease or injury, molecular target, drug or device) as some aspect of the project. Examples include but are not limited to:

* An investigator having a financial interest in or obligation to:
  + the sponsor of the project
  + an entity investigating the same/similar area as that to be studied/used in the new project
  + an entity that can reasonably be expected to benefit directly from the project
  + an entity that can reasonably be expected to compete with the product or procedure that will predictably result from the project
  + an entity that has a material transfer or confidentiality agreement for material used in the project
  + the intellectual property (IP) to be used in the project
* The investigator is/was/will be
  + the IDE/IND holder (sponsor)
  + an inventor on the IP to be used or investigated in the project
  + directly involved in the design of the project with the sponsor
  + directly involved in bringing the product to market
  + directly involved in research involving the same or similar focus as an entity in which the investigator has an interest