

## **SIMmersion Financial Conflict of Interest (FCOI) Policy**

This document serves as SIMmersion L.L.C.'s Financial Conflict of Interest Policy (FCOI) regarding all federally awarded grant funds. As such, this policy was informed by and created in compliance with all regulatory requirements including, but not limited to the federal initiative to promote objectivity in research (i.e., 42 CFR Part 50 Subpart F). This policy will be reviewed and revised from time to time as federal regulations change.

This policy applies to all Investigators, as defined below and by the federal regulation, who is planning to participate in or is participating in Public Health Service (PHS) funded research awarded to SIMmersion.

### **I. Definitions**

- a. ***Financial Conflict of Interest (FCOI)***: Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- b. ***Investigator***: 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 research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- c. ***Significant Financial Interest (SFI)***: Significant financial interest means:
  - i. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
    1. With regard to any *publicly traded entity*, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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. 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;
    2. With regard to any *non-publicly traded entity*, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
    3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  - ii. Investigators also 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; provided, however, that this disclosure requirement 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

- iii. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution 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 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; or income from service on advisory committees or review panels for 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.
- d. *Title 42 CFR 50.604*: Federal policy documenting *Responsibilities of Institutions regarding Investigator financial conflicts of interest*. Full text can be referenced at <https://ecfr.io/Title-42/Section-50.604>

**II. FCOI Institutional Officials (IO):** SIMmersion's c-level managers and highest ranking financial officer shall serve as FCOI Institutional Officials. This team will be responsible for:

- a. Notify Investigators of their disclosure and training requirements
- b. Solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities
- c. Determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI
- d. Report FCOI to funding agency
- e. Maintain records of disclosure statements and FCOI

**III. Investigator Notification:** Prior to the submission of a proposal for federal funding, the IO shall notify all Investigators of their training and disclosure responsibilities. This notification shall include a (1) copy of this policy which references federal policy and (2) FCOI disclosure form.

**IV. Investigator Training Requirements:** All Investigators must complete FCOI training online at [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) at the following times:

- a. Prior to beginning any grant-funded work
- b. At least every four (4) years
- c. Immediately, if:
  - i. SIMmersion revises its FCOI policy in a manner that affects Investigator requirements
  - ii. An Investigator is new to SIMmersion
  - iii. An Investigator is not in compliance with this policy or other management

**V. Investigator Financial Disclosure:** Investigators who are or plan to participate in federally-funded research must disclose their SFIs no later than at the time of application for funding. Once funding is obtained, the Investigator is required to continue to update their disclosure annually during the entire period of the federal award. Investigators participating in federally-funded research must also update their disclosure within thirty (30) days of discovering or acquiring a new outside activity or interest.

**VI. Review of Disclosures:** Upon receiving Investigators' disclosures, the IO will review the disclosures and determine whether any SFIs rise to the level of a FCOI. The IO will work with Investigators to manage all identified FCOIs. Management of a FCOI may include actions such as disclosure of the financial interest, elimination of the interest altogether, modification of the research plan, and disqualification of personnel from participation in part or all of the research. Management strategies will be tailored to address the specific issues raised by each particular FCOI.

**VII. FCOI Reporting:** The Institutional Official will report any identified FCOIs to the Awarding Entity (i) prior to the expenditure of funds, (ii) within 60 days of identification of an investigator who is newly participating in the project, (iii) within 60 days for new or newly identified FCOIs for existing Investigators, and (iv) annually.

The report will include: (i) project number; (ii) PD/PI or contact PD/PI if a multiple PD/PI model is used; (iii) name of the Investigator with the FCOI; (iv) name of the entity with which the Investigator has a FCOI; (v) nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) value of the financial interest (dollar ranges); (vii) a description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and (viii) a description of the key elements of the Institution's management plan, including: (A) role and principal duties of the conflicted Investigator in the research project; (B) conditions of the management plan; (C) how the management plan is designed to safeguard objectivity in the research project; (D) confirmation of the Investigator's agreement to the management plan; (E) how the management plan will be monitored to ensure Investigator compliance; and (F) other information as needed.

As required by the PHS Rules, SIMmersion will make available to the public, information concerning identified FCOIs of senior/key personnel within five (5) calendar days of the

Institutional Official receiving a written request for such information. The publicly available information will include: (i) Investigator's name; (ii) the Investigator's title and role with respect to the research project; (iii) the name of the entity in which the SFI is held; (iv) the nature of the SFI; and (v) the approximate dollar value of the SFI, (or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value).

**VIII. Records:** SIMmersion shall retain all disclosure forms, conflict management plans, and related documents for a period of three years following the date the final expenditures report is submitted to PHS unless otherwise specified in 45 CFR 75.361.

**IX. Subrecipient Requirements:** During the establishment of a subrecipient agreement, SIMmersion and the subrecipient shall establish in writing whether the subrecipient will follow the FCOI policy of SIMmersion or the FCOI policy of the subrecipient. SIMmersion will only agree to the later if the subrecipient's FCOI policy complies with federal regulations.

**SIMmersion Financial Conflict of Interest (FCOI) Disclosure Form**

You are being asked to complete this disclosure because you have been identified as an *Investigator*, an individual who is responsible for the design, conduct, or reporting of federally funded research with SIMmersion. Please provide complete typed responses to the requested information below.

**I. Research Identifying Information**

Proposal Title:

SIMmersion PI:

Sponsoring Agency Award #:

SIMmersion Reference # (if applicable):

**II. Investigator Contact Information**

Last Name, First Name:

Email Address:

Employer Name:

Employer Address:

Title or position:

Mailing Address:

Telephone Number:

**III. Financial Interests Questions**

Below, are several questions intended to identify Significant Financial Interests and relationships that may be relevant to this research. These may include Intellectual Property Interests (IP Interests), as well as relationships with entities whose interests may affect/be affected by this research. As you answer these questions, please:

- (1) consider whether, in your best judgment, any financial interest reasonably appears to be related to your institutional responsibilities or research protocols.
- (2) do not include salary, royalties, or other remuneration paid by SIMmersion if you are currently employed or otherwise appointed by SIMmersion.

**1. Publicly Traded Entities:** Over the past 12 months, have you or family members received remuneration from any publicly traded entity and/or do you or family members currently own equity interest in that entity, the value of which when aggregated exceeds \$5,000?

Yes       No

If yes-please address if a) the entity supports your research or any other sponsored activities AND b) how your involvement with the outside entity is related to your research responsibilities:

**2. Non-publicly Traded Entities:** Over the past 12 months, have you or family members received remuneration from any non-publicly traded entity the value of which when aggregated exceeds \$5,000, or do you or family members currently own any equity interest in that non-publicly traded entity ?

Yes       No

If yes-please address if a) the entity supports your research or any other sponsored activities AND b) how your involvement with the outside entity is related to your research responsibilities:

**3. Intellectual Property Income:** Over the past 12 months, have you or family members received any income derived from intellectual property rights and interests (e.g., patents, copyrights), excluding any royalties paid by the SIMmersion?

Yes       No

If yes-please address if a) the rights support your research or other sponsored activities AND b) how the income from these intellectual property rights is related to your research responsibilities:

**4. Sponsored Travel:** In the past 12 months, have you incurred travel costs in excess of \$5,000 for which you were reimbursed or that was paid on your behalf and not reimbursed to you related to your professional responsibilities? Please **DO NOT** include travel that was paid or reimbursed by your employer, by SIMmersion in connection with this research, by government agencies, or US institutions of higher education, or affiliated teaching hospitals, medical centers, or research institutes.

Yes       No

If yes-please address a) travel sponsor, b) destination, c) purpose, d) number of trips, and e) total days traveled.

### **III. Certification**

By submitting this information, I certify that the above information is complete and true to the best of my knowledge. I acknowledge that should my financial 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 calendar days of the date that I become aware of the change. Additionally, if required, I will provide additional information and/or comply with any conditions or restrictions imposed by SIMmersion.

Signature:

Date: