

**PsychoGenics Inc.**

**Financial Conflict of Interest (“FCOI”) Policy**

Updated Date: December 1, 2020

**1. Purpose and Applicability**

- 1.1. This FCOI Policy implements U.S. federal requirements pertaining to “Objectivity in Research” promulgated by the Public Health System (“PHS”) of the U.S. Department of Health and Human Services (“HHS”), which includes the U.S. National Institutes of Health (“NIH”). FCOI requirements, related to PHS-Funded Research, are published in U.S. regulations 42 CFR Part 50 (“PHS Regulations”). An electronic version of the regulation is found at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.
- 1.2. The intent of this FCOI Policy is to promote objectivity in PsychoGenics’s research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research performed by PsychoGenics will be biased by any conflicting financial interest.
- 1.3. This policy is applicable to each Investigator who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding.

**2. Definitions**

- 2.1. **Investigator Responsibilities:** An Investigator’s professional responsibilities performed on behalf of PsychoGenics in relation to any PHS-Funded Research.
- 2.2. **Designated Officials** refers to PsychoGenics’ Chief Executive Officer and VP of Finance.
- 2.3. **Equity Interest:** Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- 2.4. **Financial Conflict of Interest (“FCOI”):** A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.
- 2.5. **Financial Interest:** Any interest of monetary value, whether or not the value is readily ascertainable.
- 2.6. **Immediate Family:** An Investigator’s spouse or domestic partner and dependent children.

- 2.7. **Investigator:** The project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of a PHS-Funded Research, which may include, for example, PsychoGenics employees, collaborators or consultants.
- 2.8. **Non-Significant Financial Interests (“Non-SFI”):** include the following types of Financial Interests: (i) remuneration paid by an entity to which an Investigator owes Investigator Responsibilities, if the Investigator is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or (ii) any ownership interest in an entity held by the Investigator or 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; or (iii) income from seminars, lectures, or teaching engagements sponsored by a US federal, state, or local government agency, an Institute 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 a Institute of higher education; or (iv) income from service on advisory committees or review panels for a US federal, state or local government agency, an Institute 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 Institute of higher education.
- 2.9. **PHS:** Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including, among others, the NIH. A listing of the PHS agencies and their offices may be located on the [U.S. Department of Health and Human Services Organizational Chart](#).
- 2.10. **PHS-Funded Research:** any Research funded by way of a grant from, or a contract with, a PHS Organization.
- 2.11. **PHS Organization:** an agency that is part of the PHS.
- 2.12. **Principal Investigator (“PI”):** Investigator or any other person identified as PsychoGenics senior/key personnel in the PHS-Funded Research grant application, progress report, or any other report submitted to the PHG Organization under the PHS Regulations.
- 2.13. **Remuneration:** (i) salary and any payment for services including consulting fees and honoraria; (ii) any Equity Interest; and (iii) travel reimbursement related to the Investigator Responsibilities.
- 2.14. **Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

- 2.15. **Significant Financial Interest (“SFI”):** A Financial Interest consisting of one or more of the following interests of an Investigator (and those of the Investigator’s Immediate Family) that reasonably appear to be related to Investigator Responsibilities, but specifically excludes any Non-SFI: (i) any Remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or (ii) any Remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or (iii) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- 2.15.1. 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 excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by PsychoGenics directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to PsychoGenics relating to the trip, such as purpose of the trip, identity of the payer/sponsor, destination and duration. PsychoGenics is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCI with PHS-Funded Research.
- 2.15.2. SFI does not include the following types of financial interests: salaries, royalties or other remuneration paid by PsychoGenics to the Investigator if the Investigator is currently employed or otherwise appointed by PsychoGenics, including intellectual property rights assigned to PsychoGenics and agreements to share in royalties related to such rights; any ownership interest in PsychoGenics held by the investigator, if PsychoGenics is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirements 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 Institute of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, research institute that is affiliated with an Institute of higher education; or income from service on advisory committees or review panels for a federal, state or local government agency, an Institute 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 Institute of higher education.

### 3. Training

- 3.1. Prior to engaging in PHS-Funded Research, each Investigator will be informed of the FCOI Policy, the Investigator Responsibilities, and the PHS Regulations.
- 3.2. The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes FCOI. All Investigators must complete FCOI training prior to engaging in PHS-Funded Research, at least every four years, and immediately in the event of FCOI Policy changes, any Investigator non-compliance with the FCOI Policy, and at the addition of any new Investigator to PsychoGenics. The course is accessible at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Upon completion of the training, a certificate of completion must be turned to the VP of Finance and a copy retained by the Investigator.

### 4. Reporting Process

- 4.1. Identification of Persons Required to Disclose a Significant Financial Interest - SFI shall be disclosed in the SFI Disclosure Form (Exhibit 1) by an Investigator requesting PHS sponsored funds for a research project or when a SFI arises during the course of research. Regardless of whether a SFI exist, all Investigators are required to submit a SFI Disclosure Form annually. It is the PI's responsibility to ensure all Investigators in research complete and submit the SFI disclosure form prior to the submission of a research proposal and for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.
- 4.2. Submission and Review of Significant Financial Interest Disclosure Form - Every Investigator shall prepare a fully completed SFI Disclosure Form with supporting materials to be submitted to the VP of Finance for review. An initial review of the SFI Disclosure Form will be conducted by the VP of Finance to determine whether a potential for conflict of interest exists. If it is determined by the Designated Officials that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:
  - 4.2.1. Public disclosure of significant financial interests;
  - 4.2.2. Review of research protocols by independent reviewers;
  - 4.2.3. Monitoring of research by independent reviewers;
  - 4.2.4. Modification of research plan;

- 4.2.5. Disqualification from participation in all or a portion of the research funded;
  - 4.2.6. Divestiture of significant financial interests;
  - 4.2.7. Severance of relationships that create actual or potential conflicts
  - 4.2.8. All management plans are required to be signed by Designated Officials. Compliance of the management plan shall be monitored by the PsychoGenics Finance Department.
- 4.3. Annual Reporting and Subsequent Significant Financial Interests – All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the PI's responsibility to ensure that any newly acquired Investigator submits the required SFI report to the VP of Finance within 30 days.
- 4.4. Public Accessibility – Prior to engaging in PHS-Funded Research, within 5 days of any written request, PsychoGenics shall post publicly any FCOIs with the minimum elements provided in the PHS Regulations, update it at least annually or within 60 days of any newly identified FCOI, and maintain the information for at least three years from the date the information was most recently updated.

## **5. Enforcement and Reporting**

- 5.1. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this FCOI Policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the VP of Finance shall make recommendations to the CEO regarding the impositions of sanctions or disciplinary proceedings against the violating Investigator. In addition, PsychoGenics shall follow PHS Regulations regarding the prompt notification of the PHS Organization in the event an Investigator has failed to comply with this FCOI Policy. The PHS Organization may take its own action as it deems appropriate until the matter is resolved and PsychoGenics shall cooperate with all reasonable requests from the PHS Organization including but not limited to disclosing the FCOI in each public presentation (including requesting an addendum to already published publications) of the results of the PHS-Funded Research of which the Investigator was a part of.
- 5.2. Record Keeping – Records of Investigator SFI Disclosure reports, forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the PsychoGenics Finance Department for three (3) years from the date the final expenditure report is submitted to the relevant PHS Organization, or as required by government regulations for different situations.
- 5.3. Subrecipient Requirements – If applicable, subrecipients must agree in a written agreement to comply with this FCOI Policy or provide certification that their organization is in compliance with the PHS Regulations and that their portion of the

PHS-Funded Research, as detailed in their subrecipient agreement, is in compliance with their FCOI policies. If a SFI is identified by the subrecipient, they are required to notify the VP of Finance of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the subrecipient must certify and assure in writing that any reported conflicting interest has been managed, reduced or eliminated in accordance with applicable federal regulations.

5.4. Federal Reporting – PsychoGenics Finance Department is responsible for the reporting of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are examples of reports that may be required by a PHS component body:

5.4.1. Initial report – prior to PsychoGenics’s expenditure of any funds under a PHS-Funded Research, PsychoGenics must provide to the relevant PHS Organization a FCOI report regarding any Investigator SFI found by PsychoGenics to be a financial conflict of interest in accordance with the regulation.

5.4.2. During ongoing PHS-Funded Research – PsychoGenics shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, PsychoGenics shall submit a FCOI report to the PHS Organization within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

5.4.3. Annual FCOI report – For any FCOI previously reported to a PHS Organization, PsychoGenics shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

**Point of Contact**

If you have a conflict of interest or if you have a question to discuss, please contact the PI of the PHS-Funded Research or the VP of Finance.



Dr. Emer Leahy  
President & CEO