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## Financial Conflict of Interest (FCOI) Policy

Effective 01/01/2024

### 1. **Introduction**

Panluminate, Inc. is dedicated to maintaining the highest standards of objectivity in research by ensuring that the design, conduct, and reporting of research funded by the National Institutes of Health (NIH) are free from bias due to financial conflicts of interest. This policy applies to all NIH-funded grants and cooperative agreements, excluding Phase I SBIR/STTR awards, and ensures compliance with the HHS regulation 42 CFR Part 50 Subpart F.

### 2. **NIH Policy Background**

The HHS regulation 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (FCOI regulation), establishes standards that provide a reasonable expectation that the design, conduct, or reporting of NIH-funded research (grants and cooperative agreements) will be free from bias resulting from any Investigator's conflicting financial interest. NIH requires recipient institutions and their investigators (except Phase I SBIR/STTR applicants and recipients) to fully comply with all FCOI requirements. If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution must take reasonable steps to ensure that any subrecipient Investigator complies with FCOI requirements.

### 3. **Persons Covered by this Policy**

This policy applies to all personnel, including all Members and full-time, part-time, temporary, and contract employees, of Panluminate, Inc. ("Panluminate") who are planning to participate in, or are participating in, National Institute of Health ("NIH") funded research by means of a grant or cooperative agreement.

### 4. **General Policy Statement**

- **Objective:** Research funded by NIH grants or cooperative agreements must be designed, conducted, and reported without bias due to financial conflicts of interest involving Investigators.
- **Training:** Investigators must undergo FCOI training prior to engaging in NIH-funded research and at least every four (4) years thereafter. Immediate training is required if the policy is revised, a new Investigator is hired, or noncompliance with the policy or management plan is identified
- **Disclosure:** Investigators must disclose any Significant Financial Interests (SFIs) related to their institutional responsibilities:
  - **At the time of application** for NIH-funded research.
  - **Annually** throughout the period of the award.



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- **Within 30 days** of discovering or acquiring a new SFI.
- **Management of FCOI:** Panluminate is responsible for managing FCOIs by developing and implementing management plans, disclosing FCOIs to the NIH and the public, and taking necessary actions to eliminate or mitigate conflicts
  - This policy does not authorize any actions that are illegal, even if they are disclosed.
  - The Members retain the full authority to take any actions they deem necessary, independent of any decisions or lack of action by a Panluminate Officer.

## 5. Key Definitions

- **Disclosure:** An Investigator's disclosure of Significant Financial Interests (SFIs) to Panluminate.
- **Significant Financial Interest (SFI):** A Financial Interest that could potentially influence the NIH-funded research; 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 responsibilities at Panluminate:
  - **Publicly traded entities:** 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;
  - **Non-publicly traded entities:** 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 a management or governance position; or
  - **Intellectual property rights** and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  - **Reimbursed or Sponsored Travel:** 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 Company responsibilities;
    - provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local



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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.

- Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Panluminate will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS funded research.

- **Exclusions:**

The term Significant Financial Interest **does not include** the following types of financial interests:

- Salary, royalties, or other remuneration paid by Panluminate to the Investigator if the Investigator is currently employed or otherwise appointed by Panluminate, including intellectual property rights assigned to Panluminate 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, 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; 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.
- **Financial Conflict of Interest (FCOI):** an SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
  - **Institutional Official (IO):** A Panluminate-designated official assigned to solicit and review disclosure forms from each investigator who is planning to participate in, or who is participating in, HHS funded research and to determine whether any reported Significant Financial Interest (SFI) is a FCOI
  - **Investigator:** Any person who is responsible for the design, conduct, or reporting of research funded by the NIH (or any other federal agency), including consultants, subcontractors, and other collaborators involved in that research.
  - **Management Plan:** A strategy to mitigate or eliminate identified FCOIs.



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- **Manage:** Taking steps to manage a financial conflict of interest, which may involve mitigating or removing the conflict, to help ensure that the research design, conduct, and reporting remain unbiased.
- **Subrecipient:** An entity receiving a subaward from Panluminate to carry out part of the NIH-funded research.
- **FCOI Report:** Panluminate's report of a Financial Conflict of Interest to a PHS Awarding Component.
- **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- **HHS:** The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- **Company Responsibilities:** An Investigator's duties on behalf of Panluminate, as outlined in Panluminate's Financial Conflicts of Interest policy (FCOI), may encompass activities such as research, consultation on research, training, professional practice, and participation on panels.
- **PD/PI:** A project director or principal Investigator leading a PHS-funded research project is considered part of the definitions of senior/key personnel and Investigator within this subpart.
- **Research:** A systematic investigation, study, or experiment aimed at generating or contributing to generalizable knowledge related to public health. This term includes both basic and applied research as well as product development. In this context, it covers any activity eligible for NIH funding through various mechanisms such as research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, Panluminate training grants, program projects, or research resource awards.
- **Senior/key personnel:** Refers to the PD/PI and any other individual designated as senior/key personnel by Panluminate in the grant application, progress report, or any other document submitted to the PHS by Panluminate under this subpart.

## 6. **Policy Implementation:**

- **Pre-Funding Disclosure:** Panluminate has designated its CEO as the IO. Prior to expenditure of any funds under a HHS funded research project, Panluminate's IO will solicit and review Investigator's disclosures (or Disclosure Forms) containing SFIs to determine whether the SFI relates to the HHS funded Research and whether a FCOI exists. The determination process may involve consultation with the Investigator to gather additional information or clarification as needed.
  - If a FCOI exists, Panluminate's IO will develop and implement a management plan that specifies the actions that have been and will be taken to manage such FCOI.
- **Disclosure Requirement:** Panluminate will inform each employee of Panluminate's policy on Promoting Objectivity in Research, the investigator's responsibilities



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regarding disclosure require that a written disclosure be made as provided in this policy and inform the Panluminate Member to anticipate the receipt of a new Disclosure.

- **Disclosure Frequency:**
  - **At Application:** Disclosure must be made no later than at the time of application for NIH-funded research.
  - **Annually:** Disclosures are required each year during the period of the NIH award. If no SFI is present, a Disclosure must still be submitted that states “none.” The specific date for the annual Disclosure will be set by the Members and communicated throughout Panluminate.
  - **Within 30 Days:** Any new or changed SFIs must be disclosed promptly, within thirty (30) days of discovering or acquiring a new SFI or when a significant change occurs concerning an existing Disclosure.
  - **New Hires:** Newly hired Investigators must disclose SFIs as part of their onboarding process. Disclosures must detail the nature of the SFI, the amount, and its potential to influence NIH-funded research. The IO will document the review process, including how the FCOI determination was made.
  - **Disclosure Details:** All disclosures must include the nature of the SFI, the amount, and its relevance to the NIH-funded research.

## 7. Training Requirement:

- **Initial Training:** Investigators shall complete FCOI training provided by Panluminate on or before their becoming subject to this policy
- **Ongoing Training:** Required at least every four (4) years and immediately under certain conditions:
  - **Policy Revision:** When Panluminate revises its FCOI policy in a way that affects Investigator responsibilities.
  - **New Investigator:** When a new Investigator joins Panluminate.
  - **Non-compliance:** When an Investigator is found noncompliant with the FCOI policy or management plan.
- Training includes comprehensive information on the institution's policy, the Investigator's disclosure responsibilities, and the federal regulations as required by the NIH. This training is provided through the NIH's online tutorial:  
[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

## 8. Reporting Requirements to the NIH:

- **Initial Reporting:** Prior to the expenditure of NIH funds, Panluminate will report any identified FCOIs to NIH via the eRA Commons FCOI Module.
- **Ongoing Reporting:** Reports will be submitted:
  - **Annually:** With the annual progress report



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- **Within sixty (60) days** of receipt or identification of any additional SFI held by Senior/Key personnel performing services for the Research, related to the HHS funded Research and that is determined by Panluminate's IO to be a FCOI.
- **Retrospective Review:** Following a retrospective review, if an FCOI was not managed in a timely manner.
- The IO must **promptly** notify the NIH if any bias is discovered in the design, conduct, or reporting of NIH-funded research as a result of an FCOI. If such bias is found, Panluminate will submit a Mitigation Report to NIH detailing the impact of the bias, corrective actions taken, and measures to prevent future occurrences.
- **Report Details:** Reports must include:
  - Investigator's name, title, and role with respect to the Research project;
  - The name of the entity in which the SFI is held;
  - The nature of the SFI;
  - Approximate dollar value of the SFI (dollar ranges are permissible: \$0 - \$4,999; \$5,000-\$9,999; \$10,000-\$19,000; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or
  - a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.
  - How the FCOI is managed, and any changes to the management plan.

### 9. **Determination and Management of FCOIs:**

- **FCOI Determination:** The IO will determine if an SFI constitutes an FCOI by assessing whether the SFI could directly and significantly affect the NIH-funded research.
- **Management Plan:** If an FCOI is identified, the IO will enforce a plan management that can be:
  - **Public Disclosure:** Disclosure of FCOI in presenting or publishing the research
  - **Human Subjects Research:** Direct disclosure of the FCOI to research participants.
  - **Independent Monitoring:** Appointment of an independent monitor to oversee the research, taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI
  - **Modification of the Research Plan:** Adjustments to the research approach to minimize bias.
  - **Divestiture of the SFI:** Reduction or elimination of the financial interest (e.g., sale of equity interest); or



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- Severance of relationships that create financial conflicts.
- **Personnel Changes:** Reassignment or removal of personnel with FCOIs from the project.
- Management plans will be implemented before the expenditure of NIH funds, and ongoing monitoring of the FCOI will continue throughout the research project to ensure continued compliance and to address any changes in the Investigator's financial interests.

### **10. Retrospective Review and Mitigation Report**

If an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose an SFI that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "**retrospective review**" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

- The Institution shall document the "**retrospective review**" which must include at least the following key elements:
  - Project number;
  - Project title;
  - PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - Name of the Investigator with the FCOI;
  - Name of the entity with which the Investigator has a financial conflict of interest
  - Reason(s) for the retrospective review;
  - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
  - Findings of the review; and Conclusions of the review.

The retrospective review process will ensure that all relevant data is considered, including the Investigator's role and the impact of the SFI on the research. The review will be documented thoroughly, including methodology, panel composition, and findings.

### **11. Violations and Enforcement**

- **Sanctions:** Violations of Panluminate policies, including the failure to avoid prohibited activities or disclose an SFI in a timely manner, will be addressed through



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appropriate enforcement mechanisms. Disciplinary actions may include letters of reprimand, restrictions on the use of NIH funds, and, in severe cases, termination of employment. Panluminate will ensure that all corrective actions are documented and communicated to relevant parties.

- **Retrospective Review:** If an FCOI is identified that was not managed in a timely manner, a retrospective review will be completed within 120 days to determine if any research was biased. The review will document the methodology, findings, and conclusions.
- **Mitigation Report:** If bias is identified, Panluminate will submit a mitigation report to NIH, detailing the impact of the bias and actions taken to eliminate it.

### **12. Subrecipient Compliance**

Panluminate, through its Members, shall require sub-recipient compliance with pertinent FCOI requirements as mandated by PHS regulations:

- **Certification:** If the subrecipient follows its own FCOI policy, Panluminate will require a certification confirming that their policy complies with NIH regulations. This certification must be included in the written subrecipient agreement.
- **Reporting:** The subrecipient agreement must include a requirement for the subrecipient to report identified FCOIs for its Investigators in a timeframe that allows Panluminate to report these FCOIs to NIH as required by the regulations.
- **Review and Management:** Alternatively, the agreement may include provisions for Panluminate to solicit and review subrecipient Investigator disclosures, enabling Panluminate to identify, manage, and report identified FCOIs to NIH.
- **Monitoring Compliance:** Panluminate will monitor the subrecipient's compliance with FCOI requirements throughout the duration of the research project.

### **13. Record Maintenance**

- FCOI-related records, including disclosures and management plans, will be maintained for at least three (3) years from the date of the final expenditure report or longer if required by federal regulations.
- Records will be maintained in compliance with federal regulations and any other applicable policies, ensuring that they are accessible for audit or review by the NIH if required.

### **14. Public Accessibility Requirement**

- **Posting on Website:** Panluminate shall post this FCOI policy on Panluminate public website ([www.panluminate.com](http://www.panluminate.com)), as required by the regulation.
  - The information will be updated annually and within 60 days of identifying a new FCOI. Panluminate will ensure that the public has access to accurate and up-to-date information regarding FCOIs related to NIH-funded research





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- **Public Requests:** FCOI Informational requests by the public concerning identified FCOIs held by senior/key personnel should be made to the CEO. The CEO shall respond to requests for FCOI information within five (5) business days with minimum reporting elements as provided for under applicable regulations.

### **15. Policy Review and Updates**

- Panluminate will review and update this policy as necessary to ensure continued compliance with NIH regulations. Any updates will be communicated to Investigators, and additional training will be provided if required.
- Panluminate will ensure that any updates to the FCOI policy are disseminated to all affected personnel promptly and will provide additional training as necessary to address changes in federal regulations or internal policies.