
 <b>Heluna Health®</b>				<b>Disclosure of Financial Interests and Management of Conflicts of Interest for Public Health Service Research Awards</b>					
<b>Policies and Procedures:</b>		<input checked="" type="checkbox"/> Headquarter Employees		<input checked="" type="checkbox"/> Program Employees		<input type="checkbox"/> Medicaid		<input type="checkbox"/> Other (specify)	
<b>Responsible Department:</b> PGM				<b>Approved By:</b>					
				Signed by:  Peter Dale Chief Program Officer					
<b>Issue Date:</b> 5/20/2026				<b>Approval Date:</b> 5/20/2026					

**A. Policy Statement:**

This policy governing financial conflict of interest applies to all PHS-sponsored Investigators of the Institution and all Investigators applying for PHS funding. This policy requires disclosure and management of conflicts of interest in order to maintain an environment that supports research that is conducted free of bias resulting from investigator conflicts of interest. The policy also requires Investigator training in conflict of interest policy and requirements. Heluna Health, as the awardee institution, is responsible for ensuring compliance with this policy. Specific requirements for subrecipients of PHS-sponsored research awards from Heluna Health are also specified in this Policy.

PHS-funded research refers to projects supported by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), through grants or cooperative agreements. It requires strict investigator disclosure of financial interests, annual updates, and training to manage potential financial conflicts of interest (FCOI). PHS awarding components include CDC, NIH, and HRSA.

**B. Purpose:**

It is the policy of Public Health Foundation Enterprises, Inc. (“PHFE”), dba Heluna Health, to comply with the requirements of federal regulation 42 CFR 50 Subpart F<sup>i</sup> and 45 CFR 94 as amended through implementing this policy on conflict of interest disclosure, identification, management, and reporting pertaining to PHS-supported research.

**C. Scope:**

This policy for disclosure and management of conflicts of interest applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to PHS (NIH, CDC, HRSA, etc.) and other non-federal sponsors that adopt the PHS policy for research.

Consistent with PHS regulations, this policy will be made available via a publicly-accessible Website. All Heluna Health Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this policy and relevant reporting requirements may be accessed via the web.

**D. DEFINITIONS:**

Clinical Trial	Any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.
Family	Any member of the Investigator's immediate family, specifically, any dependent child, spouse, and/or registered domestic partner.
Financial Conflict of Interest (FCOI)	A Financial Conflict of Interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
Institutional Official	The individual within the Institution that is responsible for the solicitation and review of disclosures of Significant Financial Interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated by the Chief Program Officer or equivalent, or their designee.
Institutional Responsibilities	The Investigator's professional responsibilities associated with their Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.
Investigator	Any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator (PI), project director (PD) or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, graduate students, or other key personnel. The definition may also include collaborators or consultants as appropriate. Site principal investigators conducting administrative and/or research duties are included in this definition.
Public Health Service (PHS)	The Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease

	Control and Prevention (CDC), Federal Occupational Health, Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).
Research	A systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
Senior/key personnel	Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution for the research project.
Significant Financial Interest (SFI)	<p>Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner and dependent children for the following categories:</p> <ul style="list-style-type: none"> <li>• With regard to any publicly-traded entity (domestic or foreign), a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in the exceptions below) 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. Included are salary (other than salary described in the exceptions below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value;</li> <li>• With regard to any non-publicly-traded entity (domestic or foreign), a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in the exceptions below) 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, registered domestic partner, or dependent children) holds any equity interest;</li> <li>• Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests.</li> <li>• Travel related to the Investigator's Institutional Responsibilities must also be disclosed when the travel is reimbursed or sponsored by an individual or entity other than a U.S. federal, state or local government agency, a U.S. institution of higher education, or a research institute, academic medical center, or hospital affiliated with a U.S. institution of higher education.</li> </ul> <p><b>Exceptions:</b> The term "Significant Financial Interest" does not include the following types of financial interests:</p>

	<ul style="list-style-type: none"> <li>• Salary, royalties, or other payments (including reimbursements) made by Heluna Health to a Heluna Health Investigator who is currently employed or otherwise appointed by Heluna Health or outside sponsored party;</li> <li>• Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a government agency of the United States (including federal, state, or local government), a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with a U.S. institution of higher education;</li> </ul> <p>Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.</p>
--	--

## E. Procedure

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest. Investigators must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research. It provides mechanisms for Investigators and Institutions to manage conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation provokes questions regarding a possible conflict of interest, an Investigator should discuss the situation with the Institutional Official.

### 1. DISCLOSURE OF FINANCIAL INTERESTS

- i. All Investigators are required to disclose their significant financial interests (SFI) to the Institution on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.
- ii. Annual Disclosures
  1. All Investigators must disclose their SFI's that are related to the investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by March 31 for the previous calendar year.
- iii. Ad hoc Disclosures
  1. In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their SFI's to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.
  2. Each Investigator must disclose all Significant Financial Interests no later than at the time of application for PHS-funded research. Prior to entering PHS-sponsored projects or submitting an application for PHS-

sponsored projects, where the Investigator has an SFI, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of the SFI's.

3. In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any SFI they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the SFI.

iv. Travel

1. Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of SFI. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2. REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

- i. If the disclosure form reveals an SFI, it will be reviewed within sixty (60) days of receipt by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.
- ii. A Financial Conflict of Interest will exist when the Institutional Official or designee determines that an SFI could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, the Institutional Official will develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research funds are spent. Heluna Health will not permit the expenditure of PHS funds until all Investigators' SFIs have been reviewed and any identified FCOIs have been managed.
- iii. The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3. SUBRECIPIENT RESPONSIBILITIES

- i. Collaborating investigators from other institutions who will be conducting research under a subrecipient agreement with Heluna Health are expected to comply with the policies and procedures for disclosure and review of SFI's at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with DHHS policy, they must comply

with Heluna Health's policies and procedures for disclosure and review of SFI's related to PHS sponsored awards. The subrecipient agreement shall specify the time period(s) for the subrecipient to report all identified financial conflicts of interest to Heluna Health, so that Heluna Health can provide required reports, as needed, to PHS, within the sixty (60) day timeline required by DHHS policy.

- ii. Subrecipient agreements issued by Heluna Health will ask whether the subrecipient institution has a policy that is in compliance with DHHS policy. If the subrecipient institution has a compliant policy, the subaward will ask the subrecipient to certify that its policy complies with DHHS policy and indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending Heluna Health a notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements. If the subrecipient institution does not have a compliant policy, then the subrecipient institution will be required to comply with Heluna Health's policies and procedures for disclosure and review of SFI's related to PHS sponsored awards.

#### 4. REPORTING TO PHS

- i. The Institutional Official will report Financial Conflicts of Interest or non-compliance to PHS in accordance with PHS regulations (prior to the expenditure of funds or within sixty (60) days of any subsequently identified Financial Conflict of Interest). Additionally, for any Financial Conflicts of Interest previously reported, the Institutional Official will submit annual FCOI reports to the PHS Awarding Component for the duration of the project. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within sixty (60) days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS. Reports will include the Investigator name, project number, entity name, nature of the SFI, approximate value, and key elements of the management plan.

#### 5. INVESTIGATOR NON-COMPLIANCE

- i. Disciplinary Action
  1. In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy. This may include suspension, removal from project, or other disciplinary action.
  2. A Institutional Official's decision to impose sanctions on an Investigator

because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

ii. Retrospective Review

1. If an SFI is identified that was not disclosed by an Investigator in a timely manner, was not previously reviewed by the Institutional Official, or a Financial Conflict of Interest was not managed during an ongoing PHS-funded research project, the Institutional Official shall, within sixty (60) days, review the SFI, determine whether it is related to PHS-funded research, and determine whether a Financial Conflict of Interest exists.
2. In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose an SFI that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a designee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS- sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research. Such a retrospective review will be completed within 120 days of the Institutional Official's determination of noncompliance.
3. Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.
4. The Institutional official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

## 6. TRAINING

- i. Each Investigator must complete the following training prior to engaging in research funded by PHS, and at least every four years thereafter:
  - Training on this Policy;
  - Training on the Investigator's responsibilities regarding disclosure; and
  - Training on the PHS Conflict of Interest regulations (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94)<sup>ii</sup>.
- ii. Investigators must also complete training immediately or as soon as reasonably practicable in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.
- iii. Investigators must provide documentation of training completion to Heluna Health at the time that training is completed.

## 7. RECORD RETENTION

- i. The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee. Unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

## 8. CONFIDENTIALITY

- i. To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/ or DHHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure. Regulatory requirements for public disclosure override confidentiality considerations.

## 9. PUBLIC ACCESSIBILITY

- i. Prior to the expenditure of funds, the Institution will respond to any requestor within five business days of the request, information concerning any SFI that meets the following criteria:
  - The SFI was disclosed and is still held by the senior/key personnel;
  - A determination has been made that the SFI is related to the PHS-funded

- research; and
- A determination has been made that the SFI is a Financial Conflict of Interest.
- ii. Consistent with the requirements of DHHS policy, the information to be made available shall include the investigator name, the investigator title/role, the entity name, the nature of the SFI, and the approximate dollar value or statement if not determinable.

**10. REGULATORY AUTHORITY**

- i. This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94 as of this policy revision date; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

**F. Compliance**

- The Internal Audit department or Business Compliance Manager will periodically monitor compliance with the policy. Monitoring will be conducted at a minimum, annually.
- The policy will be reviewed annually and updated as necessary.

**G. Policy Version History**

Version	Effective Date	Description of Change	Author/Owner	Approval Authority
1.0	4/2/2013			Nancy Kindelan
1.1	5/1/2020			Peter Dale
1.2	5/20/2026	Update policy to comply with updates to CFR Title 42, Part 50, Subpart F. Update title, clarify applicability, and make minor modifications to dates.	PGM Department	Peter Dale

<sup>i</sup> § 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

<sup>ii</sup> Example: CITI Program COI training for Public Health Service (<https://about.citiprogram.org/course/conflicts-of-interest-coi-basic/>)