



**Pearl Diagnostics Policy – Financial Conflict of Interest (FCOI) Policy,
April 25, 2023**

Performance and reporting of objective research is of paramount importance to Pearl Diagnostics (PearlDx), our subgrantees, contractors and vendors, focused on ensuring trust and meeting both scientific and ethical goals of our state and federal grant efforts, including those supported by the National Institutes Health (NIH). Company policies were developed to meet criteria outlined by the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) final rules, in compliance with Financial Conflict of Interest (FCOI) Promoting Objectivity in Research 2011 (**42 CFR Part 50 Subpart F**).

PearlDx believes that the requirements of this ruling are addressed with the policy summarized below, although updates will be made in a continuous basis, based on further DHHS guidances.

Effective April 25, 2022, PearlDx's policy requires that all investigators, subrecipient, subgrantees and collaborators affiliated with PearlDx, through financial support of NIH or any other state or federal grant or contract, be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts).

The following definitions and policy guidances are established based on NIH guidance:

- **Investigator** refers to any Project Director or Primary Investigator regardless of title or position who is responsible for the design, conduct or reporting of research funded by PHS.
- **Institution** refers to any domestic or foreign, private or public, entity or organization (excluding a federal agency) that is applying for or received NIH research funding

- **Significant Financial Interests** are any financial interests of the investigator (and spouse and dependents) that appears to be related to the Investigator’s institutional responsibilities. As a non-publicly traded entity, PearlDx, would define the following items as SFIs:
 - any remuneration to an investigator >\$5000/year
 - when the investigator or spouse holds equity interests (e.g. stock, stock options, or other ownership interest
 - receipt of income related to related intellectual property (IP) rights and interests.
 - any reimbursed or sponsored travel related to their PearlDx 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, medical center, or research institute that is affiliated with an Institution of higher education. Disclosure includes, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The term **significant financial interest does not** include the following types of financial interests:

- salaries, royalties or other remuneration paid by PearlDx to the Investigator if the Investigator is currently employed or otherwise appointed by PearlDx, including intellectual property rights assigned and agreements to share in royalties related to such rights;
- any ownership interest in PearlDx 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;
- income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, academic teaching hospital, a medical center, or

income from service on advisory committees or review panels for a federal, state or local government agency, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

A **Financial Conflict of Interest (FCOI)** exists when PearlDx reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH-funded research. PearlDx will manage the FCOI with a management plan that includes reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. Any FCOI will be reported on public presentations, including research reports and manuscripts.

All PearlDx employees are required to complete training related to Financial Conflict of Interest (FCOI). If any conflicts of interest are found or known, they must be disclosed. The training must be updated no-less than every four years or as designated based on receipt of new funding sources (grants or contracts) or new roles. A tutorial on disclosure policies is provided on the NIH Web site.

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

PearlDx's designated official(s) will review all disclosures and evaluate whether they contain any FCOI. If no FCOI is found, the disclosure forms will be filed in the SFI binder. Identified FCOIs will be reported through the eRA Commons FCOI module prior to expenditure of any funds. If any interests are identified as conflicting subsequent to the initial report they must be reported to PearlDx within 30 days. PearlDx will then report it to the PHS awarding component that has issued the award within 60 days.

Each investigator must submit an updated disclosure of an SFI at least annually. Financial disclosure records and all actions taken by PearlDx will be maintained for at least three years from the date of submission of the final expenditures report.

Types of reports maintained in the SFI binder are summarized in Appendix #1. Disclosure forms are included as Appendix #2 and 3.

Failure to comply with the FCOI policy shall trigger a retrospective review of the Investigator's activities to determine potential bias. If a bias is found, PearlDx shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3). Such a mitigation report will summarize nature of the bias and actions taken to mitigate future bias events, including the management plan. In some cases, including egregious omissions or repeated events, management may choose to terminate the employee.

PearlDx mandates that all Investigators disclose FCOI in all public presentations of research.

This policy and all FCOI PearlDx guidance are also available at <https://www.PearlDx.com/fcoipolicy> (or this document, the Financial Conflict of Interest (FCOI) Policy, April 25, 2023), enabling access to the general public and company employees.

Appendix #1

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

FCOI POLICY ACKNOWLEDGEMENT

(MANDATORY FOR ALL EMPLOYEES)

I acknowledge that:

- Pearl Diagnostics, Inc. has provided me access to the Company FCOI policy.
- I have read, understood and had an opportunity to ask questions concerning this FCOI policy.

Check one:

- First reading of FCOI Policy as new employee
- First reading of FCOI Policy as Policy is introduced
- Repeated reading of FCOI Policy as Policy is updated

Print Name: _____

Signed: _____

Date: _____

FCOI TRAINING ACKNOWLEDGEMENT

(MANDATORY FOR ALL EMPLOYEES)

I acknowledge that:

- I have undergone the required FCOI training mandated in the current FCOI policy

Check one:

- First training as new employee
- First training as FCOI Policy is introduced
- Repeated training every two years
- Repeat training due to return to compliance with FCOI policy or an FCOI management plan

Print Name: _____

Signed: _____

Date: _____

FCOI COMPLIANCE CERTIFICATION

SCREENING QUESTIONNAIRE FOR SFIs

Please check YES or NO for each of the following:	Yes	No
<p>During the past twelve months, did you, your spouse, registered domestic partner, or your dependent children receive aggregated compensation – monetary or otherwise (e.g., consulting fees, honoraria, speaking fees, stipends, dividends, ownership interest, equity interest, stock, stock options and gifts)—exceeding \$5,000 in value from an external entity operating in areas relating to your responsibilities?</p>		
<p>During the past twelve months did you, your spouse, registered domestic partner or your dependent children own any equity interest including any stock, stock option, or other ownership interest, that when aggregated, exceeds \$5,000 as of the date of the disclosure as determined through reference to public prices or other reasonable measures of fair market value related to your Company responsibilities</p>		
<p>During the past twelve months, did you, your spouse, registered domestic partner, or your dependent children receive income exceeding \$5,000 related to any interests or rights in intellectual property from an external entity related to your Company responsibilities?</p>		
<p>During the past twelve months or in the next twelve months, did you participate in/do you plan to participate in any travel that was reimbursed or sponsored by an external entity operating in areas relating to your responsibilities? Do not report travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.</p>		

Check one:

Based on the Company FCOI policy and the questionnaire above:

- I DO NOT have new SFIs to report or existing SFIs to update
- I DO have SFI(s) to report or update which are attached

Check one:

Occasion for recertifying my SFI disclosures are up to date:

- Initial (start of FCOI policy)
- Initial (new employee)
- Submittal of grant application as Key Personnel: proposal # _____
- New grant award or assignment to new project: grant # _____
- Annual
- New SFI to report

I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge and that I will update promptly if my circumstances change.

Print Name: _____

Signed: _____

Signed: Date: _____

SFI DISCLOSURE FORM (one ENTITY per form)

Entity

Entity type

(e.g., energy, biomedical, service provider, or other)

Check one:

- List an SFI
- Update/edit an SFI
- Delist an SFI

1) Employee Significant Financial Interest as defined in FCOI policy

Include type of interest (remuneration, equity, intellectual property, travel), dollar amount, dates, and other details:

2) ALL open Federal Grants where employee is an investigator:

3) Explain any potential relationship between Employee, Entity and any Federal Grant for which employee is an Investigator: (e.g., vendor, subcontractor, potential investor)

4) If delisting an SFI, state reason: (e.g., equity sold)

I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge and that I will update promptly if my circumstances change.

Print Name:

Signed: Date:

SFI Review (Designated Company Official)

Check one:

- SFI is not deemed a FCOI with respect to any applicable grants
- SFI may be an FCOI with respect to grant(s) and appropriate management action has been taken, as detailed below

Print Name: _____

Signed: Date: _____

Management Plan for FCOI, as agreed with employee (check all that apply):

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc;
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflict

Management review signature _____ Date _____

Personnel review signature _____ Date _____

Additional comments and explanations on management plan, including change in roles, funding sources, or departures in monitoring plan for future management:
