

Fluid Discovery Financial Conflict of Interest Policy- US HHS Awards Program

Updated: August 15, 2022

SCOPE:

The scope of the policy herein is company-wide. The Fluid Discovery Financial Conflict of Interest Policy- US HHS Awards Program covers all projects conducted with HHS/PHS/NIH funds in Fluid Discovery and is applicable to all employees, subrecipients, consultants, or any other covered organizations or persons involved in programs sponsored by these awards.

PURPOSE:

Fluid Discovery strives to operate at the highest levels of integrity, and this includes implementing procedures to ensure the work Fluid Discovery conducts is free of any real or perceived conflicts of interest that could harm patients, the reputation of Fluid Discovery, any governmental agency providing funding, and/or external partners. As Fluid Discovery must comply with government regulations when making expenditures with Government Awards, this policy covers the processes for informing Fluid Discovery staff and associated of these requirements, the disclosure of individual financial interests, and the management and reporting of individual financial conflicts of interest in Governmental Awards. Under this Policy, Fluid Discovery strives to ensure that all work performed supported by funding from the US HHS/PHS/NIH meets or exceeds the standards required by the US HHS/PHS/NIH.

It is intended to comply with the requirements of US federal regulations, including , but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (“the PHS FCOI Rules”) as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the “Financial Conflict of Interest Rules”).

COMPANY RESPONSIBILITY:

Prior to receiving US PHS funding, Fluid Discovery will be able to certify that the company 1) has in effect an up-to-date, written, and enforced administrative process to identify and manage Financial Conflict of Interest (FCOI); 2) shall promote and enforce Investigator compliance with the regulation; 3) shall manage FCOI and provide initial and ongoing FCOI reports as required to the US Dept of Health and Human Services (HHS)/ (Public Health Service) PHS and/or (National Institutes of Health) NIH.

Upon receiving HHS-derived funding, Fluid Discovery agrees to make FCOI and significant financial interest (SFI) information (including related Institutional reviews and determinations) available to HHS, promptly, upon request. Fluid Discovery shall fully comply with the regulation’s requirements.

KEY DEFINITIONS:**Company:**

Use of “company” or “the company” in this document refers to Fluid Discovery, Inc, unless otherwise noted.

Financial Conflict of Interest (FCOI):

Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of NIH-funded research

Investigator(s):

This Policy refers to Fluid Discovery staff and associates considered “Investigators” by the US National Institutes of Health (NIH). Investigators are considered by any Fluid Discovery staff or associates responsible for the design, conduct, or reporting of research funded by the US Public Health Service (PHS), NIH inclusive.

The definition of Investigator includes, but is not limited to, those who are:

- Principal Investigators (PIs)
- Co-Investigators (Co-Is)
- Honorary Staff
- Post-Doctoral Researchers
- Students, Technicians
- External collaborators or consultants

Institution:

In this policy, Institution refers to Fluid Discovery, Inc. unless otherwise noted.

Significant Financial Interest (SFI) is defined by the NIH regulation:

(1) 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:

- (i) 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;

- (ii) 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
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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.

(3) 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.

Subrecipient:

An organization receiving a portion of PHS/NIH funds awarded to Fluid Discovery

POLICY BODY

Investigator Inform and Orientation

As part of the Fluid Discovery Orientation Program (FDOP), every Investigator will be informed of US Federal requirements and regulation for individuals engaged in PHS-funded work. This includes, but is not limited to, being provided a copy of this Policy and the disclosure responsibilities of the Investigator, and completing a training module covering FCOI, including this policy.

If an Investigator is not subject to the full FDOP for whatever reason, prior to working on any project funded by PHS funds, they will still be provided a copy of this Policy and the disclosure responsibilities and be required to complete an FCOI training module administered by Fluid Discovery.

Additionally, no more than 4 years will lapse between an Investigator completing the Fluid Discovery FCOI training module. If the Fluid Discovery Financial Conflict of Interest Policy- Government Awards Program is updated, this will trigger a requirement for updated completion of the FCOI training module for all Investigators. If an Investigator is found to be out of compliance with this Policy or the management plan, this will trigger an immediate requirement for completion of the FCOI training module, with 5 business days provided for completion.

These training requirements will be integrated into Fluid Discovery staff and consultant engagement agreements.

Disclosure, Review and Monitoring

Parties at Fluid Discovery have responsibilities in Disclosure, Review and Monitoring of SFIs and FCOIs. The responsibilities as covered in this policy are outlined below.

Financial Integrity Officer (FIO)

A role at Fluid Discovery shall be Financial Integrity Officer (FIO). Responsibilities of the FIO includes soliciting and reviewing SFI disclosures of each Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's Fluid Discovery responsibilities. The FIO will determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. The FIO shall solicit disclosures from Investigators at least annually during the period of any PHS/NIH-supported project upon which the investigator is working, and no later than at the time of an application for PHS/NIH-funded research. Additionally, prior to Fluid Discovery's expenditure of PHS/NIH funds, the FIO shall: Review all involved Investigator SFI disclosures, determine if any SFIs relate to PHS-funded research, and determine if an FCOI exists. The FIO shall also

develop and implement management plans, as needed to manage FCOIs. The FIO shall provide an update on the FCOI disclosure and management plan to the Fluid Discovery Board at least once annually, and report to the Fluid Discovery Treasurer on same at least twice annually.

Instigators

The responsibilities of each Fluid Discovery Investigator include disclosing to the FIO SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's Fluid Discovery responsibilities. This shall be done: upon solicitation from the FIO, within 30 calendar days of discovering or acquiring a new SFI, no later than at the time of application for PHS-funded research, and at least annually during the period of any PHS/NIH award with which the Investigator is involved.

Company aka Fluid Discovery

Fluid Discovery management will provide the FIO adequate guidelines consistent with PHS/NIH regulations to support the FIO in determining whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. This includes implementing these minimum processes:

New Investigator/New SFI Process

New SFIs that are reported by the Investigator to the FIO during new engagement with an Investigator, or when an existing Investigator discloses a new SFI, shall be reviewed by the FIO within one working week. After the analysis of the SFIs, the FIO will provide to a member of the executive team a report, including an assessment of whether the SFIs meet the criteria of FCOI, along with recommended actions. The executive and FIO will confirm the recommended actions, including if review of Fluid Discovery legal support, or clarification from the Investigator is necessitated. If an SFI is determined to be a FCOI, the executive and FIO will agree on a management plan and a Human Resources official will be informed of the plan, and then the Investigator will be informed.

Examples of how FCOIs might be addressed in a management plan include, but are not limited to, the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of SFIs (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts

A summary of any FCOIs and management plan outcomes will be provided to the Board twice annually.

If Fluid Discovery identifies an SFI which was not disclosed by an Investigator in a timely manner, or otherwise not previously identified, the above process will hold, with a maximum time of 60 days from identification of the SFI to the implementation of a management plan.

FCOI Management and Compliance Process

FCOIs, including any financial conflicts of a subrecipient Investigator, as applicable, shall be managed as outlined in the Disclosure, Review and Monitoring section of this policy. Additionally, if an Investigator or Subrecipient investigator is noncompliant with an FCOI Management Plan, as determined by the FIO, the Investigator will be suspended immediately from participating in the supported research project, until compliance is achieved, unless the Investigator is removed permanently from the project. If an Investigator or subrecipient Investigator is compliant with the FCOI Management Plan, as determined by the FIO monitoring every 8 weeks for the course of the project, they may continue working on the supported project, but will be required to disclose SFIs prior to being included in future PHS-supported research award applications.

Reporting to NIH

Fluid Discovery will uphold the company's responsibility for all FCOI reporting required by US PHS/NIG regulation. This includes, as applicable, initial, annual (i.e. ongoing) and revised FCOI reports and related elements from Fluid Discovery and Subrecipients. As required, FCOI reporting will also be provided:

- Prior to the expenditure of funds
- Within 60 days of identification for an Investigator who is newly participating in the project
- Within 60 days for new, or newly identified, FCOIs for existing Investigators
- At least annually (at the same time as when Fluid Discovery is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report, if appropriate.

The FIO shall ask for and shall be informed by Fluid Discovery staff of the timelines for any awards subject to FCOI management plans. The FIO is responsible for providing the reporting as required by PHS regulation.

If Fluid Discovery confirms FCOI-related bias related to the design, conduct, or reporting of NIH-funded research, including if an Investigator fails to comply with this policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, Fluid Discovery will promptly inform the NIH. A Mitigation Report in accordance with PHS regulation will also be submitted to the NIH to accompany the report. Fluid Discovery shall include the corrective actions planned for any policy or management plan noncompliance. The FIO is responsible for such reports and shall be supported by Fluid Discovery administrative staff and/or legal support, as needed. The CEO of Fluid Discovery, and the Board, shall be informed of Reports and management plans to be provided to the NIH.

Maintenance of Records

Fluid Discovery will maintain all applicable award-related FCOI-related records for no less than 4 years from the date the final expenditures report for is submitted to the PHS (NIH) for that award, and, where applicable, from other dates specified in DHHS [45 CFR 75.361](#). It is the FIO's responsibility, working with the appropriate grant administrator or other administrative staff, to secure the documents in Fluid Discovery managed folders, using company-approved nomenclature.

Enforcement Mechanisms and Remedies and Noncompliance

If Investigators do not comply with this Fluid Discovery Financial Conflict of Interest Policy- US HHS Awards Program, or the FCOI management plans provided by the FIO, they may be in breach of engagement contract, and may lose the ability to be employed or otherwise engaged with the Company.

If Fluid Discovery determines Investigator noncompliance for SFIs not disclosed in compliance with regulations, or if an FCOI is not identified or managed by Fluid Discovery in a timely manner, Fluid Discovery will conduct and document a retrospective review within 120 days, consistent with PHS regulation. The FIO will be responsible for this review, and will receive Fluid Discovery executive, administrator, and/or legal support if requested.

If the US Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Fluid Discovery as required by the regulation, Fluid Discovery shall immediately require the Investigator involved to disclose the FCOI in each public presentation of the results of the research, and to request within 30 days an addendum to any previously published presentations related to the PHS-funded research project. The FIO shall inform the CEO of Fluid Discovery of this determination by the US HHS.

It is the FIO's responsibility to record if the Investigator has completed these requirements, and to report to a Human Resources official if the Investigator is in noncompliance as this may result in breach of contract and punitive actions, not excluding termination of employment or contractor relationship.

Subrecipient Requirements

Fluid Discovery may engage with other organizations on projects funded by PHS/NIH awards. When the other organization receives a portion of the funds awarded to Fluid Discovery, the institution is considered a subrecipient. Prior to provision of the subportion of an NIH award, and ideally prior to inclusion of a potential subrecipient in a grant application, subrecipients will disclose via writing will follow this policy (Fluid Discovery Financial Conflict of Interest Policy-US HHS Awards Program), or the subrecipient FCOI policy. If the subrecipient will follow the FCOI of their own institution, Fluid Discovery FIO will obtain a certification from the subrecipient that its FCOI policy complies with NIH regulation. Additionally, prior to provision of the subportion of an NIH award, and ideally prior to inclusion of a potential subrecipient in a grant application, Fluid Discovery shall secure a written agreement from the subrecipient to report identified FCOIs for subrecipient Investigators in a time frame that allows the Fluid Discovery to report identified FCOIs to the NIH as required by regulation. The Fluid Discovery FIO will review the reported FCOIs and determine necessary actions to be taken, including reporting requirements.

Key Reference Sources:

1. Conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service ("the PHS FCOI Rules") as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) including the Checklist for Policy Development, with applicable regulatory citations.
2. 45 CFR Part 94 (titled Responsible Prospective Contractors)
3. Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the "Financial Conflict of Interest Rules")