



CORPORATE POLICY

Title: **Financial Conflicts of Interest for Research Funded by the Public Health Services of the United States of America Department of Health and Human Services**

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DOCUMENT COVER SHEET

DOCUMENT NUMBER: POL-SIM-ADMIN-025

DOCUMENT TITLE: Financial Conflicts of Interest for Research Funded by the Public Health Services of the United States of America Department of Health and Human Services

Document Approvals

The Author and Approver signatures indicate that the document is accurate and complete, to the best of the signer's knowledge on the date of the signature. The Quality Assurance signature indicates that the document is in compliance with applicable corporate policies and SOPs and applicable regulations, guidelines, and guidance documents.

Reviewed by	Approved by	QA Approval by
John Hoffman Corporate Counsel	Richard Traynor – SVP Legal Rob Aspbury – President G&A	Jeffrey Schenk Dir. QA

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1. Objective

Certara considers matters of research integrity to be of the utmost importance. It is essential that research staff should act, and be perceived to act, impartially and not be influenced, or be perceived to be influenced, in performing their research by any personal, business or other interests.

This policy considers matters relating specifically to financial conflicts of interest (FCOI) and applies to Certara employees who are applying for, or in receipt of, grant funding from the Public Health Services (PHS) of the United States Department of Health and Human Services (HHS). PHS component organizations including but not limited to:

- National Institutes of Health (NIH);
- Centers for Disease Control and Prevention (CDC);
- Food and Drug Administration (FDA);
- Agency for Healthcare Research and Quality (AHRQ);
- Substance Abuse and Mental Health Services Administration (SAMHSA);
- Agency for Toxic Substances and Disease Registry (ATSDR);
- Health Resources and Services Administration (HRSA);
- Indian Health Service (IHS)

2. Scope

The policy is applicable to any individual who is responsible for the design, conduct or reporting of research funded under PHS grants or cooperative agreements including Certara's contractors, collaborators and consultants.

Certara understands that the identification of a significant financial interest or a FCOI does not necessarily mean that there is any malpractice. However, in the interests of research integrity, Certara must monitor potential FCOI, operate transparently and put mechanisms in place to ensure that potential FCOIs do not impinge upon the integrity of research conducted.

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3. Responsibilities

CFO

- All management plans are required to be signed by the Investigator and the Chief Financial Officer. Compliance of the management plan shall be monitored by the Finance Department.
- Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the CFO shall make recommendations to the President regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

Principal Investigator of a Research Project:

- Identification of Persons Required to Disclose a Significant Financial Interest - It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators required to complete and submit a SFI Disclosure Form. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.
- Annual Reporting and After-Acquired Significant Financial Interests - All Investigators shall provide SFI Disclosure reports annually 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 thirty (30) days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the CFO.
- Submission and Review of Significant Financial Interest Disclosure Form - Each individual required to provide a SFI Disclosure Form under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted to the CFO. An initial review of the SFI Disclosure Form will be conducted by the CFO to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the



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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:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divesture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

Grants Coordinator:

- Ensure the FCOI policy is kept up-to-date and is publically accessible via its website
- Inform each Investigator that the Financial Conflicts of Interest Policy is in place
- During the development of relevant funding applications discuss the requirement of FCOI declaration and provide advice to applicants
- Obtain written assurance from any sub-recipients that their FCOI policy complies with PHS regulations and establish a written agreement with the sub-recipient to ensure compliance with the policy if the sub-recipient does not have an appropriate existing policy.

Sub-recipient Requirements

- Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F) and

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that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to notify Certara of the existence of the conflicting interest within thirty (30) days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations. If a sub-award recipient implements a management plan, Certara shall monitor Investigator compliance with the management plan on an ongoing basis.

Finance Department:

- Federal Reporting – The Finance Department is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:
 - Initial report – prior to the Company’s expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.
 - During on-going NIH-funded research projects – the Company shall submit an FCOI report within sixty (60) days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within sixty (60) days of the discovery, as well as complete a retrospective review within one hundred and twenty (120) days of discovery of noncompliance.
 - Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.
 - An update to a previously submitted FCOI report following a retrospective review.

4. Acronyms and Definitions

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- Financial conflict of interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- Investigator: the project director, principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- Research: means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge and encompasses basic and applied research (e.g. a published article) or product development (e.g. a diagnostic test) and is funded by PHS.
- Significant financial interest (SFI): a financial interest consisting of one or more of the following interests of the investigator (or the investigator's spouse and dependent children) that reasonably appears to be related the investigator's institutional responsibilities:
 - If the aggregate value of any remuneration (salary or other payments for services) and equity interest (stock, stock option or other ownership interest) from any publicly traded entity in the 12 months preceding declaration exceeds \$US 5,000; or
 - If the aggregate value of any remuneration (salary or other payments for services) from any non-publicly traded entity in the 12 months preceding declaration exceeds \$US 5,000 or when the investigator (or investigator's spouse or dependent children) holds any equity interest (stock, stock option or other ownership interest); or
 - Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests; or
 - Reimbursed or sponsored travel related to institutional responsibility (including that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact value may not be available).

*Note that the following financial interests are excluded from being classed as significant financial interests:

- Travel that is reimbursed or sponsored by a Federal, state, or local government agency, a higher education institution (HEI), an academic teaching hospital, a medical center, or a research institute that is affiliated with an HEI;

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- Salary, royalties or other remuneration paid by the institution employing the investigator;
- Intellectual property rights assigned to the institution and agreements to share the royalties from such rights;
- Any ownership interest in the Institution held by the Investigator
- Income from investment vehicles (e.g. mutual funds and retirement accounts) as long as the investigator does not directly control the investment decision made in these vehicles;
- Income from service on advisory committees or review panels for a Federal, state, or local government agency, a higher education institution (HEI), an academic teaching hospital, a medical center, or a research institute that is affiliated with an HEI;
- Income from seminars, lectures or teaching engagements sponsored by a Federal, state, or local government agency, a higher education institution (HEI), an academic teaching hospital, a medical center, or a research institute that is affiliated with an HEI.

5. Policy

5.1 Identification of financial conflicts of Interests

5.1.1 Grants Coordinator will ensure that its FCOI policy is kept up-to-date and is publically accessible via its website.

5.1.2 Grants Coordinator will inform each Investigator that the Financial Conflicts of Interest Policy is in place. In addition, during the development of relevant funding applications the Grants Coordinator or Principal Investigator will discuss the requirement of FCOI declaration and provide advice to applicants.

5.1.3 Each Investigator is required to complete online training provided by the National Institutes of Health (NIH) regarding FCOI prior to the engaging in PHS funded research. All new investigators starting during the course of the project should be directed to the training by the Principal Investigator and undertake this with thirty (30) days of taking up position. In addition, training must be undertaken by investigators on PHS funded projects in the following circumstances:

- Every four years, provided that work on the project continues;
- Immediately, should Certara change its Financial Conflicts of Interest Policy;

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- If an investigator is found to be non-compliant with the FCOI policy or a management plan which has been put in place.
- An Investigator who has undertaken FCOI training will submit evidence of completion of training to QA.
- In the event that a PHS-funded project involves research through a sub-recipient (e.g. subcontractors or collaborators), Grants Coordinator will obtain written assurance from the sub-recipient that their FCOI policy complies with PHS regulations. Certara will establish a written agreement with the sub-recipient to ensure compliance with the policy if the sub-recipient does not have an appropriate existing policy. The written agreement between Certara and the sub-recipient will ensure that suitable reporting of FCOIs is carried out in relation to the sub-recipient.

5.2 Declaration of significant financial interest

5.2.1 Prior to application for PHS funding, each investigator on the research project must submit required documentation regardless of whether they have any significant financial interest. This must be returned to the CFO, the designated person at Certara. This form identifies significant financial interests only but must be submitted even where there are no potential conflicts of interest.

5.2.2 In the event that a new Investigator joins the PHS-funded project, the Investigator must complete the Significant Financial Conflict of Interest Disclosure Form (Part II) within thirty (30) days of starting at the institution and return this to the CFO who will review it and implement any further appropriate action within thirty (30) days. This will meet the PHS requirement that any new significant financial interests which arise must be reported within sixty (60) days.

5.2.3 Each Investigator participating on the PHS-funded project must re-submit a new Significant Financial Interest Disclosure Form annually.

5.2.4 Each Investigator should resubmit a new Significant Financial Interest Disclosure Form (Part II) should the Investigator acquire or discover a significant financial interest not previously disclosed (e.g. through marriage, purchase, inheritance) within thirty (30) days of the change in circumstances.



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5.2.5 Certara will report to PHS (or the relevant component) on any significant financial interests found to be conflicting to the PHS-funded project prior to the expenditure of funds and implement a management plan. Certara will report to PHS (or the relevant component) within sixty (60) days of any subsequently identified significant financial interest.

5.2.6 For any FCOI reported by Certara, Certara will provide the PHS Awarding Component an annual FCOI report on its status and any changes to the management plan for the duration of the project.

5.2.7 Certara will provide contact details on the website so that members of the public may request information about significant financial interests related to PHS funded research. Any requests for information will be responded to within five (5) working days if the following conditions are met; significant conflicts of interest have been disclosed and relate to the PHS funded project, and have been identified as FCOIs. The information shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. Certara will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of Certara's identification of a new financial conflict of interest. Requests can be received and information disclosed up to three years after the end date of the project.

5.2.8 In each proposal submitted by Certara to PHS for funding it will be certified that:

- There is a written and enforced FCOI policy at Certara;
- Certara will report to the PHS Awarding Component on FCOIs prior to the expenditure of funds on the project and any management plans implemented

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regarding these and will submit an additional report within sixty (60) days if any new FCOIs arise;

- Certara will make available information upon request regarding all FCOIs to the HHS;
- Certara will comply with other policies regarding FCOI set by PHS.

5.3 Management of significant conflicts of interest

5.3.1 Certara, specifically the CFO, will review the declarations of significant financial interest related to PHS-funded research before expenditure of any funds to determine whether they pose a conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the institution reasonably determines that the significant financial interest could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

5.3.2 Where a financial conflict of interest is identified, Certara will develop and implement a management plan and if necessary a retrospective review and a mitigation report. Management of the financial conflict of interest could involve one or more of the following actions or other actions dependent upon the nature of the conflict:

- Public disclosure of the financial conflict of interest;
- Disclosure of the financial conflict of interest to participants involved in the research;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct or reporting of the research;
- Modification of the research plan;
- Change of personnel or personnel responsibilities;
- Reduction or elimination of the financial interest; or
- Severance of relationships that create the financial conflict.

5.3.3 Whenever Certara implements a management plan, Certara will monitor compliance with the management plan on an on-going basis until the end of the project.

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5.3.4 The CFO will maintain records relating to all Investigator disclosures and the institution's review of, response to and actions regarding such disclosures for at least three years from the date the final expenditures are submitted to PHS Awarding Component or, where applicable, from other dates specified in 45 CFR 75.361.

5.3.5 Certara will make available, within sixty (60) days, information to the PHS or HHS Awarding Component on any funded Investigator regarding their significant financial conflicts of interest and Certara's response to these.

5.4 Enforcement action

5.4.1 In the event that an Investigator fails to comply with the Policy on Financial Conflicts of Interest, appropriate investigation and disciplinary action will take place in liaison with Human Resources and in accordance with the Certara's agreed Human Resources policies.

5.4.2 In the event that a financial conflict of interest is not identified or managed in a timely manner, Certara will, within one hundred and twenty (120) days, of the determination of the non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project.

5.4.3 Certara will document the result of any investigation and if appropriate update the FCOI report submitted to the PHS Awarding Component.

5.4.4 In the event that bias relating to a FCOI is found, Certara will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS.

5.4.5 If the HHS determines that a PHS-funded project of clinical research (purpose to evaluate the safety or effectiveness of a drug, medical device, or treatment) has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by Certara as required, then Certara shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.



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5.5 Confidentiality

5.5.1 To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, Certara may be required to make such information available to the PHS and/or HHS Awarding Component, to a requestor of information concerning FCOI related to PHS funding or to the primary entity who made the funding available to Certara if requested, or required. If Certara is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.



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Revision History

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1.0	See workflow history report	New policy