

MONTARA THERAPEUTICS, INC.

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

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1 Introduction

The U.S. Department of Health and Human Services (HHS) has issued regulations at **42 CFR Part 50 Subpart F** ("Promoting Objectivity in Research") that govern the disclosure, review, and management of financial conflicts of interest in Public Health Service (PHS)–funded research. The current version of the regulation was issued in 2011. The regulations apply to all PHS-funded grants, cooperative agreements, and research contracts (including those funded by the National Institutes of Health, NIH). The regulations are **not applicable to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications or awards**.

This policy implements the regulatory requirements of 42 CFR Part 50 Subpart F for Montara Therapeutics, Inc. ("Montara" or the "Company"), a Delaware C-corporation engaged in the discovery and development of central-nervous-system (CNS)–selective small-molecule therapeutics. The policy applies to all Investigators conducting PHS-funded research at, or under a flow-through from, Montara, including subrecipient Investigators where Montara is the prime awardee.

This policy is applicable to Montara's NIH/PHS-funded awards beginning with award and to all subsequent PHS-funded awards. Compliance with this policy is a condition of employment and a condition of participation in PHS-funded research at Montara.

2 Definitions

For the purposes of this policy, the following definitions apply.

Financial Conflict of Interest (FCOI): a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities: the professional activities an Investigator performs on behalf of Montara, including research, administration, project management, and consulting performed in his or her capacity as a Montara employee or contractor.

Designated Official (DO): the individual designated by Montara to oversee the FCOI process, including solicitation and review of Significant Financial Interest disclosures and identification of FCOIs per the regulatory criteria at 42 CFR 50.604(f). Montara's Designated Official is Nicholas T. Hertz, Ph.D., CEO, reachable at nhertz@montaratx.com. The Designated Official also serves as Montara's FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module with authority to submit FCOI reports to NIH.

Investigator: the Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by a PHS award or proposed for such funding, including collaborators, consultants, and subrecipient personnel. Montara's PD/PI, in consultation with the Designated Official, will determine who meets the definition of Investigator based on the individual's role and degree of independence in carrying out the research.

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, life sciences, and behavioral and social sciences research. The term encompasses basic and applied research (e.g., journal articles, book chapters, conference presentations) and product development (e.g., drug discovery, preclinical

evaluation, IND-enabling studies). For PHS-funded research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract.

PHS: the Public Health Service of the U.S. Department of Health and Human Services and any components of the PHS to which the authority may be delegated, including the National Institutes of Health (NIH).

NIH: the National Institutes of Health, the biomedical research agency of the PHS.

Senior/Key Personnel: the PD/PI and any other person identified as senior/key personnel by Montara in the grant application, progress report, or any other report submitted to the PHS/NIH. This term is defined only as it relates to the public accessibility requirements described in Section 7.

Significant Financial Interest (SFI):

- (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 performed on behalf of Montara:
 - (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).
 - (iii) With regard to intellectual property rights and interests (e.g., patents, copyrights), a Significant Financial Interest exists upon receipt of income greater than \$5,000 related to such rights and interests.
- (2) The term Significant Financial Interest does not include the following types of financial interests; therefore Investigators are not required to disclose them:
 - (i) Salary, royalties, or other remuneration paid by Montara to the Investigator if the Investigator is currently employed or otherwise appointed by Montara, including intellectual property rights assigned to Montara and agreements to share in royalties related to such rights.
 - (ii) Any ownership interest in Montara held by the Investigator, since Montara is a commercial/for-profit organization and such interest is excluded from the SFI definition per 42 CFR 50.603.
 - (iii) 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 those vehicles.
 - (iv) Income from seminars, lectures, or teaching engagements sponsored by, or service on advisory committees or review panels for, a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

(3) Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds \$5,000 (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 the Investigator's Institutional Responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel reimbursed or sponsored by:

- (i) a federal, state, or local government agency located in the United States;
- (ii) a U.S. institution of higher education;
- (iii) an academic teaching hospital;
- (iv) a medical center or a research institute affiliated with a U.S. institution of higher education.

Foreign Financial Interests: Investigators must disclose all foreign financial interests - including income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; and reimbursed or sponsored travel - received from any foreign entity (including foreign institutions of higher education or a foreign government, including local, provincial, or equivalent governments of another country) when such income meets the \$5,000 disclosure threshold.

3 Disclosure Requirements

At the time of application, the Principal Investigator and all other individuals who meet the definition of Investigator must disclose their SFIs to Montara's Designated Official.

Any new Investigator who, after Montara's application to PHS for funding or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the Designated Official promptly and prior to participation in the project.

Each Investigator participating in research under a PHS award must submit an updated disclosure of SFI at least annually during the period of the award. The annual disclosure must include any information that was not disclosed initially or in a subsequent disclosure (e.g., any FCOI identified on an NIH-funded project, whether held directly as an NIH grantee or indirectly through a sub-award transferred from another institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Disclosures are made using Montara's SFI Disclosure Form, available from the Designated Official. Completed disclosure forms are returned to the Designated Official by email or in person.

4 Review of SFI Disclosures by Montara's Designated Official

The Designated Official will conduct reviews of all SFI disclosures. The Designated Official will compare each disclosed SFI to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research, in order to determine

whether the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest related to that research award.

Reviews will be completed prior to Montara's expenditure of any funds under a new NIH/PHS award, and within sixty (60) days of identification of a new SFI for an Investigator participating in an ongoing PHS-funded research project.

5 Guidelines for Determining "Relatedness" of SFI to PHS/NIH-Funded Research and a FCOI

The Designated Official will determine whether an Investigator's SFI is related to the research under a PHS award and, if so, whether the SFI constitutes a Financial Conflict of Interest.

An Investigator's SFI is related to the research when the Designated Official reasonably determines that the SFI:

- (i) could be affected by the PHS/NIH-funded research; or
- (ii) is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

The Designated Official may involve the Investigator in determining whether an SFI is related to the research supported by the award.

A Financial Conflict of Interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. "Significantly" means that the financial interest would have a material effect on the research.

6 Management of SFIs that Pose FCOI(s)

If the Designated Official determines that an FCOI exists, the Designated Official will develop a written management plan describing the conditions or strategies that will be applied to manage the FCOI. Examples of conditions that may be imposed include, but are not limited to:

- (i) Public disclosure of the FCOI (e.g., in presentations or publications of the research; to research personnel; to an Institutional Review Board, Institutional Animal Care and Use Committee, or Data Safety and Monitoring Board, as applicable);
- (ii) For human-subjects research, disclosure of the FCOI directly to participants in the informed consent document;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias arising from the FCOI;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- (vii) Severance of relationships that create financial conflicts.

The Designated Official will communicate the determination and the management plan in writing to the affected Investigator, to the relevant PD/PI, and to the Investigator's direct supervisor. No expenditures on any new NIH award will be permitted until the Investigator has complied with this Policy's disclosure requirements and has agreed, in writing, to comply with the management plan.

The Designated Official, in the role of Montara's FCOI Signing Official, will submit the FCOI report to NIH via the eRA Commons FCOI Module prior to expenditure of funds.

7 Public Accessibility to Information Related to FCOI

Prior to the expenditure of any funds under an NIH award, Montara will ensure public accessibility - by written response to any requester within five (5) business days of a request - to information concerning any SFI disclosed that meets all three of the following criteria:

- (i) The SFI was disclosed and is still held by Senior/Key Personnel as defined in Section 2;
- (ii) Montara has determined that the SFI is related to the research funded through an award;
- (iii) Montara has determined that the SFI is a Financial Conflict of Interest.

The information Montara will make available, via written response within five (5) business days of request, will include at a minimum:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the SFI is held;
- (iv) The nature of the SFI; and
- (v) The approximate dollar value of the SFI in the following ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000 and \$100,000 in increments of \$20,000; amounts above \$100,000 in 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 measures of fair market value.

Montara has elected to satisfy the public accessibility requirement by responding in writing to any requester within five business days. If Montara uses a publicly accessible website, the information posted will be updated at least annually and within sixty (60) days of receipt or identification of any new SFI that the Designated Official determines is related to the research and is a Financial Conflict of Interest. Information will remain available for written responses or for posting for at least three (3) years from the date the information was most recently updated.

8 Reporting of FCOI to NIH

Prior to the expenditure of any funds under an award funded by NIH, Montara will provide to NIH an FCOI report compliant with 42 CFR 50.605(b) regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

Montara's Designated Official serves as the FCOI Signing Official in the eRA Commons FCOI Module with authority to submit FCOI reports to NIH. The FCOI Module User Guide is maintained by NIH and available at the NIH FCOI Policy and Compliance website.

While an award is ongoing (including any extensions, with or without funds), Montara will provide NIH with an annual FCOI report that addresses the status of each FCOI (i.e., whether the FCOI is still being managed or no longer exists) and any changes in the management plan, if applicable.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., a new SFI is identified for a participating

Investigator, or a new Investigator joins the project), Montara will, within sixty (60) days of identifying the FCOI, submit an FCOI report and ensure that a management plan has been implemented and agreed to by the Investigator.

The initial FCOI report will include the information required at 42 CFR 50.605(b)(3) and as further described in the NIH FCOI FAQs.

9 Training Requirements

Each Investigator will be informed about Montara's Financial Conflict of Interest Policy and trained on the Investigator's responsibility to disclose foreign and domestic SFIs under this Policy and the FCOI regulation at 42 CFR Part 50 Subpart F. FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four (4) years thereafter, and immediately when any of the following circumstances apply:

- (i) Montara revises this Policy or its procedures in any manner that affects the requirements of Investigators;
- (ii) An Investigator is new to Montara's research under a PHS award (training must be completed prior to participation);
- (iii) Montara finds that an Investigator is not in compliance with this Policy or with a management plan issued under this Policy (training must be completed within 30 days in the manner specified by the Designated Official).

In fulfillment of the FCOI training requirement, Montara requires its Investigators to complete the NIH Financial Conflict of Interest tutorial, available on the NIH FCOI Training webpage, in accordance with the requirements of this Policy. Each Investigator must retain a certificate of completion and provide a copy to the Designated Official for retention in Montara's records.

10 Failure to Comply with Montara's FCOI Policy Applicable to PHS-Funded Awards

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

- (i) Failure by an Investigator to disclose a Significant Financial Interest that Montara determines constitutes an FCOI;
- (ii) Failure by Montara to review or manage such an FCOI;
- (iii) Failure by an Investigator to comply with a management plan;

Montara will, within one hundred twenty (120) days:

- (i) Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research;
- (ii) Document the retrospective review consistent with 42 CFR 50.605(a)(3)(ii)(B) and the NIH FCOI FAQs.

If bias is found, Montara will notify NIH promptly and submit a mitigation report to NIH via the eRA Commons FCOI Module addressing:

- (i) The impact of the bias on the research project; and

(ii) Montara's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Montara will continue to submit FCOI reports annually to NIH in accordance with the regulations and award terms and conditions. Depending on the nature of the FCOI, Montara may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date the FCOI is identified and the completion of the retrospective review. If no bias is found, no further action is required.

11 Clinical Research Requirements

If HHS determines that a Montara-funded clinical research project 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 Montara, Montara will require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Although the SBIR Phase II award supported by this Policy does not involve a clinical trial, this provision will apply to any future Montara PHS-funded clinical research.

12 Subrecipient Requirements

A subrecipient relationship is established when federal funds flow down from or through Montara to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to Montara for programmatic outcomes and compliance matters. Subrecipients include, but are not limited to, collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees. Subrecipients are subject to Montara's terms and conditions, and Montara will take reasonable steps to ensure that any subrecipient Investigator is in compliance with 42 CFR Part 50 Subpart F.

Montara will incorporate, as part of a written agreement with each subrecipient, terms that establish whether Montara's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s).

If the subrecipient's FCOI policy applies, the subrecipient's institution will certify as part of the agreement with Montara that its policy is in compliance with the federal FCOI regulation. In this case, the agreement will specify the time period for the subrecipient to report all identified FCOIs to Montara in sufficient time to enable Montara to provide timely FCOI reports to PHS/NIH (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Accordingly, the written agreement may establish a reporting requirement of FCOIs identified during the period of an award to be submitted to Montara within 50 to 55 days of the subrecipient's identification of an FCOI, to allow Montara to report the FCOI within the 60-day window. Montara's FCOI Signing Official will submit the subrecipient FCOI report to NIH via the eRA Commons FCOI Module.

If the subrecipient cannot provide a certification of compliance with the FCOI regulation, the agreement will state that the subrecipient Investigator is subject to Montara's FCOI Policy for disclosing SFI(s) directly related to the subrecipient's work for Montara. In that case, Montara will require submission of all Investigator disclosures of SFIs to Montara and will allow sufficient time period(s) to comply with its review, management, and reporting obligations under the regulation. When an FCOI is identified,

Montara will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit a subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

13 Maintenance of Records

Montara will keep records of all Investigator disclosures of financial interests and of Montara's review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of an FCOI), together with records of all actions taken under this Policy and any retrospective review.

Records of financial disclosures and any resulting action will be maintained by Montara for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 75.361 for different situations. Records will be retained for each competitive segment as provided in the regulation.

14 Failure to Comply with Policy

Compliance with this Policy is a condition of employment and a condition of participation for all applicable Investigators. Investigators who fail to comply with this Policy are subject to discipline, which may include letters of reprimand, restrictions on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, as may be deemed appropriate by Montara's Designated Official in consultation with the CEO.

Appendix - Useful FCOI and NIH Resources

Topic	Regulatory Citation
Training Requirements	42 CFR 50.604(b); see also the NIH FCOI Training webpage at grants.nih.gov.
Disclosure, Review, and Monitoring Requirements	42 CFR 50.603; 42 CFR 50.604(e)(1)–(3).
Designation of Institutional Officials	42 CFR 50.604(d).
Guidelines for Determining SFI	42 CFR 50.604(f).
Examples of Restrictions	42 CFR 50.605(a)(1).
Review of SFI Disclosures	42 CFR 50.605(a)(1); 42 CFR 50.605(a)(2). SFIs not discovered timely: 42 CFR 50.605(a)(3)(i)–(iii).
Taking Compliance Actions	42 CFR 50.604(g); 42 CFR 50.605(a)(4).
Reporting Requirements to NIH	Initial and ongoing reports: 42 CFR 50.604(h); 42 CFR 50.605(b). Retrospective review, mitigation report, and notification to NIH: 42 CFR 50.605(a)(3)(iii). Notification of failure to comply: 42 CFR 50.606(a).
Maintenance of Records	42 CFR 50.604(i).
Enforcement, Retrospective Review, and Remedies	Enforcement: 42 CFR 50.604(j). Retrospective review: 42 CFR 50.605(a)(3)(ii)(A). Documentation: 42 CFR 50.605(a)(3)(ii)(B). Request to disclose: 42 CFR 50.606(c).
Subrecipient Requirements	42 CFR 50.604(c); agreement with subrecipient: 42 CFR 50.604(c)(1)(i)–(iii).
Public Accessibility Requirements	42 CFR 50.604(a) (see also NIH GPS 4.1.10); 42 CFR 50.605(a)(5)(i)–(iv).

Other Sources of Information

- FCOI Regulation - 42 CFR Part 50 Subpart F, "Promoting Objectivity in Research," available at eCFR.
- NIH FCOI webpage - Financial Conflict of Interest at grants.nih.gov.
- NIH FCOI Training webpage - FCOI Training at grants.nih.gov.
- NIH FCOI FAQs - Frequently Asked Questions at grants.nih.gov.
- NIH Guide Notices Related to FCOI - at grants.nih.gov.
- NIH "Welcome Wagon" Letter for New Recipient Organizations - at grants.nih.gov.