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COMPANY POLICY

Policy Name: Financial Conflict of Interest

Policy Owner: Ethics & Compliance

Office Responsible for Review: Legal

Effective Date: December 23, 2022

SCOPE

All Draper employees responsible for the design, conduct, or reporting of Research funded by the U.S Public Health Service (PHS), an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Draper's existing Personal Conflict of Interest Policy remains in effect and applies to all other situations involving the disclosure and resolution of conflicts that are not explicitly covered by this Policy.

POLICY STATEMENT

Draper is committed to protecting the integrity and objectivity of its Research activities by ensuring the design, conduct, and reporting of Research will not be biased or appear to be biased by any personal Financial Conflict of Interest. Draper has implemented this policy to identify and mitigate or eliminate Financial Conflict of Interest for PHS-Funded Research and comply with requirements set forth at 42 CFR Part 50, Subpart F.

DEFINITIONS

For purposes of this policy, the following definitions shall apply:

Designated Official means an individual designated by Draper to oversee implementation of the Financial Conflict of Interest policy, including solicitation and review of disclosures of Significant Financial Interests and adjudication of Financial Conflict of Interest. For the purposes of this policy, the Designated Officials are the Ethics & Compliance Director and the Research Integrity Officer.

Equity Interest means any stock, stock option, or other ownership interest whose value may be determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research as determined by Draper through a Designated Official.

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

Immediate Family means an Investigator's spouse, same-sex domestic partner, and/or dependent children.

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Investigator means the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the Research or proposed Research.

PHS means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

PHS Awarding Component means the organizational unit of the PHS that funds the Research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

PHS-Funded Research means Research funded under PHS grants, cooperative agreements, or contracts.

PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Remuneration means salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, and paid authorship).

Research means a systematic investigation, study, or experiment designed to develop or 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). 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, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator and their immediate family that reasonably appear to be related to the Investigator's Draper project responsibilities, including:

1. With regard to interests in any **publicly traded entity**, a Financial Interest consisting of any Remuneration received from the entity in the 12 months preceding the disclosure and any Equity Interest in the entity as of the date of disclosure in which the value when aggregated **exceeds \$5,000**;
2. With regard to interests in any **non-publicly traded entity**, a Financial Interest consisting of any Remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated **exceeds \$5,000**, or when the Investigator or his/her Immediate Family holds any Equity Interest;
3. With regard to **Intellectual property rights and interests** (e.g., patents, copyrights), any receipt of income related to such rights and interests;
4. **any third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's Immediate Family) that is related to the Investigator's institutional responsibilities. This disclosure requirement excludes travel paid for by Draper or 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; or

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Significant Financial Interest does not include the following:

1. Salary, royalties, or other Remuneration paid by Draper (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Draper, including that paid for intellectual property rights assigned or licensed to Draper and agreements to share in royalties related to such rights;
2. 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;
3. Income from seminars, lectures, or teaching engagements sponsored by Federal, state, or local government agencies; institutions of higher education as defined at 20 U.S.C. 1001(a); academic teaching hospitals; medical centers; or Research institutes affiliated with institutions of higher education; or
4. Income from service on advisory committees or review panels for Federal, state, or local government agencies; institutions of higher education as defined at 20 U.S.C. 1001(a); academic teaching hospitals; medical centers; or Research institutes affiliated with institutions of higher education.

Training:

Each Investigator must complete FCOI training prior to engaging in Research funded by PHS, and at least every four years thereafter. In the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Policy or with a mitigation plan related to their activities, this training must be repeated within a reasonable period of time as determined by the Designated Officials.

POLICY

Reasons for this Policy

This Policy is written to conform to PHS regulations set forth at 42 CFR Part 50, Subpart F, and ensure Research performed by Draper Investigators is free from Financial Conflict of Interests. These regulations require all individuals who participate in the design, conduct, or reporting of Research funded by PHS to complete training on PHS policies and procedures for avoiding, identifying, and mitigating Financial Conflict of Interest and to disclose Significant Financial Interests that could present or appear to present Financial Conflict of Interest.

FREQUENCY OF UPDATE AND REVIEW

At least annually and upon regulatory change.

References:

[42 Code of Federal Regulations Part 50, Subpart F](#)

Procedures link(s), if applicable:

- [Financial Conflict of Interest Procedure](#)

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Related Form:

[FCOI Form](#)

Related company policy link(s), if applicable:

Approval:

Prepared by:

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12/22/2022 | 10:14 AM EST

Betty Eng
Director Ethics & Compliance

Date

Approved by:

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12/22/2022 | 10:17 AM EST

Alan Vail
Deputy General Counsel

Date

RECORD OF REVISIONS

Rev	Result of	Sections/Pages Affected	Approval/Date