

DetectoGen Inc.

DETECTOGEN INC. **FINANCIAL CONFLICT OF INTEREST POLICY**

Introduction

DetectoGen has a duty to ensure that work performed under Government Awards meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could harm the reputation of DetectoGen, the governmental agency providing the funding, or External Partners. In addition, DetectoGen must comply with government regulations when making expenditures with Government Awards. This policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards.

Definitions

- *External Partner*: a consultant, subcontractor, or subrecipient performing work under a Government Award who is not employed by DetectoGen.
- *Government Award*: government grants and cost reimbursement contracts including research grants or contracts.
- *Financial Conflict of Interest (FCOI)*: a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project.
- *Immediate Family Member*: any member of an Investigator's immediate family, specifically, any dependent children and spouse.
- *Investigator*: is the Project Director/Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of a research project at DetectoGen. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, graduate students or laboratory technicians. The definition may also include collaborators, visiting scientists or consultants, as appropriate.
- *Research*: 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.
- *Remuneration*: salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).
- *Public Health Service (PHS)*: is the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

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Institutional Responsibilities: an Investigator's professional responsibilities on behalf of DetectoGen which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

Significant Financial Interest:

- A. A financial interest consisting of one or more of the following interests of the Investigator or their Immediate Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities:
- the value of any remuneration received from a public 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; or
 - the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) holds any equity interest (e.g., 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.
- B. Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. The disclosure will include, at a minimum, the following details:
- the purpose of the trip
 - the identity of the sponsor/organizer
 - the destination
 - the trip duration. 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- C. Financial interest does not include the following:
- salary, royalties, or other remuneration from DetectoGen;
 - income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
 - equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

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POLICY:

It is the policy of DetectoGen to comply with the Financial Conflict of Interest Rules (“FCOI Rules”) to ensure that the work performed under Government Awards is carried out in a manner that is free from any bias which may result from financial conflicts of interest. All Investigators for Government Awards must disclose any Significant Financial Interests (SFI) to DetectoGen. Investigators must disclose any new SFI’s within thirty days of discovering or acquiring the SFI.

If DetectoGen determines that a SFI constitutes a Financial Conflict of Interest (“FCOI”), DetectoGen will establish and monitor a Conflict Management Plan (“CMP”) to manage or eliminate the conflict of interest. The manager of Sponsored Projects Administration (SPA) will be the conflict of interest official responsible for managing the conflict of interest process for Government Awards. No Government Award funds may be expended unless the SPA Manager has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of a CMP that has been adopted and implemented in accordance with the procedures set forth in this policy.

Education

DetectoGen will inform each Investigator of:

- DetectoGen’s Financial Conflicts of Interest (FCOI) Policy,
- The Investigator’s responsibilities regarding disclosure of significant financial interests,
- And these regulations listed in this policy.

DetectoGen will provide Financial Conflict of Interest training to Investigators on this policy, federal regulations and the Investigators’ responsibilities. This training will reflect the current policy and will be updated to meet the requirements of future amendments to the relevant CFRs. Each Investigator is required to complete DetectoGen’s standard training on the FCOI Policy prior to engaging in research related to any PHS-funded contract and at least every four years. Training is also required to be completed within thirty days when any of the following circumstances apply:

- DetectoGen revises FCOI policy in any manner that affects the requirements of Investigators;
- An Investigator is new to an Institution; or
- An Institution finds that an Investigator is not in compliance with DetectoGen’s FCOI Policy or management plan.

Public Posting of Policy

This policy will be posted on a publicly accessible Internet site for DetectoGen.

Reporting of Financial Conflicts of Interest for PHS-Funded Projects

Before the expenditure of any funds under a PHS-funded project and within sixty days of subsequently identifying a Financial Conflict of Interest, the SPA Manager will report all Financial Conflicts of Interest that have not been

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eliminated to the PHS awarding component and will ensure that an appropriate Conflict Management Plan has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI's, the SPA Manager will conduct a retrospective review to determine whether the PHS-funded project was affected by the financial conflict of interest, and if bias is found, will submit a mitigation report to the PHS awarding component. The SPA Manager also will provide an annual FCOI report that addresses the status of any previously reported FCOI's and CMP's related to an ongoing PHS-funded project.

External Partners

Any individual or organization acting as a consultant, subcontractor, or subrecipient ("External Partner") to DetectoGen on a PHS-funded award must either: (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules or (2) follow this policy.

Organizations with their own policy will certify that the policy meets the requirements of the PHS FCOI Rules by submitting an External Partner Financial Conflict of Interest Disclosure and the SPA Manager will verify the registration. The contract with DetectoGen will contain language requiring compliance with the organization's FCOI Policy.

Procedure

This procedure is for use by DetectoGen employees and External Partners that do not have their own FCOI policy.

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official 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 management plan related to their activities.

Contact information:

Manager, Sponsored Projects Administration
DetectoGen Inc.
5 Jacob Amsden Road
Westborough, MA 01581
P: 508 330-1709
E: acampos@detectogen.com