

# Accel Diagnostics

## Financial Conflict of Interest (FCOI)

### Policy and Instruction

*Updated 2.1.2021*

#### Table of Contents

<b>1</b>	<b><u>INTRODUCTION</u></b>	<b>1</b>
<b>2</b>	<b><u>PURPOSE</u></b>	<b>2</b>
<b>3</b>	<b><u>AVAILABILITY OF THE POLICY</u></b>	<b>2</b>
<b>4</b>	<b><u>WHO IS COVERED UNDER THIS POLICY?</u></b>	<b>3</b>
<b>5</b>	<b><u>DISCLOSURE REQUIREMENTS</u></b>	<b>3</b>
<b>6</b>	<b><u>RESPONSIBILITIES OF ACCEL DX REGARDING FCOI</u></b>	<b>3</b>
<b>7</b>	<b><u>PHS-FUNDED INVESTIGATORS RESPONSIBILITY</u></b>	<b>4</b>
<b>8</b>	<b><u>SUB-RECIPIENT REQUIREMENTS</u></b>	<b>4</b>
<b>9</b>	<b><u>SIGNIFICANT FINANCIAL INTEREST (SFI)</u></b>	<b>4</b>
<b>10</b>	<b><u>SPONSORED AND REIMBURSED TRAVEL FOR PHS FUNDED INVESTIGATORS</u></b>	<b>5</b>
<b>11</b>	<b><u>SFI REVIEW PROCESS AND MANAGEMENT PLAN</u></b>	<b>5</b>
<b>12</b>	<b><u>RECORD KEEPING</u></b>	<b>5</b>
<b>13</b>	<b><u>CONFIDENTIALITY</u></b>	<b>6</b>
<b>14</b>	<b><u>SANCTIONS</u></b>	<b>6</b>
<b>15</b>	<b><u>MANAGE FCOI</u></b>	<b>6</b>
<b>16</b>	<b><u>REPORTING OF FCOI</u></b>	<b>7</b>
<b>17</b>	<b><u>DEFINITIONS</u></b>	<b>7</b>

#### **1 Introduction**

The U.S. Department of Health and Human Services (HHS) has issued a final rule in 2011 that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94), that requires all individuals who participate in the design, conduct, or reporting of research funded by the Public Health Service complete training on financial conflicts and disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict.

The 42 CFR 50 Subpart F purpose is to “promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

As the recipient of external federal funds to support research activities, Accel Diagnostics (AccelDx or The Company) is required to have and enforce a Financial Conflict of Interest FCOI policy that is consistent with federal regulation, 42 CFR 50 Subpart F, governing financial conflicts of interest in research.

All AccelDx’s research professionals that are expected to work on a PHS-funded project in the upcoming year, or at any time they are named in a proposal for a PHS-funded project, they will be required to complete training and submit a FCOI screening form and disclose relevant financial interests. Key members of management and certain administrative and support department staff also will be required to complete the training and the screening form and provide relevant disclosures. This comprises any subcontracts awarded by a PHS component, and applicable to all federal awards.

This document is intended to establish AccelDx’s FCOI policy and assist AccelDx’s employees and members understanding this policy and how to handle potential financial conflicts of interest in research, and how to complete their *FCOI Disclosure Form*.

## 2 Purpose

AccelDx is a private own company with principal missions to develop novel diagnostic tools to improve disease management and transform the way a medical conditions are monitored and diagnosed on-site, in a patient’s home, doctor’s office, and at a patient’s bedside.

AccelDx as the recipient of SBIR grants from the National Institute of Health (NIH) generally encourages its members and employees to apply for SBIR funding, to further support and develop technologies that are in sync with the Company’s and NIH missions. AccelDx recognizes that in some circumstances such activities give may rise to potential conflicts of interest. *Conflicts of interest are situations that need to be disclosed and sometimes managed. They are not inherently bad and do not always lead to biased behavior.*

***Conflicts of interest in research occur when university members are in a position to influence research and their extramural activities are such that they or their family may receive a financial benefit or improper advantage from the research.*** Conflicts of interest have the potential to inappropriately influence many aspects of research – from how a study is designed, how data is collected, analyzed and reported, to what individuals/suppliers are involved in the work. In a university setting, especially one that promotes technology transfer and entrepreneurial activity, conflicts of interest are inevitable.

Federal regulations regarding financial conflict of interest in research are intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under federal grants, cooperatives agreements or contracts will be free from bias resulting from Investigator financial conflicts of interest.

AccelDx’s “Investigators” seeking or receiving funds from a PHS agency, or any other AccelDx’s personnel supported by federal funding agencies, are required to disclose “Significant Financial Interests” (SFI) that are related to their “Institutional Interests”. This includes certain remuneration received or ownership interests held by the Investigator, spouse/domestic partner or dependent children.

Investigators are responsible for ensuring their information provided to AccelDx is up to date prior to submitting a proposal for funding. *FCOI Disclosure Form* must be updated annually and within 30 days of discovering or acquiring (through marriage, purchase, gift, inheritance, etc.) a new Significant Financial Interest, as well as at other times if requested by AccelDx. At the time each proposal is submitted, AccelDx is required to certify its compliance with the PHS FCOI requirements. PHS funded Investigators are required by regulation to disclose the occurrence of certain types of reimbursed or sponsored travel related to the Investigator’s Institutional Responsibilities.

*It is important in order to complete the FCOI Disclosure Form accurately that the terms used in the regulations are well understood. A list of term definitions is provided at the end of this document.*

## 3 Availability of the Policy

AccelDx will maintain an up-to-date written, enforced policy on financial conflicts of interest that complies with applicable regulations, including any federal financial conflict of interest regulations. The policy will be posted

and available via the AccelDx publicly accessible website. The AccelDx will inform covered individuals of the policy and of their responsibilities regarding disclosure. The Company will inform covered individuals in the event the policy is revised and updated.

#### **4 Who is Covered Under this Policy?**

Federal regulations require that Investigators (as defined below) disclose financial conflicts of interest or significant financial interests to AccelDx prior to submission of a proposal for funding. In the event it is determined that an actual financial conflict of interest exists, the conflict must be managed prior to spending on the award.

This FCOI policy applies to all members of the Board of Directors and employees that are involved in PHS-funded research projects or are applying for PHS funding. AccelDx's members should only become involved in federal founded research activities insofar as they advance the Company's mission. All AccelDx's employees and members involved in federal founded research should review the FCOI policies.

#### **5 Disclosure Requirements**

By the time a proposal is submitted to PHS, all investigators, senior or key personnel requesting PHS funding—whether grant, cooperative agreement, or contract—are required to have submitted to the Company Official (CO) a *FCOI Disclosure Form*. These completed forms either indicate that the investigators, senior or key personnel, has no Significant Financial Interests (SFI) or includes a listing of known SFIs (and those of the spouse and dependent children) in entities whose financial interests would reasonably appear to be affected by the research for which PHS funding is sought. Financial disclosures must be updated by all investigators, seniors or key personnel on an annual basis during the award period or as new reportable SFIs are obtained, whichever occurs first.

#### **6 Responsibilities of AccelDx Regarding FCOI**

AccelDx shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 C.F.R. Part 50, Subpart F, and make such policy available to any requestor within five business days of a request.

AccelDx shall inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant, and renew training every four years, and immediately when any of the following circumstances apply:

- Revision of financial conflict of interest policies or procedures is required in any manner that affects the requirements of Investigators
- An Investigator is new to AccelDx
- An Investigator is not in compliance with its financial conflict of interest policy or management plan
- Record and review all *FCOI Disclosure Forms* from PHS-funded researchers to determine whether a FCOI exists.
- Provide required information concerning FCOIs to the expenditure of PHS funds, and must update such information at least annually and within 60 days of changes to Statement of Financial Interest Disclosure forms, whichever occurs first
- Prepare the Public Financial Conflict of Interest Disclosure Form, including the following information, for reported FCOIs such that it can be made publicly available upon request:
  - Project/Contract number
  - Investigator's name
  - Investigator's title and role with respect to the research project
  - Name of the entity in which the relevant significant financial interest (SFI) is held
  - Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.)
  - Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.)

Other responsibility of AccelDx includes

- Maintain for three years records of all Statement of Financial Interest Disclosure form records and FCOI Management Plans.

- Maintains the FCOI Policy and Procedure on AccelDx's external website.
- Must ensure compliance with FCOI policy and procedures.
- Manage FCOI.

## 7 PHS-Funded Investigators Responsibility

Investigators responsibility include:

- Must complete FCOI training prior to engaging in a PHS research project and thereafter, every four years.
- Must complete and submit to the CO a Financial Interest Disclosure Form prior to working on PHS-funded projects.
- Must update the Financial Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.
- Must follow management plan as prescribed by the CO for FCOIs.

## 8 Sub-recipient Requirements

AccelDx as the awardee Institutions is responsible for monitoring sub-recipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the National Institute of Health (NIH). AccelDx will provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all sub-recipient Investigators consistent with 42 C.F.R. 50, Subpart F, i.e., prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI. AccelDx will take reasonable steps to ensure that any sub-recipients (i.e., subcontractors or consortium members) performing work under a PHS-funded research project comply with the PHS Financial Conflict of Interest regulations by requesting that the sub-recipient:

- Complete and submit to the CO a Sub-Recipient *FCOI Disclosure Form* prior to working on PHS funded projects.
- Certify that it has a PHS FCOI compliant policy in place that its policy complies with 42 C.F.R. Part 50, Subpart F, or that it intends to have one in place at the time of the award or that it will abide by The Company policy.
- Certify that the investigators, senior and/or key personnel will complete required training.
- If the sub-recipient cannot provide such *FCOI Disclosure Form*, the agreement shall state that sub-recipient Investigators are subject to the financial conflicts of interest policy of AccelDx for disclosing significant financial interests that are directly related to the sub-recipient's work for AccelDx.

## 9 Significant Financial Interest (SFI)

SFI is 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:

- If with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000.
- If with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000.
- Income related to intellectual property rights and interests not reimbursed through The Company.

### **The term Significant Financial Interest does not include the following types of financial interests:**

- Salary, royalties, or other remuneration paid by the AccelDx to the Investigator if the Investigator is currently employed or otherwise appointed by AccelDx, including intellectual property rights assigned to AccelDx and agreements to share in royalties related to such rights.
- Any ownership interest in AccelDx held by the Investigator, as AccelDx 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 service on an advisory committee or review panel for a U.S. government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated

with an institution of higher education. These forms of income are not exempt from disclosure when they come from foreign entities.

- Income from seminars, lectures, teaching engagements sponsored by a U.S. government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. These forms of income are not exempt from disclosure when they come from foreign entities.

## 10 Sponsored and Reimbursed Travel for PHS Funded Investigators

Investigators do not need to disclose travel if it was sponsored or reimbursed by any of the following:

- A US federal, state or local government entity
- A US institution of higher learning,
- A US academic teaching hospital,
- A US medical center, or
- A US research institute affiliated with an institution of higher learning.

Investigators are not required to disclose travel unless the total value of travel sponsored by a single organization in a 12-month period exceeds \$5,000.

***Travel paid for by AccelDx or covered by a sponsored award does not need to be disclosed.***

When you disclose sponsored and reimbursed travel, you should provide the following information:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Duration

Disclosure of sponsored and reimbursed travel should be made by submitting an updated *FCOI Disclosure Form* to AccelDx's official. If the Investigator is funded by a PHS agency, he/she should complete this update within 30 days of the travel total for the year reaching \$5,000. Report travel as it occurs rather than tracking total value for the year is permitted.

## 11 SFI Review Process and Management Plan

The CO reviews each SFI received from Company personnel. If necessary, the CO collects additional information from the disclosing individual and/or from other individuals who possess relevant information. The CO determines whether the disclosed financial interests are significant, whether they are related to the individuals' research responsibilities at the Company, and whether a management plan is required. In conducting this review, the CO considers factors such as the value of the individual's financial interest and how it could affect their ability to objectively complete their research with the Company.

If a significant financial interest is deemed to be a financial conflict of interest, the CO will develop a management plan in consultation with the Investigator. The goal of the management plan is to reduce or eliminate the financial conflict of interest, which can include reducing or eliminating the financial conflict of interest and to ensure that the design, conduct and reporting of research will be free from bias. The management plan may include, but is not limited to: (1) requiring the individual to recuse him/herself from particular decisions or activities related to the research, (2) requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (e.g. relevant review bodies, research sponsors, co-investigators, journals to which manuscripts about the research are submitted, media, etc.), (3) requiring others to review decisions in which the individual participates, (4) requiring the individual to reduce, modify or eliminate a financial interest (e.g. divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments), (5) requiring the individual to vacate a position.

## 12 Record Keeping

The AccelDx complies with federal regulations regarding maintaining records relating to all disclosures of financial interests and the Company's review of, and response to, such disclosures. AccelDx will maintain records relating to all Investigator disclosures of financial interests and AccelDx's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a financial conflict of interest)

and all actions under AccelDx's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS.

Once AccelDx received the *FCOI Disclosure Form* they will be reviewed to determine if a financial conflict of interest exists. If no COI is identified, the *FCOI Disclosure Form* will be stored as required by law. If it appears that a COI may exist, further review is required. *FCOI Disclosure Form* and all information contained therein are to be used only for the purpose of reviewing and managing FCOI as required by law. The information is private and confidential. However, some information will be shared with funding agencies and the public as required by the funding agency regulation and policies.

### **13 Confidentiality**

All disclosures or information obtained in reviewing a potential FCOI is kept confidential, except where disclosure is required by federal regulations.

### **14 Sanctions**

Failure to comply with the Company's FCOI policy includes failing to submit a required disclosure, providing false information, omitting required information, failing to maintain confidentiality, failure to carry out duties prescribed by these policies, and refusal or failure to comply with a management plan adopted under these policies. A failure to comply with these policies may result in a decision by the CO to suspend the research project or to refuse to approve a new research project for the individual who fails to comply.

A failure to comply is also subject to: (1) formal admonition, (2) ineligibility of the individual to apply for federal research grants, (3) additional sanctions per research funding agency (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of function per application federal regulations (note: the Company will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective action), and/or (4) termination of employment.

### **15 Manage FCOI**

Prior to the expenditure of any funds under a PHS-funded research project, CO shall:

- Review all Investigator disclosures of significant financial interests
- Determine whether any significant financial interests relate to PHS-funded research
- Determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

If it is found that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the federally-funded research, the CO will take actions as necessary to manage financial conflicts of interest, including any financial conflicts of a sub-recipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to §50.605(a). Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research).
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest. Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research.
- Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- Severance of relationships that create financial conflicts.

For any significant financial interest that AccelDx identifies as conflicting subsequent to AccelDx's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), AccelDx shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the financial conflict of interest and ensure that AccelDx has implemented a management plan in accordance with 42 C.F.R. Part 50, Subpart F.

If a FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by AccelDx (e.g., was not timely reviewed or reported by a sub-recipient), AccelDx also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, AccelDx is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of AccelDx's management plan.

For any financial conflict of interest previously reported by AccelDx with regard to an ongoing PHS funded research project, AccelDx shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. AccelDx shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

## 16 Reporting of FCOI

The Company will comply with federal regulations regarding reporting of financial conflicts of interest (e.g. by submitting FCOI reports to the awarding institution, as required). The Company will comply with federal FCOI regulations regarding making publicly available information on identified FOCIs held by investigators and key personnel on PHS-funded research projects.

In the event an Investigator has a financial conflict of interest related to PHS funding, AccelDx's is required to report it to PHS funding agencies, and may be made available to the public prior to the expenditure of any funds under the award. Investigators do not need to report directly to PHS. Reports are triggered by certain events as outlined below. If determination of a FCOI is made, the report must include the following:

- Project number
- PI/PI name
- Name of the Investigator with the conflict
- Name of the entity related to the conflict
- Nature of the financial interest, e.g., equity, consulting income, travel reimbursement, etc.
- Value of the financial interest in dollar ranges (\$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above \$100,000 by increments of \$50,000), or if the interest is one whose value cannot be readily determined through reference to public information, a statement to that effect
- A description of the financial interest related to the funded research and why AccelDx determined there is a conflict;
- A description of the key elements of AccelDx's management plan.
- This report must be submitted to the funding agency within sixty (60) days of determining that a FCOI exists.

**Annual report.** For every COI, an annual report must be submitted that addresses the status of the financial interests and any changes to the management plan.

**Late FCOI Disclosure Form or review.** If an Investigator does not timely disclose a significant financial interest or AccelDx does not timely review a disclosed SFI and it is determined that a COI exists, a report must be made.

**Retrospective review.** In the event AccelDx determines that an Investigator has failed to comply with the disclosure requirements, the AccelDx is required to complete a retrospective review of the Investigator's research activities. The purpose is to determine whether any PHS funded research was biased in the design, conduct or reporting of the research.

## 17 Definitions

For the purposes of this procedure, the following definitions apply:

- **Company Official** means the individual within the Company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's family related to the Investigator's Company Responsibilities.
- **Institution Responsibilities** means the Investigator's professional responsibilities associated or on behalf with his or her Company appointment or position, and includes research, administration, and internal and external professional committee service.
- **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consuAccelDxng fees, paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership interest), intellectual property rights (e.g., patents, copyrights, and royaAccelDxes from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for 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.
- **Investigator** means the Project Director (PD) or Principal Investigator (PI) 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.
- **Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by the AccelDx in the grant application, progress report, or any other report submitted to the PHS by AccelDx.
- **Sub-recipient** means any party that has entered into an Agreement with AccelDx as a sub-grantee, subcontractor, collaborator, contractor, or consultant.
- **Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- **PHS** means 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 National Institutes of Health (NIH).
- **PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to 42 C.F.R. Part 50, Subpart F.
- **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). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- **Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **FCOI Report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- **FCOI Disclosure Form** means the attached report that serve to indentify an FCOI and that any individual requested to file it as per this policy with AccelDx is required to complete.
- **Small Business Innovation Research (SBIR) Program** means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of 42 C.F.R. Part 50, Subpart F, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.
- **HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.



# **Accel Diagnostics**

## **FCOI Disclosure Form**

**Investigator Name:**

**Funding Grant Type and Name:**

**1. OUTSIDE EMPLOYMENT OR SERVICE:**

Do you have any outside employment or provision of outside services, current or planned, which may pose a conflict of interest, as defined in the Conflict of Interest policy?

Yes

No

If yes, please explain.

**2. OUTSIDE INTERESTS, FINANCIAL AND OTHER:**

Do you have any interests or positions which you or your family, directly or indirectly, hold in any outside concern from which Company ABC secures, or will secure goods or services, or that provides services competitive with the company?

Yes

No

If yes, please explain.

**3. GIFTS, GRATUITIES, SERVICES AND ENTERTAINMENT:**

Have you accepted or given any gifts, gratuities, services or entertainment which have a cumulative market value of (ENTER VALUE) or more in one fiscal year or an individual market value of (ENTER VALUE) or more that you or your family have accepted that might be reasonably regarded as influencing or having the potential of influencing your judgment or actions concerning business of the company?

Yes

No

If yes, please explain.

**4. FAMILY OR BUSINESS RELATIONSHIP CONFLICTS:**

Do you have any family or business relationships with trustees, officers, key employees and/or any other employee of the company?

Yes

No

If yes, please explain.

**5. OTHER:**

Are there any other activities in which you or your family are engaged that might be regarded as conflicts of interest?

Yes

No

If yes, please explain.