NIH FCOI POLICY

Analytical Diagnostic Solutions, Inc (DBA) In Vitro Diagnostic Solutions Policy: EIN 45-1332462

Government Awards Financial Conflict of Interest Disclosures

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Approved By:	Robert Harper, President & CEO

SCOPE: Company Wide. The Government Awards Compliance Program (Program) covers all projects conducted with government funds in IN Vitro Diagnostic Solutions, Inc. and is applicable to all employees, subrecipients, consultants, or any other covered organizations or persons involved in governmental awards.

PURPOSE: Under this policy, IN Vitro Diagnostic Solutions, Inc. strives to ensure that all 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 patients, the reputation of IN Vitro Diagnostic Solutions, Inc., the governmental agency providing the funding, and/or external partners. As IN Vitro Diagnostic Solutions, Inc. 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. It is intended to comply with the requirements of federal regulations, including, but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service ("the PHS FCOI Rules") as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the "Financial Conflict of Interest Rules").

DEFINITIONS:

Conflict Management Plan: The document specifying the actions to be taken to manage a Financial Conflict of Interest.

External Partner: A consultant, subcontractor, or subrecipient performing work under a Government Award who is not employed by IN Vitro Diagnostic Solutions, Inc.

Government Award: Government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that IN Vitro Diagnostic Solutions, Inc. receives directly from government agencies or indirectly from pass through entities. (At IN Vitro Diagnostic Solutions, Inc., Government Awards are commonly referred to as "Sponsored Projects.") Government awards do not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)).

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: A spouse, domestic partner, child or step-child, parent or step-parent, or sibling or step-sibling.

NIH FCOI POLICY

Investigator:

(1) For PHS-funded research: the project director or 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.

(2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

***Institutional Responsibilities*:** An Investigator's professional responsibilities on behalf of IN Vitro Diagnostic Solutions, Inc., 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.

***Public Health Service (PHS*):** A division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

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).

Significant Financial Interest:

(1) 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:
   a. the value of any remuneration received from a public entity in the twelve (12) 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
   b. the value of any remuneration received from a non-publicly traded entity in the twelve (12) 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
   c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) 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.)

(3) A significant financial interest does not include the following:
   a. Salary, royalties, or other remuneration paid by IN Vitro Diagnostic Solutions, Inc. to the Investigator if the Investigator is currently employed or otherwise appointed by IN Vitro Diagnostic Solutions, Inc.
   b. Intellectual property rights assigned to IN Vitro Diagnostic Solutions, Inc, and agreements to share in royalties related to such rights.
   c. 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.

d. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined in 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; and
e. Income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

POLICY:
It is the policy of IN Vitro Diagnostic Solutions, Inc. 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 IN Vitro Diagnostic Solutions, Inc. Investigators must complete or update a disclosure survey at least annually during the period of the award and must disclose any new SFI's within thirty days of discovering or acquiring the SFI. Investigators also must ensure that the disclosure survey is completed or updated no later than the time of application for a Government Award.

If In Vitro Diagnostic Solutions, Inc. determines that a SFI constitutes a Financial Conflict of Interest ("FCOI"), IN Vitro Diagnostic Solutions, Inc. 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.

Duty to Cooperate
If the conflict-of-interest official requests additional information from an Investigator to assess whether a SFI constitutes a Financial Conflict of Interest, (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a CMP is implemented in connection with a SFI, the Investigator must comply with the CMP. Compliance with the requirements of this policy is a condition of employment with IN Vitro Diagnostic Solutions, Inc for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

Training
Investigators must complete training regarding this policy and the applicable regulations at the following times: (i) upon becoming an Investigator for IN Vitro Diagnostic Solutions, Inc; (ii) before performing work under a Government Award; (iii) when this policy is revised to alter the responsibilities of an Investigator;(iv) and at least every four years.

Public Posting of Policy
This policy will be posted on a publicly accessible Internet site for IN Vitro Diagnostic Solutions, Inc.

Reporting of Financial Conflicts of Interest for PHS-Funded Projects
Before the expenditure of any funds under a PHS-funded project and within sixty (60) days of subsequently identifying a Financial Conflict of Interest (FCOI), the SPA Manager will report all FCOI that have not been 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 IN Vitro Diagnostic Solutions, Inc 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.

(1) 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 form or registering with the FDP Clearinghouse before submission of the Government Award. The SPA Manager will verify registration with the FDP Clearinghouse before submission. The contract with IN Vitro Diagnostic Solutions, Inc will contain language requiring compliance with the organization's FCOI Policy.
(2) Individuals and organizations without their own FCOI policy are required to follow this policy. The contract with IN Vitro Diagnostic Solutions, Inc will contain language requiring compliance with IN Vitro Diagnostic Solutions, Inc's Government Awards FCOI Policy.

Procedure

This procedure is for use by IN Vitro Diagnostic Solutions, Inc employees and External Partners that do not have their own FCOI policy.

(1) Before the expenditure of funds under a Government Award, Investigators must complete the training on IN Vitro Diagnostic Solutions, Inc' Government Awards FCOI Policy. All external investigators must complete FCOI training required under the policy. Training can either be completed using the NIH FCOI tutorial found at: https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm or CITI COI training found at: https://about.citiprogram.org/en/homepage/ .
(2) Training must be documented by submitting the Government Award FCOI Training Certification form to President & CEO of IN Vitro Diagnostic Solutions, Inc. The required training is valid for four years; however, Investigators are required to certify annually that they understand and have complied with their responsibilities under IN Vitro Diagnostic Solutions, Inc' Government Awards FCOI Policy.
(3) After the training is completed, the Investigator will complete the Government Award FCOI Questionnaire. This survey must be completed no later than the time of application for a Government Award and before any funds are expended. It also must be updated as required by the policy.
(4) The principal investigator/project director will complete the Government Award Approval form, which requires verification that those meeting the definition of Investigator and External Partners have been informed of the requirement to comply with this policy.
(5) The Investigator must report and update their Government Award FCOI Questionnaire when he/she is a recipient of sponsored travel. The Investigator will disclose: the purpose of the trip; the name of the entity that paid for the travel; the travel destination; the duration of the trip; the dates of the travel; and if known, the approximate value of the Sponsored Travel.
(6) If the SPA Manager determines a FCOI exists, he/she will create a draft CMP. The draft CMP will be presented to the Research Compliance Oversight Committee (RCOC) for consideration and approval. The RCOC will act as the Conflict-of-Interest Committee for purposes of Government Awards.
(7) The actions taken by the RCOC will be documented in the RCOC meeting minutes. The SPA Manager will ensure that CMP's are properly implemented and will monitor compliance with CMP's on an ongoing basis. The RCOC will review the status of established CMP's at intervals determined by the RCOC and indicated in the CMP and will have oversight responsibility for the enforcement of CMPs and compliance with this policy.

(8) Each Investigator under a CMP must comply fully and promptly with the CMP, and each person identified in the CMP as having responsibility for monitoring compliance with the CMP must carefully and fully monitor that compliance.
(9) For PHS-funded projects, SPA will disclose the FCOI and CMP to the PHS awarding component before the expenditure of any federal funds.
(10) For PHS-funded projects, IN Vitro Diagnostic Solutions, Inc. will be make FCOI information available to those who submit a request by sending an email to robert@ivd.solutions or by writing SPA at the address below. Responses will be sent within five business days.
(11) IN Vitro Diagnostic Solutions, Inc. will keep records related to FCOI and the related CMP for the longer of at least three years after:
    a. the date of creation;
    b. the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement;
    c. the date of final resolution of any investigation, audit, or similar action involving the records; or
    d. the date required to be in compliance with In Vitro Diagnostic Solutions, Inc's Record Retention policies.
(12) RCOC will regularly evaluate compliance with this policy and will review the effectiveness of SPA's conflict of interest management program, including a review of the implementation and effectiveness of these procedures.

SPA Procedure for External Partners with their own PHS Rule policy

(1) The principal investigator/project director will complete the Government Award Approval form, which requires them to inform any External Partner if they need to comply with FCOI Rules.
(2) Prior to any application submitted by IN Vitro Diagnostic Solutions, Inc for a Government Award, SPA must receive confirmation the External Partner has a FCOI policy that meets the PHS FCOI Rules.
(3) The External Partner will have two options to verify they have a FCOI:
    a. Register with the FDP Clearinghouse, https://fdpclearinghouse.org/
    b. Submit the External Partner Financial Conflict of Interest Disclosure.

Contact information:

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