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DOCUMENT NUMBER	DOCUMENT TITLE		
SOP-011	Financial Conflicts of Interest		
	REVISION DATE	EFFECTIVE DATE	REVISION
	24-JUN-2022	15-Jul-2022	3.1

STANDARD OPERATING PROCEDURE

Document Name: Financial Conflicts of Interest
Document ID: SOP-011

Revision Level: 3.1
Document Type: SOP

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1.0 Purpose and General Policy

The principles articulated herein are intended to provide guidance in the management of formal relationships between employees and contractors of ADM Diagnostics, Inc. ("ADMdx" or "Company") and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Under the Public Health Service (PHS) and National Science Foundation (NSF) final rules on Objectivity in Research (Federal Register, July 11, 1995), each Investigator is required to disclose a listing of her/his significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding by the PHS or the NSF. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias owing to the conflict of interest. This policy statement is intended to satisfy current Federal rules for disclosure with regard to projects funded by the PHS or the NSF as well as State of California statutes involving conflict of interest situations.

Research at ADMdx is made possible through external funding from private as well as public sources. It is the Company's responsibility to assure the integrity of all aspects of such sponsored research while, simultaneously, taking care not to discourage the development of external funding opportunities. The purpose of this document is to identify situations where potential conflicts of significant financial interest are likely to arise and to establish a process whereby such conflicts are either avoided or at least managed equitably to the satisfaction of all concerned parties.

This document articulates Company policy on the management or elimination of conflicts of significant financial interest between outside constituencies and the associated funded activities carried out by Company. While this policy focuses upon avoiding, or at least managing the conflicts of significant financial interest, its primary purpose is to promote compliance with the standards of Objectivity in Research.

This procedure is predicated on the expectation that Investigators will conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this procedure informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Company to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

2.0 Scope

This document is applicable immediately to all sponsored program activity at ADMdx carried out by Company employees, consultants, scientists, trainees, technicians and other agents or research collaborators ("Company employees"). The policy and the associated procedures are derived from the final rules on Objectivity in Research promulgated by the PHS and the NSF that were published in the Federal Register of July 11, 1995. These procedures will be followed whenever ADMdx or its employees submit a request for funding from any external agency, whether it is the PHS, the NSF or another Federal agency.

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- 3.0 **External References**
- Associated references imply the most current version at the time of this document's approval:
- 3.1 42 CFR 50 Policies of General Applicability, Subpart F – Promoting Objectivity in Research
 - 3.2 45 CFR 94 Responsible Prospective Contractors
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- 4.0 **Key Terms**
- 4.1 **Clinical Trial** - research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.
 - 4.2 **Research** - a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.
 - 4.3 **Company Employee** - any individual employed on a full- or part-time basis by ADMdx and is receiving, or will receive, compensation for such employment. (Includes Consultants, Agents and Research Collaborators of Company).
 - 4.4 **Investigator** - the Principal Investigator, Co-Principal Investigators, or any other Company employee responsible for the design, conduct, reporting, or proposing funding of externally funded scientific, clinical research activities. Investigators may also include collaborators or consultants.
 - 4.5 **Institutional Official** - the individual within the Company who 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 institutional responsibilities. For the purposes of this policy, the Institutional Official is the Company CEO.
 - 4.6 **Institutional Responsibilities** - the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.
 - 4.7 **Family Member** - includes the Company employee's spouse and children or other adults who qualify as dependents under the Internal Revenue Code definitions.
 - 4.8 **Company Officers of ADMdx** - those with executive management titles and include the CEO, VP Engineering, and Chief Science Officer.
 - 4.9 **Project** - any externally funded activity such as basic, applied, or developmental research, or other activity conducted by Company employees on behalf of the Company.
 - 4.10 **Financial Interest** - anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.
- Financial Interest does NOT include:
- a) Company salary, royalties, or other remuneration
 - b) income from the authorship of academic or scholarly works
 - c) income from seminars, lectures, or teaching engagements sponsored
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by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers

- d) consulting fees from service on advisory committees or review panels for public or nonprofit entities
- e) 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
- f) financial interest in business enterprises or entities where the value of such interests would not be anticipated to exceed \$10,000 per annum or represent more than a five per cent (5%) ownership interest. The value of such equity interests is to be determined on the basis of public prices or other reasonable measures of fair market value

For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

4.11 **Significant Financial Interest** - a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) 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; or
- b) 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; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution; or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

4.12 **Conflict of Significant Financial Interest** - occurs whenever a Company Employee, or a Family Member of the Company Employee:

- a) has an existing or potential Financial Interest that impairs, or appears to impair, the Company employee's independence and objectivity in the discharge of his/her responsibilities to and/or for the Company,
- b) has a Significant Financial Interest that the Institution would reasonably determine could directly and significantly affect the design, conduct or reporting of Clinical Research,
- c) receives financial or other material benefit through inappropriate use of knowledge or information confidential to the Company.

4.13 **Negative Finding** - a determination has been made that no conflict of significant financial interest exists.

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- 4.14 **Positive Finding** - a determination has been made that a conflict of significant financial interest does exist and, therefore, appropriate administrative action will be required as given under section 4.3 below.
 - 4.15 **Public Health Service (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 of the PHS may be delegated.
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5.0 Procedure

5.1 Mandatory Disclosure of Significant Financial Interests

- 5.1.1 In accord with relevant Federal and State of California regulations, the Company is required to manage, eliminate, or reduce any potential conflicts of significant financial interest that may be inherent in the personal financial interests of an Investigator.
- 5.1.2 Annual Disclosure: Company, therefore, requires Investigators to annually disclose to the Company, any significant financial interest, including those of her/his family members, which would reasonably appear to be affected by the project being funded by external government agencies.
- The Institutional Official will distribution, collect, review and retain the Significant Financial Interest Disclosure Forms.
 - Investigators will complete the Significant Financial Interest Disclosure Form upon receipt from the Institutional Official. The first Significant Financial Interest Disclosure Form must be submitted within 30 days of appointment or employment.
- NOTE:** Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.
- 5.1.3 Ad Hoc Disclosure: Investigators are required to provide updated disclosure information during the time period in which the proposal is pending whenever new significant financial interest is obtained by the Investigator.
- Investigators will complete a new Significant Financial Interest Disclosure Form and submit it to the Institutional Official within 30 days of a new Significant Financial Interest. This includes disclosure of travel, as described above.
- 5.1.4 Prior to entering into a new sponsored project or applying for new sponsored project, the Investigator must affirm the currency of the most recently submitted Significant Financial Interest Disclosure Form to the Institutional Official or submit a new Significant Financial Interest Disclosure Form. The Company will not submit a research proposal unless the Investigator's Significant Financial Interest Disclosure Form are current.

5.2 Identification of Conflicts of Significant Financial Interest

- 5.2.1 In conjunction with the administrative review of applications for grants, the Officers of ADMdx will review each Financial Disclosure submitted and shall make the determination of whether or not a Conflict of Significant Financial Interest exists.
- A Conflict of Significant Financial Interest exists when the Institutional Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the sponsored research.
- 5.2.2 If the Officers of ADMdx determine that no Conflict of Significant Financial Interest exists, the resulting negative finding will be filed in the Company's Legal and Human Resource files. For negative findings no further review is required.

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5.3 Managing Positive Findings of Significant Financial Interest

- 5.3.1 If a Conflict of Significant Financial Interest exists, the Institutional Official will initiate action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.
- 5.3.2 Following the determination of a positive finding, the Officers of ADMdx shall make a final determination involving one of the following administrative actions:
- 1) Accepting the sponsored project award;
 - 2) Not accepting the sponsored project award; or
 - 3) Accepting the sponsored project award subject to suitable modifications in the award documentation or in the Investigator's, or his/her family's, affiliation with the external constituencies involved.
- 5.3.3 If Officers of ADMdx decide to accept the award, the Institutional Official will develop and implement a written COI Management Plan. The affected Investigator must formally sign the COI Management Plan before any related sponsored research goes forward. The Institutional Official will oversee adherence to the COI Management Plan.
- 5.3.4 Reasonable modifications under option 3) above can include one or more of the following actions:
- 1) Requiring that public disclosure of the identified financial interests be made;
 - 2) Requiring that the data and research results be reviewed by independent reviewers identified by the ADMdx Officers and the Investigator;
 - 3) Requiring that the research plan be modified;
 - 4) Requiring that the Investigator be disqualified from participation in a portion of the research;
 - 5) Requiring that the Investigator and/or her/his family member(s) divest certain significant financial interests related to the positive finding; or
 - 6) Requiring that the Investigator and/or his/her family member(s) sever relationships that create the conflict of significant financial interest.

5.4 Reporting Conflicts of Significant Financial Interest

- 5.4.1 The Institutional Official will report Conflicts of Significant Financial Interest or non-compliance with the procedure to the research sponsor or funding agency prior to research initiation and within 60 days of any subsequently identified Conflicts of Significant Financial Interest.

5.5 Disclosure of Conflicts of Significant Financial Interest

- 5.5.1 In the event of non-compliance with reporting and/or management of a Conflict of Significant Financial Interest involving a sponsored clinical trial or research project, the Investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected sponsored clinical trial or research and request an addendum to previously published presentations

5.6 Compliance

- 5.6.1 If an Investigator who is required under this policy to file a Conflict of Significant Financial Interest Disclosure Form fails to do so or fails to disclose a Significant Financial Interest on the disclosure form, the Investigator may be subject to company and legal procedures.

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- 5.6.2 If an unreported Significant Financial Interest involves a research project administered by the Company, appropriate administrative action required by the funding agency will also be taken.
- 5.6.3 Intentional disregard for this policy, including non-adherence to the agreed upon COI Management Plan, shall constitute serious misconduct and maybe the basis for further administrative or legal inquiry.
- 5.6.4 The Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this procedure, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator.
- 5.6.5 ADMdx will promptly notify the funding agency or research sponsor of sanctions imposed on Investigators, and if it is determined that AMDdx is unable to manage satisfactorily any Conflict of Significant Financial Interest.

5.7 Retrospective Review

- 5.7.1 When the Institutional Official determines that a Conflict of Significant Financial Interest was not identified or managed in a timely manner, the Institutional Official will complete a retrospective review of the Investigator's activities and the sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.
- 5.7.2 The Institutional Official will promptly document the retrospective review, including the project number, project title, Investigator, Principle Investigator, the Conflict of Significant Financial Interest, name of the entity with which the Investigator has the conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.
- 5.7.3 The Institutional official will update any previously submitted report to the research sponsor or funding agency relating to the research, specifying the actions that will be taken to manage the Conflict of Significant Financial Interest going forward.
- 5.7.4 If bias is found, the Company will promptly notify the research sponsor or funding agency and submit a mitigation report. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5.8 Training

- 5.8.1 Each Investigator must complete training on this procedure:
 - When new to the Company
 - When this procedure is revised or updated
 - If it has been determined that the Investigator has not complied with this procedure
 - At a minimum of once every four years.

5.9 Confidentiality

- 5.9.1 To the extent permitted by law, all disclosure forms, COI Management Plans, and related information will be confidential. However, the Company may be required to make such information available to research sponsors or funding agencies. The Investigator will be informed of this disclosure.

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5.9.2 Prior to the expenditure of funds, the Company will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- A determination has been made that the Significant Financial Interest is related to PHS-funded research; and
- A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

5.10 Record Retention

5.10.1 The Institutional Officer will retain the following documentation for a period of three years from the date the final expenditure report is submitted to the research sponsor or funding agency, unless any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken:

- Significant Financial Interest Disclosure Forms
- COI Management Plans and related documentation

6.0 Revision History

