

DxDiscovery, Inc.

Policy on Financial Conflict of Interest and Conflict of Commitment

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Applies to:

Employees responsible for research at DxDiscovery, Inc., and sub-contract collaborators responsible for research associated with federal state grants for which the DxDiscovery is the grantee.

Definitions

Conflict of Commitment (COC)- A conflict arising when time expended on Outside Activities such as consulting or entrepreneurial activities interferes with an Employee's ability to meet his or her Company Responsibilities.

Conflict of Interest (COI)- A situation occurring when the professional, commercial, or Financial Interests or activities of an Employee outside DxDiscovery have the potential to or actually influence his or her professional obligations to DxDiscovery, Inc.

Dependent- Any person, whether or not related by blood or marriage who receives more than one-half of his or her financial support from another individual.

Employee- For annual disclosure, this includes personnel employed by DxDiscovery involved in research or research proposals funded by federal agencies. The Financial Interest of the individual Employee includes his or her Immediate Family.

Financial Interest- Anything of monetary value including: ownership of stocks,

bonds, stock options, partnership or other equity interests, patent rights or royalty payments, consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, or other remuneration. Financial Interests do not include stock owned through mutual funds.

Significant Financial Interest- Per NIH definition, available here under Question 8:
https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3181

“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.

- (i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that 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 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. The Institution’s FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution’s FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution 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 seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as



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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 income from service on advisory committees or review panels for 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.”

Immediate Family- One’s spouse, dependent children, and any other person residing in the same household as the Employee who is a Dependent of that Employee or of whom the Employee is a Dependent.

Company- The private for-profit company, DxDiscovery, Inc.

Company Responsibilities- An Investigator’s professional responsibilities on behalf of the Company, which may include activities such as research, consulting, teaching, institutional committee memberships, and service on committees.

Outside Activities- These include self-employment, participation in business partnerships, and employment or consulting arrangements with entities other than DxDiscovery that relate to an Employee’s Company Responsibilities, whether compensated or not.

Research- A systematic investigation designed to develop knowledge encompassing basic and applied research

Trainee- Students or visiting scholars receiving short-term training at the Company.

Reason for this policy

DxDiscovery encourages its Employees to develop creative ways to perform their tasks, especially when involving research and development of new products. It is of utmost importance that these efforts be conducted with the greatest integrity, avoid the appearance of bias, use the Company’s resources appropriately, and maintain public trust.

Occasionally, the interests or commitments of Employees may have the potential to conflict with those of the Company. This policy is designed to educate Employees on actual and apparent Conflicts of Interest and Conflicts of Commitment, to foster a culture of disclosing external financial interests and activities, and to create appropriate administrative procedures for the management of such conflicts.

It is essential that potential Conflicts of Interest be avoided or managed appropriately. Constructive engagements with other corporate or academic sponsors can be beneficial to scientific advancement. There are federal policies that address potential Conflicts of Interest and/or Commitment. This document is intended to identify such policies and to define the process for disclosing and adjudicating potential conflicts.

Policy Statement

DxDiscovery Employees shall not conduct Outside Activities that interfere with their Company Responsibilities.

Except as approved by the Company, remuneration for the conduct of Employee's responsibilities shall only be received through DxDiscovery.

Employees shall not conduct Company business, training, or research under circumstances in which a reasonable person would infer that the integrity of their performance of these activities was compromised by the expectation of external personal advantage.

Company resources such as facilities, equipment, computer networks, and personnel shall not be used by Employees for the financial benefit of external entities, unless authorized by the Company (except for incidental use of internet and phone systems).

All Employees shall disclose significant financial and commitment relationships with organizations outside of DxDiscovery that relate to their Company Responsibilities, as described herein.

Procedures

Training

Financial Conflict-Of-Interest (FCOI) training is required. Each Investigator must complete training (website link: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) prior to engaging in research related to any NIH-funded grant and at least every four years.

What Significant Financial Interests should be disclosed to the Company

Employees shall disclose the all Significant Financial Interests in organizations outside of the Company that relate to their Company Responsibilities as described in the definition section above for "Significant Financial Interests". Briefly, this includes:

- any reimbursed or sponsored travel related to their Company Responsibilities during the previous year;
- \$5,000 or more in total remuneration plus equity interest (i.e. stock ownership) in a publicly traded entity that is related to their Company Responsibilities;
- \$5,000 or more in remuneration from a non-publicly traded entity during the previous year that is related to their Company Responsibilities; and
- Significant equity interest in a non-publicly traded entity that is related to their Company Responsibilities.

Disclosure must be made annually and within 30 days of establishment of new Financial Interests that occur between annual declarations.

What Financial Interests should not be disclosed to the Company

DxDiscovery Employees are not required to disclose:

- reimbursed or sponsored travel paid by a federal, state, or local government, or an institution of higher education/academic medical center/academic research institute, or from *bona fide* professional medical or other business associations;
- income from agreements to which the Company is a party;



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- income from financial instruments that are not controlled by the Employee (e.g., mutual funds).

If a Significant Financial Interest is identified the following must be disclosed to the Company

The individual Employee shall disclose his or her Significant Financial Interests as described below;

- *Disclosure to the Company.* Employees are required to disclose annually Significant Financial Interests that relate to their Company Responsibilities using the form provided (DxD_FCOI_Disclosure_Form_2020). New Significant Financial Interests must be disclosed within 30 days. New Employees must disclose their Significant Financial Interests within 30 days of their initial appointment
- *Disclosure to the Institutional Review Board.* Principal investigators engaging in human subjects research at the Company are required to ensure disclosure of the Significant Financial Interests of all study personnel to the Institutional Review Board, when proposing a new protocol or when a new Significant Financial Interest arises during the course of an IRB-approved study that might be perceived to influence the outcome of that study. These reports are required in addition to the annual disclosures described above.

Reporting to NIH

The FCOI regulation does not apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs Phase I applications/awards. The Company provides FCOI reports to NIH on Phase II SBIR and STTRY awards through the eRA Commons FCOI Module:

- o Prior to the expenditure of funds
- o During the period of award
 - Within 60 days of identifying a new FCOI.
- o Annually
 - Report on the status of FCOI and any changes in management plan.
 - Due at same time as when grantee submits annual progress report, including multi-year progress report, or at time of extension.

Review of the Institution Financial Disclosures

Review of conflicts of commitment. The President of the Company, Dr. Thomas Kozel will review the significant financial interest disclosures of employees for potential Conflict of Commitment. The Company Chief Operations Officer (COO) will review the disclosures of the Company's President. If the review suggests that a Conflict of Commitment exists, the reviewer shall discuss the conflict with the employee and take steps to assure management of the conflict. If the reviewer is unable to resolve the conflict, he or she shall consult with the President's designee. The President will make a final determination on the disposition of all conflicts of commitment.

Management of Conflicts of Interest.

Conditions of Management plans include:

- Defining role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan include
 - Disclosure of the conflict to collaborators, and in publications and presentations.
 - Agreements about the use of shared resources.
 - A requirement for an independent investigator to review manuscripts and abstracts for evidence of bias.
 - A requirement that project personnel be notified of the nature of the Significant Financial Interest.
- Management plan design
 - The management plan is designed to safeguard objectivity by assigning a non-conflicted management plan administrator to assure compliance with the terms of the plan and to evaluate whether the design, conduct, or reporting of research has been negatively influenced by the investigator's significant financial conflict of interest.
- Confirmation of the investigator's agreement to the management plan
 - The conflicted investigator will sign the management plan.
- Management plan monitoring to ensure investigator compliance
 - The management plan administrator will submit an annual status report on each of the terms of the management plan.

Confidentiality of Significant Financial Interest Disclosures

Significant Financial Conflicts of Interest associated with federal funded research projects will be made available by the Company in response to any request for that information. The confidentiality of other information contained within these financial disclosures shall be secured.

Retention of Financial Disclosures and Documentation on Conflicts of Interest and Commitment

- Documentation of COIs shall be retained for three years after filing of the final financial report for that competitive award period.
- Documentation for COI/COC reviews that result in a management plan (non-Public Health Service) shall be retained for three years after completion of the activity requiring management.
- Documentation for COI/COC reviews that do not result in further management shall be retained for three years after the final decision by the President of the Company.

Retrospective Review

Whenever an FCOI is not identified or managed in a timely manner, the company shall complete a retrospective review of the Investigator's activities and the project to determine if there was bias in the research, and, if relevant, notify NIH and submit a Mitigation Report.

Penalties for non-compliance with this policy

The President may apply sanctions in the following situations:

- Non-compliance by an Employee with his/her responsibilities under this policy.
- Failure of an Employee to adhere to a decision by President concerning a Conflict of Interest or Conflict of Commitment.



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- Inappropriate release of confidential information on financial disclosures by individuals with administrative responsibility under this policy.

Policy History

Created by David Maine COO/AOR

DxDiscovery, Inc.

Approved: