FCOI POLICY

NIH-RELATED FINANCIAL CONFLICT OF INTEREST POLICY AND PROCEDURE

Updated: May 17, 2023

PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest ("FCOI") to safeguard the integrity of certain NIH-related research carried out by GoDx, Inc. or its controlled affiliates ("Company") and to comply with certain federal regulations (42 CFR Part 50 Subpart F; the "Regulations"). While our collaborations may be governed by the FCOI policies and processes of our collaborative research institutions, the purpose of this policy is to ensure when there is no institutional FCOI to rely upon, Company research will still be in compliance with the Regulations. Specifically, our research agreements with subawardees/ subrecipients will establish if they will follow the Company's FCOI policy or that of their institution of employment.

The Company must be able to certify, in each application for funding subject to the Regulations, that the Company (i) has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI; (ii) promotes and enforces compliance with the Regulations by the individual investigator(s) ("Investigator(s)"); (iii) manages FCOI and provides initial and ongoing FCOI reports; (iv) agrees to make FCOI and Significant Financial Interests (SFI) information (including related Institutional reviews and determinations) available to HHS, promptly, upon request; and (v) fully complies with the Regulations.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulations, Promoting Objectivity in Research (42 CFR part 50 subpart F). These Regulations were developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under certain National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. An electronic version of the Regulations is found at http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf.

SUMMARY OF PROCESS

Significant Financial Interests ("SFI"; as defined below) shall be disclosed on the Significant Financial Interest Disclosure Form ("SFIDF") by an Investigator requesting government-sponsored or company-sponsored funds for a research project or by an Investigator when a Significant Financial Interest arises during the course of research. Regardless of whether a SFI exists, all Investigators and key personnel are required to submit a SFIDF annually.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for human subjects' approval.

The SFIDF and supporting materials are forwarded to the Company's designated administrator of this FCOI Policy ("Financial Administrator") for review. The Financial Administrator will be responsible for (in consultation with CEO) evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the Financial Administrator is required prior to engaging in government-sponsored research. An SFI review must be completed before any expenses are incurred under an award. Typically, the CEO provides approval as signatory of the research agreement, simple agreement, or engagement contract, or provides written approval for the Financial Administrator (an AOR) or Company signatory to sign in their stead.

Annual updates are required of all Investigators. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the Financial Administrator. Annual updates and newly acquired interests are reported using the SFIDF. This process is meant to inform each Investigator of the (i) Institution policy; (ii) Investigator's disclosure responsibilities; and (iii) the Regulations (42 CFR 50.604(b)).

TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project subject to the Regulations, which includes all Investigators, consultants and employees of GoDx, Inc. engaged in such NIH-funded research or its compliance.

The course is accessible at http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm. Upon completion of the training, a certificate of completion must be turned into the Financial Administrator. You should retain a copy for your records. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or new to the Company. At a minimum, the FCOI training shall be taken every four (4) years. This process is designed to require each PHS-supported Investigator to complete FCOI training: (i) prior to engaging in research related to any PHS-funded grant; (ii) at least every four (4) years; and (iii) immediately if (a) Institution revises its FCOI policy that affects requirements of Investigators; (b) an Investigator is new to the Institution; and (c) an Investigator is not in compliance with the policy or management plan (42 CFR 50.604(b)).

KEY DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the Regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for or receiving NIH research funding.

Investigator – means the project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

Institutional responsibilities – means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial interest – means anything of monetary value, whether or not the value is readily ascertainable. Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

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.

Senior/Key Personnel – means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the Regulations.

Significant Financial Interest (SFI) – Includes any one or more of the following from any single entity OUTSIDE THE COMPANY for activity that is related to the investigator's professional qualifications:

(1) 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;

(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) Upon receipt of income related to intellectual property rights and interests (e.g., patents, copyrights) that exceeds $5000.

(2) 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 excluded sources provided in the Regulations. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e., the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g., monetary value) and whether the travel constitutes a FCI with NIH-funded research.

(3) Significant Financial Interest does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

(ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;

(iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

(iv) 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;

(v) income from seminars, lectures, or teaching engagements 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; or

(vi) income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defied 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.

(4) For simplicity, a Significant Financial Interest of Conflict would exist in the following (non-exclusive) examples:

(i) the Investigator (or spouse/child/dependent) has a Significant Financial Interest in an entity that sponsors their research project;

(ii) the Investigator (or spouse/child/dependent) has a Significant Financial Interest in an entity that produces products (equipment, software, compounds, drugs, devices, etc.) or services used in their research project;

(iii) the Investigator (or spouse/child/dependent) has a Significant Financial Interest in an entity that develops product or services their research project intends to evaluate or develop; or

(iv) the Investigator (or spouse/child/dependent) has a Significant Financial Interest in an entity with whom they are consulting in an area that overlaps with or is the main subject of his/her research. Significant Financial Interest Disclosure Form (SFIDF) – Company form by which required person provides an itemized disclosure statement with regard to SFI categories. The form is submitted to the Financial Administrator upon assignment of work sponsored by a federal, state, or local government grant, yearly thereafter, and when any occurrences of a new SFI arises. Training is required to be completed upon first submission, and every three years unless further education is required.

PROCEDURES

1. Identification of Persons Required to Disclose a Significant Financial Interest – It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFIDF is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed. To assist PIs with this responsibility, the financial administrator will send out reporting reminders, SFIDF forms, and receive completed SFIDFs and provide to the Financial Administrator for review, these will occur yearly and just prior to application submissions. PIs are responsible for reporting SFIs that occur between these reporting timelines.

- This process is established to require each Investigator to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigators institutional responsibilities that meets or exceeds the regulatory definition of SFI (42 CFR 50.03): (i) no later than at the time of application for PHS-funded research; (ii) at least annually during the period of award; and (iii) within 30 days of discovering or acquiring a new SFI (42 CFR 50.604(e)(1)-(3)).

1. Submission and Review of SFIDF – Every individual having a SFI requiring disclosure under this policy shall prepare a fully completed SFIDF that shall be submitted to the Financial Administrator. An initial review of the SFIDF will be conducted by the Financial Administrator to determine whether a potential for conflict of interest exists. The Financial Administrator will utilize a Review of Conflicts Form (RCF) to consider if a potential financial conflict of interest exists. The RCF compares the focus, contractual involvements, and research goals of the research project against the SFIDF provided by the researcher. If it is determined that there is an actual or potential FCOI, then steps will be taken to determine what measures are needed to address it. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to these actions) to be taken in order to manage, reduce or eliminate any actual or potential FCOI:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts.

All management plans are required to be signed by the Investigator and the Financial Administrator (in consultation with the Company's CEO). Compliance of the management plan shall be monitored by the Financial Administrator and implemented within 60 days of identified FCOI.

- This process designates Institutional officials to solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities (4s CFR 50.604(d)).
- This process provides adequate guidelines consistent with the Regulations for the designated Institutional officials to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI (4s CFR 50.604(f)).
- This process requires the designated Institutional officials, prior to Institution expenditure of funds, to:

(i) review all Investigator SFI disclosures;

(ii) determine if any SFIs relate to PHS-funded research;

(iii) determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research; and develop and implement management plans, as needed to manage FCOIs (4s CFR 50.605(a)(1)).

- This process reviews the disclosures for SFIs, makes determinations of FCOIs, and implements a management plan within sixty days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution (42 CFR 50.605(a)(3) and (i)-(iii)).
- This process reviews the disclosures for SFIs, makes determinations of FCOIs, and implements a management plan when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI (42 CFR 50.605(a)(2)).
- This process identifies and implements actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project (42 CFR 50.604(g) and 42 CFR 50.605(a)(4)).

1. Annual Reporting and After-Acquired Significant Financial Interests – All Investigators shall provide annual SFIDFs or more frequently if required by the management plan or acquired interests. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFIDF within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFIDF to the Finance Administrator. The Finance Administrator must report to NIH any FCOIs within 10 days of notification of new SFIs identified by the PI on either notification report, or annual report, and immediately upon review and determination of any bias found with the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the Regulations, and including the following NIH FCOI reporting items:

- The name of the Investigator with the FCOI
- The name of the entity with which the Investigator has an FCOI
- The nature of the Significant Financial Interest (SFI)
- The value of the financial interest
- Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- Description of the key elements of the Company's management plan, including other required information
- This process is established to require each Investigator to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigators institutional responsibilities that meets or exceeds the regulatory definition of SFI (42 CFR 50.03):

(i) no later than at the time of application for PHS-funded research;

(ii) at least annually during the period of award; and

(iii) within 30 days of discovering or acquiring a new SFI (42 CFR 50.604(e)(1)-(3)).

- This process defines the reporting steps to send initial, annual (i.e., ongoing) and revised FCOI reports, including reporting elements required by the Regulations to the NIH for the Institution and its subrecipients, if applicable, as required by the Regulations (42 CFR 50.604(h) and 42 CFR 50.605(b)):

(i) prior to the expenditure of funds;

(ii) within 60 days of identification for an Investigator who is newly participating gin the project;

(iii) within 60 days for new, or newly identified, FCOIs for existing Investigators; (iv) at least annually (at the same time as when the Institution is required to submit the annual progress report, multiyear progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and

(vi) following a retrospective review to update a previously submitted report, if appropriate (42 CFR 50.605(a)(3)(iii)).

- This process establishes a policy and procedure to notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the Regulations, and the policy includes all the reporting elements as required by the Regulations (42 CFR 50.605(a)(3)(iii)).

1. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Financial Administrator shall make recommendations to the CEO regarding the impositions of sanctions or disciplinary proceedings against the violating individual. The Financial Administrator and CEO will review together with the employee or Investigator the specific behaviors and consequences that are determined relevant based upon review, and any other administrative actions to assure Investigator compliance, including but not limited to supervised research activities. The Financial Administrator and CEO must conduct retrospective reviews within 120 days of the Institution determining noncompliance for SFIs not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the Regulations.

In addition, the Company shall follow the Regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The

federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved. In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluation the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not compliantly managed or reported, the Investigator involved will be required to:

(i) disclose the FCOI in each public presentation of the results of the research, and

(ii) request an addendum to previously published presentations of the same. Investigator will provide evidence of these disclosures to the Company.

- This process establishes a policy and procedure to notify NIH promptly if an Investigator fails to comply with the Institution FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research (42 CFR 50.606(a)). This policy addresses the Institution requirement to notify NIH promptly and take corrective action for noncompliance with the Institution policy or the management plan.
- This policy establishes adequate enforcement mechanisms and provides for employee sanctions or other administrative actions to ensure Investigator compliance (42 CFR 50.604(i)).
- This policy establishes a requirement to complete and document retrospective reviews within 120 days of the Institution determining noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the Regulations (42 CFR 50.605(a)(3)).
- This policy establishes a procedure for any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluation the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not compliantly managed or reported by the Institution, as required by the Regulations, the Institution share require the Investigator involved to:

(i) disclose the FCOI in each public presentation of the results of the research, and

(ii) request an addendum to previously published presentations (42 CFR 50.606(c)).

75. Record Keeping – Records of Investigator SFIDFs, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Finance Administrator for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 C.F.R. 75.361 for different situations.

- This process establishes a policy and procedure to maintain all FCOI-related records that meets or exceeds the regulatory requirements:

(i) for at least 3 years from the date of the final expenditures report is submitted to the PHS (NIH); and

(ii) from other dates specified in 45 CFR 75.361, where applicable (42 CFR 50.604(i)).

1. Sub-recipient Requirements – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, 2011 Revised Financial Conflict of Interest Regulations, Promoting Objectivity in Research (42 CFR part 50 subpart F) and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. Prior to Notification of Award, Company and sub-awards will establish in written agreement which FCOI policy will be followed by which Investigator, and if applicable, certification that the sub-award policy complies with the Regulations, requirement to report identified FCOIs in a timeframe that permits Company to report identified FCOIs to NIH as required by the Regulations, or that Company will solicit and review subrecipient Investigator disclosures to enable identification, management and reporting of FCOIs as required by NIH. If an SFI is identified by the subaward recipient, they are required to notify the Financial Administrator of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with the Regulations.

- This policy establishes a procedure to address subrecipient requirements (42 CFR 50.604(c) and also NIH Grants Policy Statement 15.2.1).
- This policy establishes a parameter for written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient and:

(i) obtain certification that subrecipient FCOI policy complies with the Regulations;

(ii) or includes in written agreement with the subrecipient a requirement for the subrecipient to report identified FCOIs for its Investigators in a timeframe that allows the awardee Institution to report identified FCOIs to the NIH as required by the Regulations; or

(iii) if applicable, includes in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage, and report identified FCOIs to the NIH (42 CFR 50.604(c)(1)(i)-(iii)).

1. Federal Reporting – The Finance Team is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

(i) Initial report – prior to the Company's expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any

Investigator SFI found by the Company to be a financial conflict of interest in accordance with the Regulations.

(ii) During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

(iii) Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

1. Public Accessibility Requirements – The Company will provide public access to this policy on publicly accessible page of https://www.godiagnostic.com/ The Financial Administrator will ensure that any updated versions of this policy are provided for updated posting immediately upon implementation. In addition, and FCOI determined to exist for any Investigator or Senior Key Personnel will be posted to this same webpage in compliance with the Regulations, including the date of posting and

(i) the minimum elements as provided in the Regulations;

(ii) posting within 5 days of a written request;

(iii) annual updates, unless written requests are made which should continue to be available;

(iv) any updates within 60 days of newly identified FCOI; and

(v) remain available for three years from the date the information was most recently updated.

- This policy makes the Institution FCOI policy publicly accessible on the Institution web site (42 CFR 50.604(a) and NIH GPS 4.1.10).
- This policy establishes a process to make available information concerning identified FCOIs held by senior/key personnel (as defined by the Regulations), publicly accessible prior to the expenditure of funds. The information will:

(i) include the minimum elements as provided by the Regulations;

(ii) be posted on a public website or made available within 5 calendar days of a written request;

(iii) be updated, at least annually (website only but any response to a written request should include the updated information);

(iv) be updated, within 60 days of a newly identified FCOI (website only but any response to a written request should include the updated information);

(v) remain available for three years from the date the information was most recently added (42 CFR 50.605(a)(5)(i)- (iv)).