FINANCIAL CONFLICT OF INTEREST GUIDANCE POLICY

CHOSEN DIAGNOSTICS INC

Introduction

Chosen Diagnostics Inc (CDI) supports principled relationships with industry and other organizations with which its employees collaborate. Chosen Diagnostics Inc (Institution) is required by the National Institutes of Health (NIH) and other applicable U.S. public health services (PHS) agencies to abide by the regulations set forth by the Code of Federal Regulations (CFR), Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*. The goal of the policy is to ensure objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funding under PHS grants or cooperative agreements will be free from bias resulting from any financial conflict of interest (FCOI) of any individual investigator. CDI is committed to maintaining an up-to-date, written and enforced policy and a process whereby investigator conflicts of interest are disclosed to promote integrity of all research-related activities it undertakes. Furthermore, the Institution adopts this guidance policy to support the highest level of research integrity, safety of human subjects, objectivity of education, and reputation of employees. Chosen Diagnostics Inc, all of its employees, and affiliates shall comply with this Policy and applicable regulations for PHS funding.

Definitions

- *Investigator* is defined as 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 NIH/PHS awarding agency, or proposed for such funding, which may include, for example, collaborators or consultants.
- *Senior/key personnel* is defined as 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 PHS by the Institution under the regulation.
- *Significant Financial Interest* (SFI) is defined as anything of monetary value, whether or not readily ascertainable 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.
    - For a non-publicly traded entity, a significant financial interest exists if the value of any income received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the investigator (or family member of the investigator) holds any equity interests;
    - For a publicly traded entity, a significant financial interest exists if the value of any income 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, exceed $5,000; or
    - All royalties and intellectual property rights and interests

- *Non-Significant Financial Interest* (Non-SFI) is defined as salary, royalties, or other remuneration paid by *CDI* to the Investigator if the Investigator is currently employed or otherwise appointed by *CDI*, including intellectual property rights assigned to *CDI* and agreements to share in royalties related to such rights; 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; and income from seminars, lectures or teaching engagements sponsored by, and 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. Non-SFI does not need to be reported in the FCOI disclosure.

- *Other duality of interest* is defined as interactions or relationships with commercial entities (such as pharmaceutical, biotechnology, and medical device manufacturers) whose products or services may be used, test and/or affected by or whose products or services might be perceived as conflicts of interest related to PHS-funded research. All activities that would qualify as duality should be reported to the Institution. In addition, all relationships with commercial entities whose products/services are being used/tested or are in direct competition with those being used/tested should be disclosed to the Institution. Examples of interest that should be disclosed are:
    - Ownership of stock, equity, or other financial interest in a company/entity which has products that might be used in or benefit from or be harmed by the research results;
    - Employment, office, or directorship in any company/entity involved or potentially involved with the research study;
    - Personal compensation from any company/entity involved or potentially involved with the research study;
    - Consulting/advisory arrangements with any company/entity involved or potentially involved with the research study, including service on data and safety monitoring boards, external evaluation committees, or advisory boards;
    - Involvement with grants, contracts, research, training, or other support (restricted or unrestricted) from any company/entity involved or potentially involved with the research study;
    - Travel grants to attend educational symposia provided by any company/entity involved or potentially involved with the research study. This includes services in one of the aforementioned consulting/advisory arrangements;
    - Intellectual property rights (i.e., copyright, patent, trademark) related to the activities of the research study; or
    - Relationship with a company/entity that may affect academic advancement or status, such as sponsorship of an endowed chair or establishment of a fund for use by the study investigator(s).

Training Requirements and Duties

Each Investigator must complete FCOI training prior to engaging in PHS-funded research, at least every four years, and immediately, if Chosen Diagnostics revises the FCOI Policy that affects requirements of Investigators, an Investigator is new to CDI, or an Investigator is non-compliant with the FCOI Policy. Training can either be completed using the NIH FCOI tutorial found at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html, or by review their responsibilities related to this policy with the Chosen Diagnostics Inc's FCOI Policy manager. Confirmation of understanding of the Investigator's responsibilities under this policy will be recorded upon completion of training.

Disclosure, Review, and Monitoring Requirements

Investigator(s), subrecipient investigator(s), and contract research organization investigators must complete disclosure forms (1) at the time of application to participate in any NIH/PHS-funded research or when first engaged in the research and (2) annually each May with updated information. New conflicts should be reported within 30 days of acquiring a new SFI or substantial change in external relationships or activities.

To meet the qualifications for completion of a potential conflict of interest disclosure form, individuals are required to disclose both research and non-research related outside interests, regardless of value or income received. individuals should specify their level of interest in combination with levels of interest of their spouse and children as follows:

- No financial interest or equity;
- Financial interest in any publicly traded entity with a value of >$5,000 including the value of equity interest;
- Financial interest >$5,000 in a commercial entity that is NOT publicly traded OR ANY equity interest in such an entity;
- Intellectual property rights and/or licenses

Personal compensation from any company/entity involved or potentially involved with the research study
Chosen Diagnostics Inc will take the necessary actions to manage FCOIs of their Investigators, including subrecipient Investigators, train Investigators to follow the FCOI policy, document training, obtain required documents from Investigators including disclosures as stated above, maintain records, communicate SFIs with Chosen Diagnostics Inc's CEO/board, and monitor compliance.

Reporting Requirements

Chosen Diagnostics Inc will submit initial, annual, and revised FCOI reports to the NIH/ PHS awarding agency as require under the FCOI Regulations [§50.605(b)(3), (4)] prior to expenditure of funds, within 60 days of identification for an Investigator who is newly participating in the project or within 60 days for new, newly identified FCOI for existing Investigators.

The FCOI Policy manager will (1) monitor ongoing investigator compliance and (2) submit annual updates to the NIH/PHS awarding agency at the time and in the manner specified by the agency, both until the completion of the funded research project to which the FCOI relates.

With respect to FCOI related to research sponsored by NIH/PHS awarding agencies, annual FCOI reports will be submitted through the eRA Commons FCOI Module for the duration of the project period (including extensions with or without funds) at the same time annual progress reports are required to be submitted and at the time of the extension.

If the FCOI is identified and eliminated prior to the expenditure of any NIH/PHS-awarded funds, no FCOI report needs to be submitted.

A financial conflict of interest exists when the FCOI policy manager reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. In determining whether there is an FCOI, the FCOI policy manager will consider all relevant factors and information, including but not limited to the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision whether an FCOI exists, the FCOI policy manager may impose interim measures, may ask the investigator to submit additional information, and may meet or communicate with the investigator.

Maintenance of Records

Chosen Diagnostics Inc will maintain all disclosure forms and records from FCOI determinations or actions taken as a result of SFI not being reporting in a timely manner for a period of three years from the date of the submission of the final expenditure report to the NIH/PHS awarding agency or other dates specified in 45 CFR 75.361, where applicable.

Enforcement Mechanisms, Remedies, and Noncompliance

Chosen Diagnostics Inc has the authority to enforce this policy. Sanctions, administrative actions, and other actions, including immediate termination, may be taken to ensure Investigator compliance. Chosen Diagnostics Inc may require that one or more of the following actions is taken in order to manage, reduce, or eliminate the potential FCOI:

- Public disclosure of FCOI when presenting or publishing research related findings or provide an addendum to previously published presentations;
- Research involving human subjects that involves disclosing FCOI to participants;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research; and/or
- Reduction or elimination of financial interest or eliminating relationships creating the conflict.

Individuals, with the Institution, subrecipient institutions, or contract research organizations, have an obligation to comply with this guidance policy. Examples of conduct that violate this policy includes, but is not restricted to:

- Failure to comply with annual disclosure process by refusal to respond;
- Intentional deception or dishonesty in disclosures;
- Omission of industry relationship disclosures;
- Failure to comply with management plan requirements; or

If an Investigator fails to comply with this FCOI policy, for whatever reason, the FCOI Policy manager will conduct a retrospective review of the Investigators activities within 120 days of CDI's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner. At that time, it will be determined whether any NIH/PHS-funded research or portion thereof conducted during the period of noncompliance was biased in design, conduct or reporting. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)], and include project number, project title, PD/PI, name of investigator with FCOI, name of entity with which the investigator has a FCOI, reason for retrospective review, detailed methodology used for retrospective review, findings of the review, and conclusions of the review.

If, during the review, the failure of a research investigator to comply with this policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, the FCOI Policy manager at the Institution must promptly notify the PHS awarding component of the findings. In addition, a mitigation report will be submitted to the PHS awarding component, detailing the impact of the bias on the research project and plan of action to mitigate or eliminate the effect of the bias consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. The PHS awarding component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, such as determining how to maintain appropriate objectivity in the funded project.

Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures. Penalties for failure to comply will be commensurate with the breach and may include, but are not limited to:

- Reimbursement to the institution for misused resources, including salary and/or other forms of institutional compensation and other applicable fines imposed by outside entities;
- Written admonition for placement in Individual's employee file indicating that the individual's good standing has come into question;
- Ineligibility to participate in grant applications, IRB, or IACUC applications or on committees;

- Performance improvement counseling; or
- Dismissal of employment.

Subrecipient Requirements

Chosen Diagnostics Inc will require that all subrecipient institutions report identified FCOIs in sufficient time to allow timely reporting of the FCOI to NIH/PHS awarding agency. FCOI of all Senior/Key Personnel of the subrecipient institution shall be disclosed to CDI by submitting a certification that its FCOI policy complies with the regulation set forth in 42 CFR 50 subpart F and a written subrecipient agreement that requires it to report identified FCOIs for its Investigators (i.e., Senior/Key Personnel). Additionally, CDI may request, as part of the subrecipient agreement, to review subrecipient Investigator disclosures that allow it to independently identify, manage, and report FCOI to NIH/PHS awarding agency. Certification and written subrecipient agreement shall be submitted to CDI no later than 10 days before an application for grant funding to NIH/PHS applicable agency or 30 days after discovering or acquiring a new SFI.

Review/Revision of Policy

This policy shall be reviewed by the management at least every three from the effective date. Responsible parties are as follows: policy owner, CEO/board; procedure, CEO; supervision, CEO; implementation, COO.

Public Accessibility Requirements

Chosen Diagnostic Inc has made its FCOI policy publicly accessible by posting it on its website (https://www.chosendiagnostics.com). It will be updated (1) annually with revision of policy, or (2) within 60 days of Institution's receipt or identification of additional SFI of senior/key personal for the PHS-funded research project that was not previously and/or disclosed SFIs of new senior/key personnel. The FCOI policy data will be remain available for three years from the date the information was mostly recently updated and posted.

Identified FCOIs, held by PHS-supported Investigators, can be made available within 5 business days of a written request if the following three criteria are met: (a) the SFI was disclosed and is still held by the investigator, (b) the Institution determines that the SFI is related to the PHS-funded research, and (c) the Institution determines that the SFI is a FCOI. Information provided in a written response to any requestor shall include, at a minimum, the investigator's name, title and role with respect to the research project, name of entity in which SFI is held, nature of SFI, and approximate dollar value range of the SFI. Records for such disclosure requests will be maintained for three years from the date of the final expenditure of funds.