



RESEARCH FINANCIAL CONFLICT OF INTEREST POLICY

Purpose:

To document the requirements and responsibilities of identifying and managing financial conflicts of interest to protect the integrity of the Global Genomic Medicine Collaborative (GGMC). The purpose of **this** policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is sought or awarded.

Scope:

This policy applies to Global Genomic Medicine Collaborative's Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by Public Health Service (PHS) or National Institute of Health (NIH).

GGMC must be able to certify, in each funding application, that the organization:

- a. has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI;
- b. promotes and enforces Investigator compliance with the regulation;
- c. manages FCOI and provides initial and ongoing FCOI reports;
- d. agrees to make FCOI and Significant Financial Interests (SFI) information (including related Institutional reviews and determinations) available to HHS, promptly, upon request; and
- e. fully complies with the regulation's requirements.

Definitions:

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 PHS, including, 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.



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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 PHS-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.

PD/PI - means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS - means the Public Health Service of the U.S. Department of Health and Human Services, and any components.

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

Significant Financial Interest (SFI) – means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. 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 the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b. 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 (and/or the Investigator's spouse and/or dependent children) 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 that exceeds \$5,000.



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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 in excess of \$5,000), 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.

3. The term significant financial interest **does not include** the following types of financial interests:

- a. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- b. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- c. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- d. 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;
- e. 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 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

Each year any investigator who conducts research on any GGMC project must disclose changes via the electronic form all significant financial interests (SFIs) that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated.

Investigators are required to complete an annual disclosure form even if they have no financial interest to report. Significant financial interests must be disclosed by the PI and any other person that meets the definition of Investigator at the time a research proposal is submitted to GGMC's Finance Director in order to ensure compliance with Federal disclosure and management requirements as required in Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F.

Investigator Responsibilities

Investigators are responsible for:

- a. Disclosing all significant financial interests;



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- b. Providing updates to disclosed information as needed within 30 days of acquiring or discovering a new SFI;
- c. If acting as the PI/PD, providing a list of individuals who meet the definition of “investigator” within the required disclosure timeline;
- d. Completing all required training and education;
- e. Completing the annual disclosure form even if they have no financial interests to report;
- f. Ensuring that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals.

Training Requirements

GGMC requires that each Investigator completes the FCOI NIH Financial Conflict of Interest tutorial. The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Upon completion of the training, a certificate of completion is provided to the Investigator. Investigators should also keep a copy of the completion certificate for their records.

This training is required for the Investigator:

- a. prior to engaging in research relating to any NIH-funded grant;
- b. an Investigator is new to a subrecipient and will be working on PHS- funded research;
- c. for non-compliance of the Investigator/Key Personnel to the policy and management plan;
- d. at a minimum, every three (3) years;
- e. if this policy changes in a manner that affects Investigator requirements.

Management of FCOIs

(1) Prior to the GGMC’s expenditure of any funds under a PHS-funded research project, the Steering Committee will: review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d. Modification of the research plan;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

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- g. Severance of relationships that create financial conflicts.

Review of FCOIs

- (2) An Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to GGMC, the Steering Committee will, within sixty days:
 - a. review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research;
 - b. determine whether a financial conflict of interest exists;
 - c. and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest,
 - d. GGMC may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

Investigator/Institutional Non-Compliance

(3) If GGMC identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Steering Committee during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Steering Committee will review the significant financial interest, within sixty days; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

- a. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
- b. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by GGMC to constitute a financial conflict of interest;
- c. failure by GGMC to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan,
- d. within 120 days of GGMC's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(4) GGMC is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- a. Project number;
- b. Project title;
- c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- d. Name of the Investigator with the FCOI;
- e. Name of the entity with which the Investigator has a financial conflict of interest;
- f. Reason(s) for the retrospective review;

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- g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- h. Findings of the review; and
- i. Conclusions of the review.

(5) If GGMC is unable to satisfactorily manage a conflict of interest involving NIH funding, GGMC's Executive Director will appropriately notify NIH's Office of the General Counsel.

Records

Records of Investigator financial disclosures, and of actions taken to manage actual or potential conflicts of interest, shall be retained by GGMC for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

Research Involving Humans

Special consideration and scrutiny must be given to protect human subjects in research. Investigators with an identified financial conflict of interest or a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. This presumption against the participation in human subjects' research by financially interested individuals may be rebutted by compelling circumstances. Compelling justification may include factors such as unique investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

The compelling justification and the degree of risk to human subjects must be presented and reviewed by the Scientific Steering Committee. If compelling circumstances justify a waiver of this policy, the research will be subject to the development and implementation of an action plan to ensure the safety of human subjects and the integrity of the research. The Steering Committee must review the research with consideration given to the requirements of the action plan. They may require additional safeguards to be implemented but may not determine less stringent financial conflict of interest management requirements.

Subrecipients

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by GGMC to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

Subrecipients who do not have such a conflict of interest policy will be required to follow GGMC's Research Financial Conflict of Interest policy. A subrecipient's failure to promptly comply with the GGMC policy will be considered grounds for immediate termination by GGMC of any applicable



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subcontract or subaward. The written agreement terms required by GGMC will contain a provision that subrecipients will report to GGMC as the pass-through entity, any identified FCOI in sufficient time to allow GGMC to report and manage the FCOI and meet the reporting obligations described above.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the GGMC in sufficient time to allow the GGMC to report the FCOI to the PHS Awarding component.

Appeals

Investigators may appeal the Steering Committee's decisions in writing within 7 days of receipt of the finalized action plan or other decision of the committee. The written appeal should include details regarding circumstances which support the request for a proposed revision to a Steering Committee's decision. An Appeals Committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Committee will be convened to review the SFI information, the Management and Monitoring Plan, and previous meeting minutes, to make a decision. The Investigator may be invited to describe reasons for the appeal and to address further questions.

The appeals process will take no more than 10 days from the date requested by the Investigator. The decision of the Appeals Committee is final and binding. GGMC will ensure the management and reporting of the FCOI will meet the PHS 60 day requirement.

Confidentiality

Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest for people who meet the definition of senior/key personnel as described in this policy.

Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or GGMC.

Policy Revisions

GGMC may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The Steering Committee will have 30 business days to review and comment on any proposed revisions.

GGMC's Steering Committee is responsible for granting final approval for these policy revisions. It will review all proposed revisions, in collaboration with management, and will consider the committee's



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feedback during the review process. When necessary, procedures will be developed or modified to implement this policy.

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- a. Status of the FCOI;
- b. Changes to the action plan;
- c. Justification that an FCOI no longer exists.

Public Accessibility

(1) GGMC will ensure public accessibility to this policy via their publicly accessible www.GGMC.com website or written response within five business days of a request, of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

- a. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- b. The Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
- c. The Institution determines that the Significant Financial Interest is a **Financial Conflict of Interest**.

(2) The information that GGMC makes available via their publicly accessible website or written response shall include, at a minimum, the following:

- a. Investigator's name;
- b. Investigator's title and role with respect to the research project;
- c. Name of the entity in which the Significant Financial Interest is held;
- d. Nature of the Significant Financial Interest; and
- e. If the dollar value exceeds \$5,000 of the SFI.