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Department Compliance
Applicability GBMC HealthCare System

Policy on Financial Conflicts of Interest in Public Health Service Funded Research

I. POLICY

In all their dealings with and on behalf of GBMC Healthcare Inc. (GBMC), Research Investigators shall adhere to a strict rule of honest and fair dealing, act for the benefit of GBMC, and follow standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under United States Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

This Policy applies to all research, with a Notice of Award on or after August 24, 2012, where any part of the funding (by grant, cooperative agreement or contract) is received from the PHS, and where GBMC is a direct or subcontracting recipient of the funding. This Policy applies to all Investigators, as defined below, if they are participating in, or planning to participate in PHS-funded research.

This Policy complies with *Code of Federal Regulations Title 42, Part 50, Subpart F - Promoting Objectivity in Research*.

II. DEFINITIONS

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to GBMC.

Financial Conflicts of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means GBMC's report of a financial conflict of interest to a PHS Awarding Component.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution or Awardee Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives PHS research funding. In this policy, this term means GBMC.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution which includes activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board.

Investigator means 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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which authority may be delegated, including the National Institutes of Health (NIH).

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g. a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the project director or principal Investigator 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.

Significant financial interest means:

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:
 - 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 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;
 - 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 (or the Investigator's spouse 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.
2. Investigators must also 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, this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources, as defined in the regulations.
 3. The term significant financial interest does not include the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by GBMC to the Investigator if the Investigator is currently employed or otherwise appointed by GBMC, including intellectual property rights assigned to the GBMC and agreements to share in royalties related to such rights;
 - b. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - c. 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;
 - d. 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
 - e. 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.

III. PROCEDURE

A. Policy and Regulatory Awareness

1. This Policy shall be maintained in an up-to-date, written form and made publicly available on the GBMC website located at www.gbmc.org (see the GBMC IRB webpage <http://www.gbmc.org/institutionalreviewboard>.)
2. This Policy shall also be maintained on PolicyStat.
3. Each Investigator shall be informed of this Policy, the Investigator's responsibilities regarding disclosure of **significant financial interests (SFI)**, and the applicable Federal regulations (42 CFR 50, Subpart F - Promoting Objectivity in Research).

B. Training

1. Prior to engaging in PHS-funded research, each Investigator shall be trained on this Policy, the Investigator's responsibilities to disclose SFIs, and the applicable Federal regulations. Thereafter, each Investigator shall be trained every four years.

2. Initial training shall consist of:
 - a. Documented completion of a "Conflicts of Interest" course.
 - b. Written confirmation that this Policy has been received and read.
3. Training every four years shall consist of documented completion of the "Conflicts of Interest Course".
4. Training shall also take place within 30 days when any of the following circumstances apply:
 - a. This Policy is revised in a manner that affects the requirements of Investigators.
 - b. The Institution finds that an Investigator is not in compliance with this Policy or GBMC's financial conflict of interest management plan.
5. Training shall be provided and monitored through the GBMC Institutional Review Board Office.

C. Disclosure of Significant Financial Interests

1. Each Investigator who is planning to participate in PHS-funded research shall disclose to the Institution the Investigator's SFIs (and those of the Investigator's spouse and dependent children).
2. Each Investigator (including sub-recipient Investigator, if applicable) who is participating in PHS-funded research shall submit an updated disclosure of SFIs at least annually. Such disclosure shall include any information that was not disclosed previously to the Institution and updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
3. Each Investigator who is participating in PHS-funded research shall submit an updated disclosure of SFIs within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
4. SFIs shall be disclosed on the "Financial Conflict of Interest Disclosure Statement for Projects Funded by the Public Health Service (PHS) Including NIH" form (see Appendix A).
5. All completed "Financial Conflict of Interest Disclosure Statement for Projects Funded by the Public Health Service (PHS) Including NIH" forms shall be submitted to the GBMC Institutional Review Board Office.

D. Review and Management of Significant Financial Interests

1. All "Financial Conflict of Interest Disclosure Statement for Projects Funded by the Public Health Service (PHS) Including NIH" forms shall be solicited and reviewed by the GBMC Institutional Review Board, under the guidance of the Institution's Corporate Compliance Officer, to determine if a significant FCOI exists. A financial conflict of interest exists when GBMC, through the Institutional Review Board in cooperation with the Corporate Compliance Officer, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

2. If GBMC determines that an Investigator has disclosed a SFI resulting in a FCOI, a FCOI report shall be submitted to the PHS Awarding Component by the GBMC Compliance Department, and a formal management plan shall be developed and implemented by the GBMC Compliance Department, in cooperation with the GBMC Legal Department and an independent member of the GBMC Institutional Review Board, pursuant to 42 CFR 50.605. This plan shall specify the actions that have been, and shall be, taken to manage the disclosed SFI. The conditions or restrictions that may be applied include, but are not limited to:
 - a. Public disclosure of the 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
 - g. Severance of relationships that create financial conflicts.
3. If GBMC identifies a SFI that was not disclosed in a timely manner by the Investigator or, for whatever reason, was not previously reviewed by GBMC during an ongoing PHS-funded research project, the GBMC Institutional Review Board, under the guidance of GBMC's Corporate Compliance Officer shall, within 60 days, review the SFI and determine whether a financial conflict of interest exists; and, if so:
 - a. The GBMC Compliance Department, in cooperation with the GBMC Legal Department and an independent member of the GBMC Institutional Review Board, shall develop and implement an interim management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.
 - b. If 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 GBMC to constitute a financial conflict of interest; failure by GBMC 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, the GBMC Compliance Department, in cooperation with the GBMC Legal Department and an independent member of the GBMC Institutional Review Board, shall:
 - i. within 120 days of GBMC's determination of non-compliance, complete and document 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 non-compliance, was biased in the design, conduct, or reporting of such research.

- E. Based on the results of the retrospective review, if appropriate, the GBMC Compliance Department shall update any previously submitted FCOI report. If bias is found, the GBMC Compliance Department shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Thereafter, the GBMC Compliance Department shall submit FCOI reports annually regarding the status of the FCOI and any changes in the management plan.

F. Monitoring of Investigator Compliance

When implementing a management plan, GBMC shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. Investigator compliance shall be monitored by the GBMC Compliance Department.

G. Appeals

If the Investigator believes that a determination made by GBMC in a specific case is not appropriate or is based on erroneous information, the Investigator may request additional review by submitting a written request to the Chairman of the GBMC Institutional Review Board.

H. Sanctions for Failure to Comply

Failure to comply with this Policy and with GBMC's recommendations may result in:

- a. The investigator being removed from IRB-approved PHS-funded research projects
- b. The suspension of IRB-approved PHS-funded research projects

I. External Reporting and Public Accessibility

1. Prior to GBMC's expenditure of any funds under a PHS-funded research project, GBMC shall ensure public accessibility to information concerning any SFI disclosed to GBMC that meets the following three criteria:
 - a. The SFI was disclosed and is still held by the senior/key personnel,
 - b. GBMC has determined that the SFI is related to the PHS-funded research, and
 - c. GBMC has determined that the SFI is a FCOI.
2. All requests regarding publicly accessible SFI information must be made to GBMC in writing. All requests shall be directed to GBMC's Corporate Compliance Officer. GBMC shall make a written response to any requestor within 5 business days. The written response shall include the following information:
 - a. The Investigator's name,
 - b. The Investigator's title and role with respect to the research project,
 - c. The name of the entity in which the SFI is held,
 - d. The nature of the SFI, and

- e. The approximate dollar value of the SFI, or
- f. A statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

GBMC's written response shall note that the information provided is current as of the date of the response and is subject to updates, on at least an annual basis and within 60 days of GBMC's identification of a new FCOI, and that such updates should be requested subsequently by the requestor.

J. Sub-recipients

If GBMC carries out the PHS-funded research through a sub-recipient (e.g., subcontractor or consortium members), the awardee Institution shall take reasonable steps to ensure that any sub-recipient Investigator complies with the Code of Federal Regulations Title 42, Part 50, Subpart F -Promoting Objectivity in Research.

1. In the event that the sub-recipient's FCOI policy applies to sub-recipient investigators, the sub-recipient shall certify, as part of the agreement, that its policy complies with the above-referenced PHS regulation. If the sub-recipient cannot provide the certification, the agreement shall state that sub-recipient Investigators are subject to this Policy.
2. In the event that the sub-recipient's FCOI policy applies to sub-recipient Investigators, the agreement shall specify time period(s) for the sub-recipient to report all identified FCOIs to the awardee Institution (GBMC). Such time period(s) shall be sufficient to enable GBMC to provide timely FCOI reports, as necessary, to the PHS Awarding Component.
3. In the event that the sub-recipient Investigator is subject to this Policy, the agreement shall specify time period(s) for the sub-recipient to submit all Investigator disclosures of SFIs to GBMC. Such time period(s) shall be sufficient to enable GBMC to comply with its review, management, and reporting obligations under the above-referenced PHS regulation. GBMC shall submit any FCOI report for sub-recipient Investigators, as necessary, to the PHS Awarding Component.
4. GBMC shall provide FCOI reports to the PHS Awarding Component regarding all FCOI of all sub-recipient Investigators consistent with the above-referenced PHS regulation, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

K. Research Indirectly Funded by the PHS

If GBMC carries out PHS-funded research and is the indirect recipient of any PHS-awarded funds (via another organization, agency, cooperative group, etc.), this Policy and Code of Federal Regulations Title 42 Part 50, Subpart F - Promoting Objectivity in Research shall be applied in full and shall apply to all persons who meet the definition of Investigator as already set forth above in this Policy.

L. Record Retention

GBMC shall maintain records relating to all Investigator disclosures of financial interests and GBMC's review of, or response to, such disclosures (whether or not a disclosure resulted in GBMC's determination of an FCOI) for at least three years from the date the final expenditures report is submitted to the PHS Awarding Component or, where applicable, according to other specified dates. All records shall be maintained in both the GBMC Institutional Review Board Office and GBMC Compliance Department, as appropriate.

Attachments

[A: Institutional Review Board Financial Conflict of Interest Disclosure Statement for Projects Funded by the Public Health Service \(PHS\) Including NIH](#)

Approval Signatures

Step Description	Approver	Date
Step 3: Executive Leadership	Allyson Abernathy, JD: Assistant General Counsel	11/7/2023
Step 2: Assistant General Counsel - Chief Privacy Officer	Lauren Klemm: Assistant General Counsel - Chief Privacy Officer	8/25/2023
Step 1: Owner	Lauren Klemm: Assistant General Counsel - Chief Privacy Officer	8/25/2023
Step 1: Owner	AMANDA LEONARD: Senior Regulatory Risk Specialist	10/26/2021

Applicability

GBMC, GBMC Department of Pathology & Laboratory, GBMC Health Partners, Gilchrist

Standards

No standards are associated with this document