
Dept: Baton Rouge General Medical Center
Authority: Institutional Review Board and
Institutional Research Oversight Committee
Operations Council**Effective Date:** 1/15
Review Dates: 12/15, 5/17
Revised Dates: 5/18

PURPOSE:

Baton Rouge General Medical Center (BRGMC) promotes objectivity in medical research and has established standards to ensure that the design, conduct, or reporting of research to be performed will not be biased by any conflicting financial interest of an Investigator. Opportunities to profit from research may affect – or appear to affect – the judgment or decisions of an Investigator. Significant financial conflicts of interest in human subjects research are regarded as potentially problematic, and therefore, require close scrutiny. It is the purpose of this policy to inform Investigators about situations that can generate conflicts of interest related to research and the procedures for reviewing and addressing those potential conflicts that occur. This is done to ensure that the research may be performed in a manner consistent with preserving the safety and welfare of human subjects who participate in such research, as well as ensure the overall integrity of the research.

The specific purpose of the policy is:

- A. To maintain the integrity of research endeavors
- B. To identify actual or potential financial conflicts of interest in research, and to eliminate, reduce or manage such conflicts;
- C. To maintain compliance with federal and state laws and regulations regarding financial conflict of interest as it relates to research

SCOPE:

The basic policy governing financial conflict of interest applies to all Investigators and Key Personnel affiliated with the medical center in some manner who, on behalf of BRGMC, are responsible for, or are in the position to influence the design, conduct, or reporting of the research or other scholarly activity. This applies to all research regardless of source of funding or lack of funding. This may include:

- Employees of BRGMC
- Members of the Medical Staff at BRGMC
- Trainees and students

The basic policy governing financial conflict of interest also applies to members of the BRGMC Institutional Review Board (IRB).

Investigators/Key Personnel applying for or who receive Public Health Service (**PHS**) research funding by means of a grant, cooperative agreement, or subcontract with a prime **PHS** awardee, are required to follow additional requirements as stated in this policy. These additional requirements will also apply to research funded by other entities that have adopted the **PHS** Financial Conflict of Interest rules and regulations.

DEFINITIONS:

Family means the Investigator's or Key Personnel's spouse and dependent children as defined by Louisiana state law.

Financial Interest means anything of monetary value received or held by an Investigator/Key Personnel or an Investigator's / Key Personnel's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from BRGMC;
- b) income from the authorship of academic or scholarly works;

- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator/Key Personnel does not directly control the investment decisions made in these vehicles.

For Investigators/Key Personnel, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator/Key Personnel and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator/Key Personnel rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest of the Investigator/Key Personnel or Investigator's / Key Personnel's Family that reasonably appears to be related to the Investigator's / Key Personnel's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the BRGMC.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of a research project.

Institutional responsibilities means an Investigator's / Key Personnel's professional responsibilities on behalf of BRGMC, which may include activities such as research, research consultation, teaching, clinical activities, administration, and internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of a proposal for **PHS** funding or any research project regardless of funding source. The definition may also include collaborators or consultants as appropriate.

Key Personnel means any individual who is responsible for the design, conduct, or reporting of any research project regardless of funding source.

Public Health Service or **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Federal Occupational Health, Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA).

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to health, including behavioral and social sciences research. The term encompasses basic and applied research and product development.

POLICY:

1. Disclosure of Financial Interests

- A. All Investigators/Key Personnel with active research at BRGMC are required to complete a Research Financial Disclosure Form and submit to the Institutional Research Oversight Committee (IROC) within ninety (90) days of final approval of this policy. At a minimum, forms must be completed by the Principal Investigator and all Sub-Investigators and Key Personnel for all active research protocols and members of the BRG IRB.

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- B. Exceptions for Investigators/Key Personnel at collaborating institutions who are required to follow their institution's Research Conflict of Interest policies will be decided by IROC on a case-by-case basis.
 - C. Other individuals may be asked to complete a Disclosure Form if requested by the IROC or the GHS Corporate Compliance Officer.
 - D. New Investigators/Key Personnel will be required to submit a Research Financial Disclosure Form to the Research Compliance Office at the time of initial review of a research project.
 - E. When there is a change in the Principal Investigator, addition of Sub-Investigators, or change in Key Personnel for an on-going research project, all new Investigators/ Key Personnel must submit a Research Financial Disclosure Form to the Research Compliance Office.
 - F. Investigators /Key Personnel will be required to submit a Research Financial Disclosure Form on an annual and *ad hoc* basis, as described below.
 - a. Annual Disclosures: All Investigators, Key Personnel, and IRB members must complete the Research Financial Disclosure Form and submit to the Research Compliance Office on an annual basis no later than March 31 for the previous calendar year. The Research Compliance Office will pre-review and present disclosures to IROC for review as needed.
 - b. *Ad hoc* Disclosures: In addition to annual disclosure, certain situations require *ad hoc* disclosure
 - i. All Investigators/Key Personnel with existing **PHS** funded research projects must disclose their Significant Financial Interests to BRGMC, through the Research Compliance Office within 30 days of their initial employment at BRGMC.
 - ii. Prior to entering into **PHS** sponsored projects or applications for **PHS** sponsored projects, where the Investigator/Key Personnel has a Significant Financial Interest, the Investigator/Key Personnel must submit to the Research Compliance Office an *ad hoc* updated disclosure of his or her Significant Financial Interests. BRGMC will not sign off on a **PHS** research proposal unless the Investigator(s)/Key Personnel have submitted such *ad hoc* disclosures.
 - iii. Investigator will disclose to the Research Compliance Office, by completing the Research Financial Disclosure Form, any Financial Interest held by the Investigator and/or Key Personnel for each new research project.
 - iv. In addition, all Investigators/Key Personnel must submit to the Research Compliance Office an *ad hoc* disclosure of any Significant Financial Interest they acquire during the course of the year.
 - This disclosure must be within thirty (30) days of discovering or acquiring the Significant Financial Interest for **PHS** supported Investigators/Key Personnel.
 - G. Travel: All Investigators/Key Personnel must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum:
 - a. the purpose of the trip
 - b. the identity of the sponsor/organizer
 - c. the destination
 - d. the duration
 - e. the monetary value, if known

The Research Compliance Office or the Corporate Compliance Officer will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's / Key Personnel's research.

Regardless of the disclosure requirements, the Investigator/Key Personnel, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest to a research project.

2. Review and Decision of IROC

- A. Review of the Research Financial Disclosure Forms will initially be conducted by the Research Compliance Office. If the disclosure form reveals a Significant Financial Interest, as defined above, the Research Compliance Office will submit to IROC. IROC will determine whether it constitutes a Financial Conflict of Interest (FCOI), as defined above. This determination is based on an analysis that includes, but is not limited to:
 - a. the nature of the science;
 - b. the nature of the overlapping interests;
 - c. how closely the interest is tied to the research;
 - d. the degree to which the interest may be affected by the research; and
 - e. the degree of risk that the research poses to human subjects and the integrity of the research.

- B. If a FCOI exists, IROC will require action to eliminate, reduce, or manage the conflict, as appropriate. If the FCOI can be managed, IROC must approve a written management plan before any related research goes forward or any **PHS** funds are expended. The Investigator/Key Personnel is responsible for developing and submitting a proposed management plan to IROC for review and approval.

Restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- a. Public disclosure of significant financial interests;
 - b. Disclosure of FCOI to research participants;
 - c. Disclosure of FCOI in publications and articles;
 - d. Monitoring of the research by independent reviewers;
 - e. Modification of the research plan;
 - f. Divestiture of significant financial interests;
 - g. Severance of relationships that create actual or potential conflicts;
 - h. Disqualification of Investigator/Key Personnel from participation in all or a portion of the research, which may include, but not limited to:
 - i. Not enrolling possible research participants in the study,
 - ii. Not administering the informed consent,
 - iii. Not be involved in subjective assessments of eligibility criteria and intervention outcomes
- C. For all **PHS** supported research, or to address complex situations, the Research Compliance Office, will periodically review the ongoing research activity, to monitor the conduct of the activity, to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.
- D. When the BRGMC IRB is the IRB of record for any research project, all Research Financial Disclosure Forms, IROC findings, and FCOI management plans will be submitted to the IRB for review and approval at a fully convened IRB meeting. The IRB may impose additional conditions or restrictions to manage a FCOI. The decision to grant approval of the research remains with the IRB.
- E. The Research Compliance Office is responsible for the receipt, retention, and distribution for review of disclosure forms to IROC and BRG IRB (when applicable).

3. Investigator/Key Personnel Non-Compliance

- A. Disciplinary Action
- a. In the event of an Investigator's / Key Personnel's failure to comply with this Policy, IROC or the IRB (when applicable) may suspend all relevant activities or take other action until the matter is resolved. The IROC Chair will submit a written explanation of the decision to the Investigator/Key Personnel and, where applicable, the IRB of record.
 - b. If the failure of an Investigator/Key Personnel to comply with the conflict of interest in research policy of BRGMC has biased the design, conduct, or reporting of the research, BRGMC will consider the situation, and as necessary, take appropriate action. Sanctions may include, but are not limited to:
 - i. Letter of reprimand
 - ii. Notification to funding agencies and/or professional journals or societies
 - iii. Termination of research project
 - iv. Suspension
 - v. Termination
- B. Retrospective Review for **PHS**-Supported Project
- a. If IROC determines that a FCOI was not identified or managed in a timely manner for a **PHS**-supported project, including but not limited to an Investigator's / Key Personnel's failure to disclose a Significant Financial Interest that is determined to be a FCOI, or failure by an Investigator/Key Personnel to materially comply with a management plan for a FCOI, a sub-committee appointed by the IROC Chair will complete a retrospective review of the Investigator's / Key Personnel's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research. At a minimum, the

Corporate Compliance Officer, Director of Finance and Director of Legal Services shall be part of the sub-committee.

- b. Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator/Key Personnel with the FCOI, name of the entity with which the Investigator/Key Personnel has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review. The sub-committee will report its findings to IROC.
- C. The IROC Chair will update any previously submitted report to the **PHS** or the prime **PHS**-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the **PHS** regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

4. **Reporting to PHS**

When a research project is **PHS** funded, the IROC Chair will report all FCOI or non-compliance to **PHS** in accordance with **PHS** regulations. If the funding for the research project is made available from a prime **PHS**-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the **PHS**.

5. **Training**

- A. Before engaging in research, all Investigators, Key Personnel, and IRB members must read this Policy and complete the Research Financial Disclosure Form attesting to understanding their disclosure responsibilities. In the event that this Policy is substantively amended in a manner that affects the requirements of Investigators/Key Personnel, all Investigators/Key Personnel must read the amended Policy and complete new Research Financial Disclosure Forms.
- B. In addition, if the Investigator/Key Personnel is engaging in research funded by **PHS**, the Investigator/Key Personnel must complete the Conflict of Interest module on the CITI training website and at least every four years thereafter.
- C. If it is determined that a **PHS**-funded Investigator/Key Personnel has not complied with this policy or with a management plan related to their activities, the Investigator/Key Personnel must review this Policy and repeat the Conflict of Interest module on the CITI training website.

6. **Record Retention**

The Research Compliance Office will retain all Research Financial Disclosure Forms for three years. The Research Compliance Office will retain all disclosure forms, conflict management plans, and other Financial Disclosure documents related to **PHS** funded research for a period of three years from the date the final expenditure report is submitted to the **PHS** or to the prime **PHS** awardee

7. **Confidentiality**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, BRGMC may make such information available to an agency funding research of the Investigator/Key Personnel, to a requestor of information concerning FCOI related to **PHS** funding or to the primary entity who made the funding available to BRGMC, if requested or required. If BRGMC is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator/Key Personnel will be informed of this disclosure.

8. **Public Access**

This Policy will be available on BRGMC's publically accessible website. The Corporate Compliance Officer will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets all of the following criteria:

- A. The Investigator/Key Personnel is supported by **PHS** funds;
- B. The Significant Financial Interest was disclosed and is still held by the Investigator/Key Personnel;
- C. A determination has been made that the Significant Financial Interest is related to the **PHS**-funded research; and
- D. A determination has been made that the Significant Financial Interest is a FCOI.

The information to be made available shall be consistent with the requirements of the **PHS** policy. Requests should be made in writing to Baton Rouge General Medical Center, Research Compliance Office, 3600 Florida Blvd., 4th Floor IRB Office, Baton Rouge, LA 70806.

REFERENCES:

1. American Association of Medical Colleges (AAMC) Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research (March 2012),
2. Federal laws and regulations that include, but are not limited to, 21 CFR Parts 54, 42 CFR 50, Subpart F, and 45 CFR part 94

ASSOCIATED FORMS:

Research Financial Disclosure Form
Research Financial Disclosure Addendum