

# UNIVERSITY OF GHANA MEDICAL CENTRE FINANCIAL CONFLICT OF INTEREST POLICY FOR RESEARCH PROJECTS AND OTHER AWARDS AND SUB-AWARDS TO THE CENTRE

#### 1. INTRODUCTION

The University of Ghana Medical Centre (UGMC) is an ultra-modern medical centre offering world-class quaternary level Health services, Training and Research in Ghana, West Africa and beyond. The centre through its Medical and Scientific Research Centre (MSRC) aims to facilitate cutting edge translational research that will discover new treatments, methods and procedures to improve the health status of Ghanaians, Africa and the world. In that regard MSRC receives and manages grant funding on behalf of UGMC to conduct research.

### 2. PURPOSE AND APPLICABILITY

In fulfillment of its mandate for research, MSRC receives grant funds from government, local and foreign funders for the conduct of research in diverse subject areas of medicine.

This Financial Conflict of Interest Policy for Project/Research and other awards and Sub-Awards to MSRC ("the Policy") represents ethical obligations and functions as the ultimate terms of reference and guide for the conduct of research, projects, awards, sub-awards.

# 2.1 The objectives of this policy are to:

- a. Prevent fraud, corruption and financial irregularities among the research community i.e., both staff and researchers.
- b. Create awareness and conscientize members of the research community on the offence and effect of financial conflict of interest.
- c. Ensure early detection of, and sanction conducts of financial conflict of interest.
- d. Investigate allegations and reports of incidents of financial conflict of interest at the Centre with regards to research.

### 3. GUIDING PRINCIPLES OF THE POLICY

This policy would therefore be established pursuant to the Laws of the Republic of Ghana which include but not limited to the **1992 Constitution of Ghana** ("the Constitution"), **the Statutes of the University of Ghana** ("the Statutes"), Public **Financial Management Act 2016** (**Act 921**) and international best practices regarding financial conflict of interest in relation to any funding grants, awards, sub-awards as shall be received by MSRC.

### 3.1. Standards under Laws of the Republic of Ghana

The values and ethics of the public service as contained in the Constitution, particularly Article 282, shall be the main source of guidance in ethical behaviour for all members of the research community i.e., researchers and staff of UGMC and any of its affiliate institutions and the general public that deals with UGMC. All persons are expected to promote the Core Values of "freedom, justice, probity and accountability".

- **3.2.** UGMC, as a medical institution in Ghana, is bound by the standards set by national laws regarding financial conflict of interest management.
- **3.3.** Researchers and research staff of UGMC and any of its affiliate institutions and the general public that deal with UGMC in any manner shall not put themselves in a position where their personal interest conflicts or is likely to conflict with the performance of the functions of their office (Article 284 of the Constitution).
- **3.4.** UGMC shall have general oversight over the adequate management of funds designated for Project/ Research and other Awards and Sub-Awards, and assets received by UGMC for research.
- **3.5.** Researchers and research staff of UGMC and any of its affiliate institutions and the general public that deal with UGMC in any manner or an organ of the UGMC who have an interest whether directly or indirectly in Project/ Research and other Awards and Sub-Awards, and assets:
  - **3.5.1.** shall disclose the nature of that interest and the disclosure shall form part of the record of the consideration of the matter; and
  - **3.5.2.** shall not participate in the deliberations or undertaking in respect of that matter.
  - **3.5.3.** Such person(s) shall cease to be members or part of the personnel, group or committee if such person(s) have an interest in a matter under consideration and
    - a. fail to disclose that interest, or
    - b. Participate in the deliberations and/or undertakings in respect of the matter.

- **3.6.** UGMC may nullify a decision taken in which the interested member participated in the deliberations or consideration of the matters related to the decision.
- **3.7.** Disclosure of any interest that could adversely affect the efficient design, conduct, or reporting of any research, project, or other funds by any grants, awards, asset or co-operative agreements is a prerequisite to entering into such transaction or undertaking.
- **3.8.** Researchers and research staff of UGMC and any of its affiliate institutions and the general public that deal with UGMC in any manner, who are, in any way, directly or indirectly interested in any contract, transaction or other decision being considered by UGMC or other body related to, affiliated or overseen by UGMC shall, at any meeting at which such contract, transaction or decision is being considered, declare their interest and the nature and extent thereof and shall abstain from participating in discussion and decisions with respect to the matter.
- **3.9.** No decision taken by any Researchers and research staff of UGMC and any of its affiliate institutions shall be invalid in whole or in part by reason of the existence of a financial conflict of interest except that the interested member or person shall not be allowed to benefit from the decision, contract, transaction or undertaking in any way, directly or indirectly.

### 4. STANDARDS UNDER INTERNATIONAL LAWS

UGMC through MSRC receives funding for research from external/international sources in all areas in medicine. This Policy sets out international standards to be considered and adhered to by Researchers and research staff of UGMC and any of its affiliate institutions and the general public that deals with UGMC in any manner regarding any grants, awards, sub-awards received by UGMC through MSRC to ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded grants, awards, sub-awards or co-operative agreements will be biased by any conflicting financial interest of an Investigator from UGMC.

### 4.1 Review of Conflict of Interest Disclosure

UGMC will designate an official ("Designated Official) or institute a Financial Conflict of Interest Committee (FCOIC) to conduct reviews of disclosures. The COIC/Designated Official will review any Significant Financial Interest (SFI) that has been identified in a disclosure; these interests will be compared to each research based grant, award, sub-award received by UGMC on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to the research grants, awards, sub-awards received by UGMC.

### 4.2 Membership

- a. The Committee shall be composed of five (5) members: a Chairperson and four (4) other members
- b. The Chairperson shall be a person with relevant experience in research and corruption related cases and principles.
- c. There shall be gender parity in the composition of the Committee.
- d. Competent external individuals from other relevant disciplines may be invited to serve on the Committee as ex-officio members, or to act as expert advisers.

### 4.3. Responsibilities of the Investigator

- 4.3.1. Prior to the submission of an application to the Grantee for funding, the Principal Investigator and all other Investigators at UGMC must have disclosed to UGMC's Conflict of Interest Committee (COIC)/designated official an up to date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined in this Policy. Any Investigator, who, subsequent to the submission of an application to the Grantee for funding from the Grantee, or during the course of the research project, plans to participate in the project must similarly disclose their SFI to the COIC/designated official promptly and prior to participation in the project.
- 4.3.2 Each Investigator who is participating in research under a grant, awards, sub awards received by UGMC or proposed to be received by UGMC must submit an updated disclosure of

SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to UGMC, pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a funded project directly as a Grantee and/or indirectly through a Sub award) that was transferred from another Institution and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

- 4.3.3 Each Investigator who is participating in research under a grant, awards, sub awards received by UGMC must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- 4.3.4 UGMC shall ensure that each investigator undergoes training or tutorials which will be organized by MSRC from time to time in accordance with the requirements and expectations of this Policy. MSRC must ensure that all investigator obtain a certification of completion at the end of training and retain it for audit purposes.

### 5. GUIDELINES FOR DETERMINING FINANCIAL CONFLICT OF INTEREST

- 5.1. The COIC/Designated Official will determine whether an Investigator's SFI is related to the research funded grants, awards, sub awards received by UGMC and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research funded grants, awards, sub awards received by UGMC when the COIC/Designated Official reasonably determine that the SFI: could be affected by the research conducted under the funding; or is an entity whose financial interest could be affected by the research. The COIC/Designated Official may involve the Investigator in the determination of whether an SFI is related to the research supported by the grants, awards, sub awards received by MSRC.
- 5.2. A financial conflict of interest exists when the COIC/Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the funded research.

- 5.3. In determining if an Investigator's SFI is related to the research funded grants, awards, sub awards received by MSRC, and if so, whether the relationship creates a FCOI, the COIC/Designated Official shall consider the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the COIC/Designated Official may also consider the following factors:
  - 1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
  - 2. Whether the degree of replication and verification of research results is such that immediate commercialization or application is not likely; or
  - 3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
  - 4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
  - 5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or
  - 6. whether the research could have a significant impact on the company's business or financial outlook, or
  - 7. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
  - 8. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
  - 9. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
  - 10. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
  - 11. Whether other scientific groups are independently pursuing similar questions; or
  - 12. Whether sufficient external review of the research conducted, and the reporting of research results exist to mitigate undue bias; or

- 13. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has an SFI; or
- 14. Whether the project involves a grant, awards, sub-awards to an entity in which the Investigator has an SFI.

# 6. MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS THAT POSE FINANCIAL CONFLICT(S) OF INTEREST

- 6.1 If a Conflict of Interest exists, the COIC/Designated Official will determine by what means such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monito ring of the activity by a subcommittee the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the COIC/Designated Official will be guided by the principles discussed in this Policy. The COIC/Designated Official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.
- **6.2** Conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:
  - **6.2.1** Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
  - **6.2.2** For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
  - **6.2.3** 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;

- **6.2.4** Modification of the research plan;
- **6.2.5** Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- **6.2.6** Reduction or elimination of the financial interest (e. sale of an equity interest);
- **6.2.7** Severance of relationships that create financial conflicts;
- **6.2.8** For research projects involving human subjects research, use of a data and safety monitoring board;
- **6.2.9** Double blind conditions:
- **6.3.** Provisions to conduct the work simultaneously at multiple sites;
  - **6.3.1** Written disclosure of the financial conflict of interest to all individuals working on the research project;
  - **6.3.2** Annual reports on the research progress to the COIC/Designated Official.
  - **6.3.3** If the COIC/Designated Official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor.
  - **6.3.4** The COIC/Designated Official will keep a record of the disclosure and other relevant information for at least three (3) years. If the COIC/Designated Official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

- **6.3.5** No expenditures on grants, awards, sub awards received by MSRC will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the COIC/Designated Official as necessary to manage the Conflict of Interest. The COIC/Designated Official will communicate, in writing, with the Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditure can be incurred until the Investigator has reported the FCOI to the Grantee. The Grantee will notify MSRC when it may incur expenditure.
- **6.3.6** The COIC/Designated Official will keep a record of Investigator disclosures of financial interests and the COIC/Designated Official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three (3) years from the date the final expenditure report is submitted and in accordance with the terms and conditions of the Research/Project funded grants, awards, sub awards received by MSRC.

# 7. PUBLIC ACCESSIBILITY TO INFORMATION RELATED TO FINANCIAL CONFLICTS OF INTEREST

- 7.1. Prior to the expenditure of any Research/Project funded grants, awards, sub awards, UGMC will ensure public accessibility, via its website or by written response to any requestor within ten (10) business days of a request of information concerning any SFI disclosed that meets the following three criteria:
  - 7.1.1. The Significant Financial Interest was disclosed and is still held by the Senior/key personnel Senior/key personnel are the PD/PI and any other person identified as senior key personnel by MSRC in the Award application to the Grantee, progress report or any other report submitted to the Grantee;
  - 7.1.2 UGMC has determined that the Significant Financial Interest is related to the research funded Research/Project funded grants, awards, sub awards received by MSRC,

- 7.1.3 UGMC has determined that the Significant Financial Interest is a financial conflict of interest.
- 7.1.4 The information that UGMC will make available via a publicly accessible website or in a written response to any requestor within ten (10) days of request will include, at a minimum, the following:
- ➤ The Investigator's name;
- ➤ The Investigator's title and role with respect to the research project;
- The name of the entity in which the Significant Financial Interest is held;
- ➤ The nature of the Significant Financial Interest; and
- The approximate dollar value of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
  - 7.1.5 Where UGMC uses its website to publicize the disclosure requirements, the information posted will be updated at least annually, and within sixty (60) days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the funded research project, if it is determined by the COIC/Designated Official that the Significant Financial Interest is related to the research and is a financial conflict of interest.
  - 7.1.6 If UGMC responds to written request for the purpose of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of UGMC's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

7.1.7 Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via UGMC's publicly accessible website for at least three (3) years from the date that the information was most recently updated.

### 8. REPORTING OF FINANCIAL CONFLICTS OF INTEREST

- 8.1. Prior to the expenditure of any funds under a Research or Project grants, awards, sub awards MSRC will provide to the Grantee a FCOI report regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. MSRC cannot incur expenditure until it has received notification to do so from the Grantee.
- 8.2. While the grants, awards, sub awards are ongoing (including any extensions with or without funds), MSRC will provide to the Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.
- 8.3 For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing funded research project (e.g., upon the participation of an Investigator who is new to the research project), MSRC will provide to the Grantee, within forty-five (45) days, an FCOI report regarding the financial conflict of interest and ensure that MSRC has implemented a management plan and the Investigator has agreed to the relevant management plan.

### 9. TRAINING REQUIREMENTS

9.1. Each Investigator must complete training on UGMC's Financial Conflict of Interest Policy applicable to grants, awards, sub awards prior to engaging in research related to any funded grants, awards, sub awards and at least every four (4) years, and immediately as defined below when any of the following circumstances apply:

- 9.2. UGMC revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
- 9.3. An Investigator is new to MSRC research funded grants, award or sub award (training is to be completed prior to his/her participation in the research); or MSRC finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within thirty (30) days in the manner specified by the COIC/Designated Official).

# 10. FAILURE TO COMPLY WITH UGMC'S FINANCIAL CONFLICT OF INTEREST POLICY PROJECT/RESEARCH FUNDED GRANTS, AWARDS, SUB AWARDS

- 10.1 When an FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by a second-tier sub recipient or by MSRC; or because an investigator failed to comply with a management plan; then MSRC shall within ninety (90) days:
  - 10.1.1 Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
  - 10.1.2 Document the retrospective review consistent with the regulation;
  - 10.1.3 Document MSRC's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's noncompliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research; and,
  - 10.1.4 Notify the Grantee in writing.
    - 10.4.1.1 If bias is found, MSRC shall notify the Grantee promptly and submit a mitigation report to the Grantee that shall address the following:

- > Impact of the bias on the research project; and MSRC's plan of action or actions taken to eliminate or mitigate the effect of the bias.
- ➤ Thereafter, MSRC shall submit FCOI reports annually to the Grantee, in accordance with the regulation and terms and conditions of the grant, awards or sub award agreement depending on the nature of the Financial Conflict of Interest.

10.4.1.2 MSRC may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of MSRC's independent retrospective review.

### 11. FAILURE TO COMPLY WITH THIS POLICY

- 11.1 No expenditure of funds on a grant, award or sub award will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any COIC/Designated Official approved FCOI management plan.
- 11.2 Any failure by an individual to adhere to this Policy may be a cause for disciplinary action, including, in severe cases, and termination of grants, awards, sub award by the Grantee.

# 12.DEFINITIONS

Term	Description		
Investigator	Project Director (PD) or Principal Investigator (PI)		
	and any other person who is responsible for the		
	design, conduct, or reporting of research funded		
	grants, awards, sub-awards received by UGMC		
	through MSRC or proposed for such funding. In this		
	policy, "Investigator" includes the investigator's		
	spouse and dependent children		
Institution	Any domestic or foreign, public or private, entity or		
	organization that submits a proposal, or that receives,		
	research funding grants, awards, sub-awards and for		
	the purpose of this policy.		
Institutional responsibilities	An Investigator's professional responsibilities on		
	behalf of the Institution, and as defined by the		
	Institution in its policy on financial conflicts of		
	interest, which may include for example: activities		
	such as research, research consultation, professional		
	practice, institutional committee memberships, and		
	service on panels such as Institutional Review Boards		
	or Data and Safety Monitoring Boards.		
Key personnel	Includes the PD/PI and any other personnel		
	considered to be essential to work performance and		
	identified as key personnel in the proposal and		
	agreement.		
Research	A systematic investigation designed to develop or		
	contribute to generalizable knowledge relating		
	broadly to public health including behavioral and		
	social sciences research. For the purposes of this		
	policy, this comprises basic and applied research		

	(e.g., a published article, book or book chapter) and		
	product development (e.g., a diagnostic test or drug).		
	This includes any such activity for which research		
	funding is available from an Awarding Component		
	through a grant or cooperative agreement.		
Financial Interest	Anything of monetary value, whether the value is		
	readily ascertainable. Includes but is not limited to,		
	salary or other payments for services (e.g., consulting		
	fees or honoraria); equity interests (e.g., stocks, stock		
	options or other ownership interests); and intellectual		
	property rights (e.g., patents, copyrights and royalties		
	from such rights)		
Significant Financial Interest (SFI)	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. 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;
- (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) Intellectual property rights and interests(e.g., patents, copyrights), upon receipt of income related to such rights and interests.

# Exceptions:

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

- salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control

Financial Conflict of Interest (FCOI)	the investment decisions made in these vehicles;  • income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;  • income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.  A significant financial interest that could directly and significantly affect the design, conduct, or reporting		
FCOI report	of a funded research.  An Institution's report of a financial conflict of interest to a Grantee of an award or sub-award.		
Grantee	A Funder of a project or research		
The International Laws and Regulations	The International laws includes the US adopted regulations from PHS' Promoting Objectivity in Research (42 CFR Part 50 Subpart F and 45 CFR Part 94) and any other international law or regulation that may be considered from time to time		
Conflict of Interest	Any interest that may that reasonably affect or appears to affect the Investigator's institutional		

responsibilities under project/research funded grants,
awards, sub-awards received by USL.

# Schedule I

# VERSION CONTROL AND CHANGE HISTORY

Version Control	Date Effective	Approved By	Amendment
Version 1	February 20, 2022	Director, MSRC	