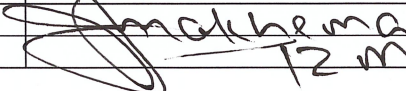


**Botswana Harvard Health Partnership (BHP)**

**FINANCIAL CONFLICT OF INTEREST POLICY**

<b>NAME:</b>	<b>Financial Conflict of Interest</b>
<b>NUMBER:</b>	<b>BHP/Grants/POL/03</b>
<b>REVISION:</b>	<b>2</b>
<b>DATE:</b>	<b>23/02/2024</b>
<b>AUTHORITY:</b>	<b>Chief Executive Officer</b>
<b>SIGNATURE:</b>	
<b>DATE:</b>	<b>12 Mar 2024</b>

## FINANCIAL CONFLIT OF INTEREST POLICY

### INTRODUCTION

As an institution of research and training, the Botswana Harvard Health Partnership (BHP) plays a prominent role in disseminating ideas and knowledge to audiences within and beyond Botswana. BHP employees do so through clinical research, scholarly publications, the training of clinicians in the community and of students in the laboratory, BHP's partnerships with both local and international organizations, and through daily interaction with members of the community. In addition, at times employees engage in additional interactions with industry and other external constituencies. Consultancies, advisory engagements, service on for-profit and not-for-profit boards, and numerous other outside activities provide opportunities for employees to direct their expertise and learning to socially useful applications.

Employee collaboration with outside organizations and communities furthers BHP's mission of societal service and also benefits BHP. Such interactions promote intellectual exchange, enhance professional development, spawn further discovery, and augment and renew the vitality of the BHP. Accordingly, the BHP encourages its employees to engage with the world through outside pursuits. At the same time, the BHP is cognizant that an individual's relationship with outside enterprises can engender opportunities for personal gain or financial advantage that may be at odds with the primary obligations the individual assumes as a member of the BHP staff.

The BHP enjoys the trust of many constituencies – students and trainees, clinicians, governments, businesses, a global community of scholars, and the general public. At root, their trust rests on the BHP's reputation for objective and independent research and training. Indeed, the BHP's greatest asset is its reputation for integrity, a reputation that benefits all members of the BHP community and undergirds the institution's merit for support in all forms – public and private grants, donations, academic collaborations, and others.

It is therefore appropriate that the BHP ensure that members of its community do not engage in behaviours that risk compromising the BHP's reputation and integrity. Because financial conflicts of interest especially may corrode the BHP's reputation and, thereby, erode confidence in the BHP and diminish its trustworthiness and stature, the BHP must ensure that employees are made aware of such conflicts and are dutiful in internally disclosing them, that the disclosed conflicts receive scrupulous attention and management, and that all of BHP is held to standards of conduct that meet the needs of the BHP as a whole.

The policy put forth here establishes BHP's system for identifying, evaluating, and managing financial conflicts of interest. This policy applies to all sponsored grant funding for the BHP investigators. The BHP Chief Operating Officer (COO) is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the COO is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to BHP policy.

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## DEFINITIONS

*Clinical Trial* means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

*Family* means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

*Fiduciary or Management Role* means services as an officer, director or service on an advisory board (including scientific advisory boards), whether paid or unpaid.

*Financial Interest* means anything of monetary value received or held by an Investigator or an Investigator'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 the BHP;
- 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; 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 does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is 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* includes, but is not limited to, the following:

- a) financial remuneration, including travel, from consulting, employment, managerial, and fiduciary relationships that, when aggregated over the preceding twelve months, exceed \$5,000;
- b) equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit, entity;

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c) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

*Financial Conflict of Interest* means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

*Institutional official* means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the BHP Chief Operating Officer (COO).

*Institutional responsibilities* mean an individual's professional responsibilities on behalf of BHP. Such responsibilities include, but are not limited to: research, research consultation, training, professional practice or clinical activities, institutional committee memberships, and service on committees or panels such as research ethics committees and other bodies monitoring the conduct of research (Institutional Review Boards, Data Safety Monitoring boards, etc.).

*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 collaborators or consultants.

*Public Health Service* or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services (HHS), 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, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

*Research* means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioural 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).

## **CONFLICT OF INTEREST**

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this

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policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

## 1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

### a) Annual Disclosures

All Investigators must disclose their significant financial interests that are related to the Investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by March 1 for the previous calendar year.

### b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their significant financial interests to the Institution, through the Institutional Official, within 30 days of their initial employment with BHP.

Prior to entering into applications for PHS-sponsored projects or PHS-sponsored awards, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her significant financial interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any significant financial interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the significant financial interest.

### c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of financial interest and significant financial interest. There is a \$5,000 de minimis threshold imposed, meaning if the dollar amount of the travel plus the interest in the entity does not exceed \$5,000 per calendar year, then the travel does not need to be disclosed.

Disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Institutional Official will

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determine if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

Note that investigators do not need to disclose travel funded by:

- Federal, state, or local government agencies
- An Institution of higher education
- An academic teaching hospital, medical center or research institute that is affiliated with an Institution of higher education.

In addition, if the funds flow through BHP as part of a sponsored award or other mechanism, travel on those funds does not need to be disclosed.

## **2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL**

If the disclosure form reveals a significant financial interest, it will be reviewed by the Institutional Official or designee for a determination of whether it constitutes a financial conflict of interest. If a financial conflict of interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate, prior to BHP's expenditure of any funds under the PHS-funded research project.

A financial conflict of interest will exist when the Institutional Official or designee determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a financial conflict of interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

## **3) CLINICAL TRIALS**

### **Review of Significant Financial Interests Related to Clinical Trials**

Clinical trials involve particularly sensitive issues if the Investigator has a financial interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this policy, the Investigator must disclose the financial conflicts of interest in each

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public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

#### 4) REPORTING TO PHS

The Institutional Official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the research 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 fulfil their reporting obligations to the PHS.

#### 5) INVESTIGATOR NON-COMPLIANCE

##### a) Disciplinary Action

In the event of an Investigator's failure to comply with this policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The Institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

##### b) Retrospective Review

In addition, if the Institutional Official determines that a financial conflict of interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a significant financial interest that is determined to be a financial conflict of interest, or failure by an Investigator to materially comply with a management plan for a financial conflict of interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS-sponsored 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.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the financial conflict of interest, name of the entity with which the Investigator has the financial conflict of interest, reason(s) for

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the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official 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 financial conflict of interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, 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.

## **6) TRAINING**

Each Investigator must complete training on this policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

## **7) RECORD RETENTION**

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

## **8) CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required.

## **9) PUBLIC ACCESSIBILITY**

The BHP will maintain an up-to-date, written, enforced policy on financial conflicts of interest, and will make this policy available via its publicly accessible Web site.

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Prior to the expenditure of funds, BHP will respond to any requestor within five business days of the request, with information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

## 10) REGULATORY AUTHORITY

This policy implements the requirements of [42 CFR 50 Subpart F and 45 CFR 94](#); where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

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