

UNIVERSITI MALAYA POLICY ON FINANCIAL CONFLICT OF INTEREST FOR UNITED STATES NATIONAL INSTITUTE OF HEALTH (U.S. NIH) FUNDED RESEARCH

1.0 INTRODUCTION

The purpose of this policy is to protect the credibility and integrity of the University Malaya (UM) academics and non-academics staff so that public trust and confidence in UM funded and sponsored activities is ensured.

This policy applies to all Investigators of the (UM) who are involved in all United States (U.S.) National Institute of Health (NIH) funded research. The Institutional Official 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 Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to UM policy.

2.0 DEFINITIONS

2.1 Clinical Trial

Clinical Trial means any sponsored 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.

2.2 Family

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

2.3 Institutional Official(s)

Institutional official(s) means the individual or a committee within UM staff 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(s) is designated as a committee appointed by UM as per stipulated on the checklist for policy.

2.4 Institutional Responsibility

Institutional responsibilities mean the Investigator's professional responsibilities associated with his or her Institutional appointment or position in UM, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service either in or outside UM.

2.5 Investigator

Investigator means the Principal Investigator or Project Director and any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposed for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

2.6 Research

Research means a systematic investigation, study, or experiment designed to 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).

2.7 Senior/Key Personnel

Senior/Key personnel means the Principal Investigator and/or other person identified as senior or key personnel by the University in a grant application, award, or contract or in any progress report, or any other report submitted to the funding sources.

2.8 Funder

Funder means individual or organization financing a part or all of a project's cost as a grant.

2.9 Financial Interest

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.

All UM investigators must comply with the Malaysia Public Officers' regulation (conduct and discipline) 1993 and service circular No. 3/2002- Ownership and Declaration of asset by Public Officers to declare all their assets using the Human Resource Management Information system or any system that is endorsed by UM or the authority.

On top of the above, investigators must also disclose all foreign (outside of U.S) financial interests, which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel received from any foreign entity, including foreign Institutions of higher education or foreign government, which includes local, provincial, or equivalent governments of another country when such income meets the threshold for disclosure.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the UM;
- 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 the U.S Federal, state or local governmental agencies located within the U.S.; a U.S. institutions of higher education; research institutes affiliated with a U.S. institution 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 located within the U.S., a U.S. institution of higher education, research institutes affiliated with a U.S. institution of higher education, academic teaching hospitals, and medical centers.

2.10 Significant Financial Interest

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator'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 or equivalent to \$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 exceeding or equivalent to \$5,000 in cumulative related to intellectual property rights and interests, arising from the sponsored project, not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel in excess of \$5,000 closely related to the investigator institutional responsibilities .

2.11 Financial Conflict of Interest

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that UM reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

The term "Significant Financial Interest" does NOT include the following types of financial interests:

- a) Salary, royalties, incentives, or other payments made by the UM to a UM Investigator who is currently employed or otherwise appointed by the UM;
- b) Payments or the entitlement to payments from the UM derived from royalties and fees paid to the UM by a third-party for Intellectual Property assigned by an Investigator or Innovator to the UM;
- c) Income from seminars, lectures, teaching engagements, or services on advisory committees or review panels sponsored by U.S. federal, state, or local government agency located in the U.S., a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with a U.S. institution of higher education;
- d) Income from investment vehicles, such as mutual funds and retirement funds, in which the investigator does not directly control investment decisions.

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

3.1 Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests as defined above to UM on an annual and on an ad hoc basis, as described below, using the Financial Interest Disclosed Form.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to UM, 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 or as determined by authority.

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 appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, 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. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official 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 research.

The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

3.2 Review and Decision of the Institutional Official

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly 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.

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.

3.3 Review of Significant Financial Interests Related to Clinical Trials

All studies involving human participants, their medical records and tissues (for tissues, only if the personal identity of the subject is required) require clearance by the UM clinical ethic committee.

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

4.0 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 fulfill their reporting obligations to the PHS.

5.0 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.

A 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 sponsored research project within 120 days of determining noncompliance with the regulation or the university's policy 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 the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

In the case of PHS sponsored project, 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.

6.0 TRAINING

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the regulations prior to engaging in research funded by the U.S. NIH, 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, or 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.

All related investigators must complete FCOI training:

- a) prior to engaging in research related to any PHS-funded grant,
- b) at least every 4 years
- c) immediately, if
 - i. institution revises its FCOI policy that affects requirements of Investigators
 - ii. an Investigator is new to an Institution
 - iii. an Investigator is not in compliance with the policy or management plan

7.0 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 funders or to the prime 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.

8.0 CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, UM may be required to make such information available to the funders, to a requestor of information concerning financial conflict of interest related to respective funding or to the primary entity who made the funding available to UM, if requested or required. If UM is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9.0 PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, UM will respond to any requestor within five business days of the request, 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 sponsored funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information that UM makes available via a written response shall include, at a minimum, the following:

- a) Investigator's name;
- b) Investigator's title and role with respect to the research project;
- c) Name of the entity in which the Significant Financial Interest is held;
- d) Nature of the Significant Financial Interest; and
- e) Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) 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.

10.0 REGULATORY AUTHORITY

This policy implements the requirements of the PHS regulations on responsibility of applicants for promoting objectivity in research for which PHS funding is sought (42 CFR 50 Subpart F) and responsible prospective contractors (45 CFR 94); where there are substantive differences between this policy and the requirements of the regulations, the requirements shall take precedence.

Approved by
JKPU: 27 March 2023