

TITLE: NIH CONFLICT OF INTEREST PROCEDURES

APPROVAL DATE: 1 April 2021

REVIEW DATE: 1 April 2024

1. PURPOSE

The purpose of these Procedures is to set out the conflict of interest obligations of QIMR Berghofer Personnel who carry out research funded by the United States National Institutes of Health (**NIH**).

1.1. These Procedures should be read in conjunction with the Conflict of Interest Policy and any other QIMR Berghofer Conflict of Interest Procedures.

2. DEFINITIONS

In these Procedures, unless the context otherwise requires or a contrary intention appears, the following terms shall have the following meanings:

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

2.2. **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:

- (a) salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works);
- (b) any equity interests (e.g., stocks, stock options, or other ownership interests); and
- (c) 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 Institution;
- (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 centres; or
- (d) equity interests or income from investment vehicles, such as superannuation accounts and mutual funds so long as the Investigator does not directly control the investment decisions made in these vehicles.

2.3. **Financial Conflict of Interest** has the meaning given to the term in clause 4.1.

2.4. **Institutional Official** means the Chief Operating Officer.

- 2.5. **Institutional Responsibilities** means the Investigator's professional responsibilities associated with their position at QIMR Berghofer.
- 2.6. **Investigator** means any QIMR Berghofer Personnel who are responsible for the design, conduct, or reporting of NIH sponsored research, or proposals for such funding.
- 2.7. **Key Personnel** means the Principal Investigator of an NIH funded project and any other Personnel identified as senior or key Personnel in the application for NIH funding or any reports submitted to the NIH during the term of the NIH grant.
- 2.8. **Personnel** means all Institute staff, students, volunteers and researchers (however described).
- 2.9. **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 total 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 total 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 exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
 - (e) is reimbursed or sponsored travel related to their Institutional Responsibilities.
- 2.10. **Sub-recipient** is a third party organisation contracted by the principal recipient of the grant, that performs any of the principal recipient's grant supported research activities.

3. DISCLOSURE OF FINANCIAL INTERESTS

- 3.1. All Investigators are required to disclose their outside Financial Interests to the Institute as set out in these Procedures.

Annual Disclosures

- 3.2. All Investigators must disclose their Significant Financial Interests:
- (a) That would reasonably appear to be related to the research funded by the NIH; and
 - (b) In entities whose financial interests would reasonably appear to be affected by the research funded by the NIH.
- 3.3. Disclosures under clause 3.2 must be made to the Institutional Official:
- (a) At the time of application for NIH funding; and
 - (b) By 1 July of each year during the term of the research project funded by the NIH.

Ad hoc Disclosures

- 3.4. In addition to annual disclosure, 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. Such disclosure must be made within thirty (30) days of discovering or acquiring the Significant Financial Interest.
- 3.5. All new Investigators must disclose their Significant Financial Interests to the Institutional Official within 30 days of their initial appointment or employment.

4. REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

- 4.1. A Financial Conflict of Interest will exist where the Institutional Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of NIH funded research.
- 4.2. The Institutional Official will review disclosures made by Investigators pursuant to these Procedures to determine whether a Financial Conflict of Interest exists.
- 4.3. If the Institutional Official determines that there is a Financial Conflict, they must develop and implement a written management plan, which may include supervision, reduction or elimination of the Financial Conflict of Interest.
- 4.4. The Institutional Official will periodically review the ongoing activity, monitor the conduct of the research and otherwise oversee compliance with the management plan.
- 4.5. In the event that an Investigator has not disclosed a Significant Financial Interest in a timely manner, the Institutional Official must within 60 days of becoming aware of the Significant Financial Interest, determine whether a Financial Conflict of Interest exists.
- 4.6. If the Institutional Official determines under clause 4.5 that a Financial Conflict of Interest exists, the Institutional Official must, within 120 days of the determination:
 - (a) implement a management plan in accordance with clause 4.3; and
 - (b) complete a review of the Investigator's activities during the period of noncompliance to determine whether there was bias in the design, conduct or reporting of the NIH funded research (a **Retrospective Review**).
- 4.7. In conducting a Retrospective Review, the Institutional Official must document the following:
 - (a) Project number;
 - (b) Project title;
 - (c) Principal Investigator name and contact details;
 - (d) Name of the Investigator with the FCOI;
 - (e) Name of the entity with which the Investigator has a Financial Conflict of Interest;
 - (f) Reason(s) for the Retrospective Review;
 - (g) Detailed methodology used for the retrospective review;
 - (h) Findings of the review; and
 - (i) Conclusions of the review.

5. NIH REPORTING OBLIGATIONS

5.1. The Institutional Official will report Financial Conflicts Of Interest to the NIH at the following times:

- (a) Prior to the expenditure of NIH funds;
- (b) Within 60 days of identification of new, or newly identified Financial Conflicts of Interest; and
- (c) Promptly following a Retrospective Review.

5.2. Reports issued pursuant to clause 5.1 must contain sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest. Such reports must include:

- (a) Project number;
- (b) Principal investigator name;
- (c) Name of the Investigator with the Financial Conflict of Interest;
- (d) Name of the entity with which the Investigator has a Financial Conflict of Interest;
- (e) Nature of the Financial Interest;
- (f) Value of the Financial Interest;
- (g) A description of how the Financial Interest relates to the NIH funded research and the basis for the Institution's determination that the Financial Interest conflicts with such research; and
- (h) A description of the key elements of the Institution's management plan.

5.3. At least annually, the Institutional Official must provide NIH with a report that addresses the status of Financial Conflicts of Interest that have been previously reported to the NIH. Such a report must include:

- (a) An update on the status of the Financial Conflict of Interest;
- (a) Any changes to the management plan; and
- (b) Whether the Financial Conflict of Interest is still being managed or an explanation that the Financial Conflict of Interest no longer exists.

5.4. The Institutional Official must promptly notify the NIH if a Retrospective Review determines that there was bias in the design, conduct or reporting of NIH funded research. Such a report must include a mitigation report that sets out:

- (a) The key elements documented in the Retrospective Review;
- (b) A description of the impact of the bias on the research project; and
- (c) The Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

5.5. Where the Institute is a subrecipient of NIH funding, the reports contemplated by this clause 5 shall be made to the prime awardee rather than the NIH.

6. TRAINING

6.1. Each Investigator must complete training on these Procedures and the Investigator's responsibilities regarding disclosure at the following times:

- (d) Prior to engaging in research funded by the NIH;
- (e) At least every four years thereafter; and
- (f) If an Investigator fails to comply with these Procedures or a management plan implemented pursuant to these Procedures, promptly following the discovery of a non-compliance.

6.2. The Grants Manager is responsible for managing training in accordance with these Procedures.

7. NON-COMPLIANCE

7.1. Failure to comply with these Procedures, or a management plan implemented pursuant to these Procedures, may amount to a breach of the QIMR Berghofer Code of Conduct. If this is the case, QIMR Berghofer may take disciplinary action up to and including dismissal.

7.2. If an Investigator who designs, conducts or reports NIH funded clinical research that evaluates the safety or effectiveness of a drug or medical device, fails to disclose a Financial Conflict of Interest, the Investigator must:

- (a) Disclose the Financial Conflict of Interest in each public presentation of the results of the research; and
- (b) Request an addendum to previously published presentations.

8. PUBLIC ACCESSIBILITY

8.1. Members of the public may, by written request, seek disclosure of information concerning any Significant Financial Interest disclosed to QIMR Berghofer that meets the following criteria:

- (a) The Significant Financial Interest was disclosed and is still held by Key Personnel;
- (b) The Institute determines that the significant financial interest is related to NIH funded research; and
- (c) The Institute determines that the Significant Financial Interest is a Financial Conflict of Interest.

8.2. The Institute must provide a written response within five business days to any request made pursuant to clause 8.1.

9. RECORD KEEPING

9.1. All records made pursuant to these Procedures must be maintained for at least:

- (a) 3 years from the date the final expenditure report is submitted to NIH for a project; or
- (b) Such period as determined by the Institute's obligations pursuant to the *Public Records Act 2002* (Qld),

whichever is later.

10. SUBRECIPIENT REQUIREMENTS

10.1. Where the Institute is a prime awardee of NIH funding and wishes to collaborate with a **Subrecipient**, the Subrecipient must contractually agree to either:

- (a) Comply with these Procedures as if the Subrecipient were the Institute; or
- (b) Warrant that the Subrecipient's conflict of interest policy complies with the requirements of the Code of Federal Regulations Title 42, Part 50, Subpart F.

11. CONTACT OFFICER

General Counsel

12. REFERENCES

QIMR Berghofer policies:

Conflict of Interest Policy

Code of Conduct

External resources:

The United States Code of Federal Regulations Title 42, Part 50, Subpart F

13. AMENDMENT HISTORY

Approved by the Director and CEO – 1 April 2021



Professor Fabienne Mackay PhD FAHMS
Director and CEO
QIMR Berghofer Medical Research Institute