



<b>MANUAL:</b> Institutional Review Board Policy and Procedure Manual	<b>FOLDER:</b> Financial Conflict of Interest - Investigators and Key Personnel
<b>TITLE:</b> Financial Conflict of Interest in Research	<b>POLICY OWNER:</b> IRB Manager
<b>POLICY ADMINISTRATOR:</b> Vice President - Administration	<b>COMPLIANCE REVIEW:</b> IRB Manager
<b>ORIGINAL DATE:</b> January 14, 2003	<b>REVISION DATE(S):</b> April 8, 2003; November 11, 2003; February 10, 2004; April 13, 2004; September 11, 2007; September 11, 2012
<b>KEYWORDS:</b> Conflict of Interest	

**SCOPE:**

This policy applies to all investigators, sub-investigators, key personnel and others involved in the conduct of research at The Reading Hospital and Medical Center.

**PURPOSE:**

To set forth The Reading Hospital and Medical Center Institutional Review Board’s policy addressing reporting and managing of financial conflict of interest in research.

**POLICY:**

A conflict of interest is considered to occur whenever an investigator, sub-investigator or key personnel (hereinafter defined) has an existing or potential financial interest that impairs or appears to impair their independence and objectivity in the design, conduct and reporting of research.

Investigators, sub-investigators and key personnel (hereinafter defined) should avoid conflicts of interest and/or the potential for conflicts through financial arrangements with entities that have a special interest in a research project or its findings.

All investigators, sub-investigators and key personnel (hereinafter defined) are required to submit a Financial Disclosure Form to the IRB Office at the time of initial review of the research, annually thereafter and within 30 days of discovering or acquiring a new financial interest.

**DEFINITIONS:**

**Conflict of Interest (COI)** means any situation in which an investigator, sub-investigator or other key personnel (hereinafter defined) has significant financial interest or other personal involvement that may compromise, or have the appearance of compromising, his or her professional judgment or integrity in the conduct of research.



Conflicts of Interest could include:

- Compensation that could increase with favorable research results. Such compensation could be equity in the company or companies sponsoring the research. Compensation could also include royalties from sales.
- Payments to the investigator(s) conducting the research. These payments could be in the form of grants, equipment, and retainers for consultation or honoraria.
- Proprietary interests in the product under investigation. Such interests include patents, copyrights, trademarks or license agreements.
- Any ownership of stocks or stock options whose value cannot be determined readily by reference to public prices.
- Equity in a publicly traded corporation.

**Disclosure of Significant Financial Interest** means the investigator's disclosure of significant financial interests to the Institution.

**Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

**Financial Interest (FI)** means anything of monetary value, whether or not the value is readily ascertainable.

**Institution** means The Reading Hospital, which includes The Reading Hospital and Medical Center (TRHMC), The Reading Hospital Medical Group (TRHMG), Reading Professional Services (RPS), The Highlands at Wyomissing (THAW) and Berkshire Health Partners (BHP).

**Institutional Responsibilities** means an investigator's professional responsibilities on behalf of the Institution which may include activities such as:

- Research,
- Research consultation,
- Teaching,
- Professional practice,
- Institutional committee memberships,
- Service on panels such as Institutional Review Boards or Data Safety Monitoring Boards

**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.

**Key personnel** means the project director, Principal Investigator and any other person identified as senior/key personnel by the institution. These include:

- Principal Investigators
- Project Directors



- Sub-investigators
- Study coordinators
- Data Managers
- Research assistants

**Manage** means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

**Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

**Significant Financial Interest (SFI)** means

1. A financial interest consisting of one or more of the following interests of the Investigator or Key Personnel (*and those of their spouse and dependent children*) including:
  - a) 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 the disclosure, when aggregated, exceeds **\$5,000.00**.
  - b) 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 **\$5,000.00**, or when the Investigator (*or the Investigator's spouse or dependent children*) holds any equity interest.
  - c) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such interests

For the purpose 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.

2. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities provided that this disclosure does not apply to travel that is reimbursed or 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.
3. The term Significant Financial Interest **does not** apply to the following:
  - a) Salary, royalties or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
  - b) Any ownership interest in the Institution held by the Investigator, if the Institution is a for-profit organization;



- c) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- d) 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 research institute that is affiliated with an Institution of higher education;
- e) 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 affiliated with and Institution of higher education.

## **PROCEDURE:**

### **1. Responsibilities of the IRB Office Staff**

It is the responsibility of the IRB Office Staff to:

- Be aware of and comply with federal regulations pertaining to research FCOI
- Be aware of and comply with the TRHMC Research FCOI policy
- Notify IRB members, Investigators and Key Personnel of changes to the TRHMC Research FCOI Policy
- Inform IRB members, Investigators and Key Personnel of the need to complete and/or renew FCOI education
- Maintain accurate records of IRB member, Investigator and Key Personnel FCOI education
- Solicit Financial Disclosure Forms at the time of new protocol submission and annually thereafter or when an individual requests to be added to the approved Key Personnel
- File Financial Disclosure Forms, management plans and other correspondence in the IRB Protocol File
- At the direction of the IRB Manager, draft disclosures for publicly accessible website

#### **Policy Notification:**

IRB members, Investigators and Key Personnel will be made aware of the federal regulations and TRHMC Research FCOI Policy in the following ways:

- Direct mailing of initial policy and updates as needed
- Reminder language will be included in Approval Letters
- New Protocol and Continuing Review Applications will include reminders of the need to disclose financial interests
- Policy will be included as a module of the required Human Subject Protections education

### **2. Responsibilities of the Investigator and Key Study Personnel**

It is the responsibility of the Principal Investigator to:

- Be aware of and comply with federal regulations pertaining to research FCOI
- Be aware of and comply with the TRHMC Research FCOI policy
- Ensure that all members of key personnel comply with the requirements of the policy
- Complete education as required
- Submit Financial Disclosure Forms as requested by the IRB and at the time of :
  - Initial review
  - Continuing review
  - Acquisition of a new financial interest
- Review key personnel Financial Disclosure Forms prior to submission
- Disclose COI (financial or other)
- Ensure disclosure of COI in the informed consent document

It is the responsibility of other Investigators and Key Personnel to:

- Be aware of and comply with federal regulations pertaining to research FCOI
- Be aware of and comply with the TRHMC Research FCOI policy
- Complete education as required
- Submit Financial Disclosure Forms as requested by the IRB and at the time of:
  - Initial review
  - Continuing review
  - Request to join approved personnel
  - Acquisition of a new financial interest
- Disclose COI (financial or other)

### **3. Responsibilities of the IRB Manager**

It is the responsibility of the IRB Manager to:

- Be aware of and comply with federal regulations pertaining to research FCOI
- Be aware of and comply with the TRHMC Research FCOI Policy
- Review the TRHMC Research FCOI Policy annually, document review and suggest changes as needed
- Ensure public accessibility of the policy on the TRHMC website
- Respond to written requests for copies of the policy
- Review submitted Financial Disclosure Forms to determine the presence of FI.
- In collaboration with the IRB Chair, determine if the FI represents an SFI.

- If an SFI exists determine if it represents an FCOI (could directly and significantly affect the design, conduct or reporting of the research). This may be done in collaboration with the Principal Investigator.
- Promptly notify the Chief Compliance Officer of Investigator or personnel FCOIs.
- At the direction of the Chief Compliance Officer draft correspondence, to report FCOI or update a previously submitted report, to the appropriate institutional officials, department heads, and government agencies.
- At the direction of the Chief Compliance Officer, post information about specific FCOI on the TRHMC website. This information is to be:
  - Posted within 60 days of discovery.
  - Reviewed annually,
  - Updated as necessary *and*
  - Accessible for at least 3 years after discovery.
- Monitor Investigator with FCOI management plans

#### 4. Responsibilities of Chief Compliance Officer (CCO)

It is the responsibility of the Chief Compliance Officer to:

- Review documents forwarded by the IRB Manager to confirm FCOI exists
- If the CCO agrees an FCOI exists, he/she will convene a meeting to determine the appropriate course of action. This meeting is to include the following individuals:
  - Institutional Official
  - Appropriate Department Chair
  - Chair of the Institutional Review Board
  - IRB Manager
  - Principal Investigator – if necessary

**NOTE:** For the purposes of this policy the attendees of the meeting will be referred to as the *Research Conflict of Interest Advisory Board (RCOIAB)*.

- Ensure research funds are not expended until the FCOI has been Managed or ameliorated.
- Ensure information pertaining to identified FCOIs is publicly accessible prior to expenditure of research funds.

#### 5. Responsibilities of the Research Conflict of Interest Advisory Board

It is the responsibility of the RCOIAB to:

- a) Review information pertaining to the FCOI and determine what actions, if any, are required to Manage or ameliorate the conflict.

- b) Communicate with the Institutional Review Board the need to defer approval of the proposed research until such time as the management plan is determined.
- c) Determine an appropriate management plan. Examples of appropriate actions to resolve FCOI include but are not limited to the following:
- Disclosure of the SFI in the consent document, publications or presentations,
  - Monitoring of research by independent reviewers,
  - Modification of the research plan,
  - Selection of a non-conflicted PI,
  - Disqualification from participation in all or a portion of the research which may include:
    - Subject recruitment and consent
    - Subjective assessments of eligibility criteria and/or intervention outcomes
  - Reduction or elimination of the financial interest
  - Severance of relationships that create actual or potential conflicts,
  - Participation of one or more non-conflicted persons in the evaluation of the research data and/or preparation of manuscripts
- d) Review SFI that were not reported in a timely manner by the Investigator or, for whatever reason, were not previously reviewed by the Institution during the conduct of the research to determine if the SFI is an FCOI.

Such reviews are to be completed within 60 days of discovery.

- e) Perform a complete retrospective review of the Investigator's activities in the research project to determine whether any portion of the research was biased in design, conduct or reporting. Instances where this would be necessary include:
- Failure of the Investigator to disclose an SFI in a timely manner
  - Failure of the Institution to review and/or Manage an FCOI in a timely manner
  - Failure of an Investigator to comply with an FCOI management plan.

Such reviews are to be completed within 120 days of discovery of the above

- f) Document the retrospective review process. Documentation is to include:
- Project number and title
  - Name of Principal Investigator and study contact
  - Name of the individual with the FCOI
  - Name of the entity with which the individual has an FCOI
  - Reasons for the retrospective review
  - Detailed methodology of the review
  - Findings and conclusions of the review

- g) Recommend and initiate actions leading to sanctions for non-compliance with this policy or the approved management plan. Sanctions may be applied in the same way as for non-compliance with any other TRHMC policy including:
- a letter of reprimand,
  - special monitoring of future research projects,
  - removal from a particular project,
  - probation of research privileges,
  - suspension of research privileges,
  - termination of research privileges
- h) In instances where it is determined that a research project was designed, conducted or reported by an Investigator with an FCOI that was not Managed or reported by the Institution the Investigator will be required to:
- Disclose the FCOI in each publication or presentation of the research and
  - Request an addendum to previously published presentations.

## **6. Reporting requirements**

When necessary, and at the direction of the Chief Compliance Officer, the IRB Manager will draft correspondence to report FCOI to the appropriate institutional officials, department heads and government agencies. The documentation is to include:

- Project number and title
- Name of the Principal Investigator
- Name of the individual with the FCOI
- Name of the entity with which the individual has an FCOI
- Nature of the financial interest (equity, consulting fee, travel reimbursement, honorarium)
- Value of the financial interest (dollar ranges are permissible) or a statement that the value cannot be readily determined
- Description of how the financial interest relates to and conflicts with the research
- Description of the management plan including:
  - Role and principal duties of the conflicted individual
  - Conditions of the management plan
  - How the management plan is designed to safeguard objectivity in the research
  - Confirmation of the Investigator's agreement to the management plan
  - How the management plan will be monitored
  - Any other relevant information

Reports of FCOI are to be made:

- Prior to the expenditure of funds
- Within 60 days of identification for an Investigator or who is newly participating in the research
- Within 60 days for new or newly identified FCOI for existing Investigators
- At least annually
- Following retrospective review to update a previously submitted report

When necessary, and at the direction of the Chief Compliance Officer, the IRB Manager will draft correspondence to report bias found with the design, conduct or reporting of research. The report is to include all of the reporting elements listed above and a Mitigation Report.

When necessary, and at the direction of the Chief Compliance Officer, the IRB Manager will draft correspondence to report failure of an Investigator to comply with the TRHMC FCOI policy, and approved FCOI management plan or if a management plan appears to have biased the design, conduct or reporting of research. The report is to include the Corrective Action Plan.

## **7. Public Disclosure**

When necessary, and at the direction of the Chief Compliance Officer, the IRB Manager will make available, via the TRHMC website, the following information pertaining to an identified FCOI:

- The title and TRHMC number of the research
- The name of the individual with the FCOI
- The individual's role in the research
- The name of the entity in which the individual has an FCOI
- Nature of the financial interest (equity, consulting fee, travel reimbursement, honorarium)
- Value of the financial interest (dollar ranges are permissible) or a statement that the value cannot be readily determined
- The date of the posting and/or update of posting

Public disclosures are to be updated:

- At least annually
- Within 60 days of discovery of a FCOI

## **8. Subrecipient Requirements**

In the event that the TRHMC enters into an agreement with an outside entity (e.g. subcontractors) to assist with the conduct of a research project, the written agreement shall include:

- A statement as to whether the FCOI policy of TRHMC or the outside entity will be followed
- Certification that the outside entity complies with the requirements of all applicable laws and regulations pertaining to FCOI



- A requirement for the outside entity to report identified FCOI in such a manner as to allow TRHMC time to promptly report to appropriate institutional officials, department heads and government agencies with the appropriate time periods specified
- If applicable, a requirement that the outside entity solicit and review disclosures from their personnel in such a manner as to allow TRHMC to identify, Manage and report FCOI to appropriate institutional officials, department heads and government agencies.

## **9. Records Maintenance**

All records pertaining to the FCOI will be maintained in the IRB Protocol Files. This includes but is not limited to:

- Financial Disclosure Forms, including the TRHMC IRB's review of and response to such disclosures
- Reports of FCOIs
- FCOI management plans
- All correspondence relating to the FCOI
- Subrecipient contracts and certifications

The records will be maintained for a period of not less than 3 years from the date of submission of the final expenditures report or final payment, or where applicable, for such other time period specified in the regulations.

## **EDUCATION AND TRAINING:**

All Investigators, sub-Investigators, Key Personnel and others involved in the conduct of research at TRHMC must complete FCOI training at the following times:

- Prior to engaging in research
- Every 2 years thereafter
- Immediately if:
  - The TRHMC IRB revises its FCOI policy in a way that affects the requirements of Investigators, sub-Investigators, Key Personnel and others involved in the conduct of research
  - An Investigator is new to the Institution
  - An Investigator is not in compliance with the FCOI policy or management plan

## **REFERENCES:**

- Code of Federal Regulations, Title 42, Part 50
- Code of Federal Regulations, Title 45, Part 94
- The Reading Hospital and Medical Center Standards of Conduct
- The Reading Hospital and Medical Center Administrative Policy and Procedure 10.2 "Conflict of Interest"



**COMMITTEE/COUNCIL APPROVALS:**

The Reading Hospital and Medical Center Institutional Review Board

**CANCELLATION:**

This policy supersedes all previous policies, memoranda, and/or other communications pertaining to this policy.