CONFLICT OF INTEREST GUIDE

V2
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This handbook is written to assist Baker IDI staff in understanding and complying with the Baker IDI Conflict of Interest Policy. The policy has been developed to assist individual staff members and the Institute navigate the often complex environment where outside or third party interests intersect with the day to day activities of the staff and the Institute.

The aim of the Policy on Conflict of Interest is to protect the integrity of professional judgment and to preserve public trust rather than create an environment of mistrust and bureaucratic meddling.

1. STAKEHOLDERS
Baker IDI and its researchers obtain funding from a variety of sources, including government, private donors and industry partners. Each of these has expectations that they impose on the Institute and individual.

2. INDIVIDUAL CONFLICTS OF INTEREST
It is not possible to identify all potential conflicts of interest that may arise for any given staff member. If a staff member is in doubt whether a conflict of interest exists they should raise the matter with their supervisor. A key question in determining whether a particular situation may represent a perceived, actual or potential conflict of interest is: would relevant others [my supervisor, my patients, professional colleagues or the general public] have confidence my decision making if they knew I was in this situation?

The perception that a conflict of interest may exist can be as significant as an actual conflict, as it raises concerns about the integrity of the individual and/or Baker IDI and on this basis a perceived conflict of interest should be managed as if a conflict actually existed.

Disclosure is a key component in the management of conflicts of interest by the Institute and staff should consider whether their own, or their family member’s, activities in the following categories may give rise to or constitute a conflict of interest1:

- research grants and contracts
- consulting agreements
- participation as paid speakers at an event
- honoraria
- royalties and licensing fees
- stock, options and other ownership
- position within a company including, governing boards, advisory boards, company employee (part or full time)
- authorship of publication prepared by an industry partner
- expert witness
- other payments or financial relationships
- gifts (including travel and entertainment) from companies or donors

Set out below are a number of scenario’s that may arise for Baker IDI staff that represent actual or potential conflicts of interest. This list is not exhaustive and should only be used as a guide. In addition, the management plans are indicative only as the appropriate response

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1 Adapted from Conflict of Interest in Medical Research, Education and Practice Edited by B Lo and M Field. Institute of Medicine, The National Academic Press 2009 p3-25 Table 3-3
will depend on individual circumstances. Actual management plans must be developed with the CI Officer.

A. **Travel and accommodation**

**Scenario:** It is common for drug companies to offer to pay for a staff member’s travel and other expenses to attend scientific or clinical meetings and to present a seminar.

**Concern:** As significant funds are being expended for their benefit the staff member may feel some pressure to speak favourably about the company’s drug. Even if there is clear scientific evidence that the company’s drug is beneficial there may be a public perception that the staff member’s views are coloured by the financial support they have received.

**Management:** If travel to the conference or event is on the whole beneficial the staff member may attend on the basis that: 1) they have disclosed the potential conflict of interest before departure; 2) their presentation includes a disclaimer that acknowledges the source of financial support; 3) care is taken to ensure that the presentation and the views presented are well balanced and based on scientific evidence.

B. **Gifts & Bequests**

**Scenario:** A staff member develops a close relationship with a donor. Regular contact, coupled with home visits, can lead to close personal relationships which often transcend professional boundaries and develop into friendships. This can often occur as part of the major gift or bequest solicitation process.

**Concern:** While it is not unusual that a personal relationship would develop between the staff member and the donor over time it is possible that the staff member could be perceived to have taken advantage of the donor in the course of their employment for personal benefit. This may occur because the staff member is the recipient of personal gifts which may range from small tokenistic trinkets through to valuable presents such as jewellery or large cash gifts. The gifts may be received by staff in the donor’s lifetime or via a bequest when they have passed on. As the personal relationship has been progressed via a professional association the acceptance of the gift may present a conflict of interest. The Institute recognises that there is a fine line between the personal and professional relationships and that in most instances staff do not actively seek to benefit from their relationship with a donor. A strong personal rapport is often necessary in order to secure a major gift or bequest, and a staff member should not be disadvantaged for doing their job effectively providing they comply with the policy outlined and actively seek to avoid opportunities for personal benefit.

**Management:** As a general rule, staff should report receipt of gifts or benefits valued in excess of $50. The staff member should notify their supervisor and the CI Officer as soon as they are aware that they may receive a personal benefit from their relationship with a donor. If it was determined that the staff member had taken advantage of the donor the staff member would be removed from the activity immediately and sanctioned. If it was determined that the staff member had not acted improperly a management plan would be agreed between the individual and the Institution: some management options include the individual retaining the gift, donating the gift to the Institute or returning the gift to the donor.

C. **Advertorials**

**Scenario:** A staff member is asked by a pharmaceutical company to develop a paper on the use of a particular drug for a “journal” which is designed to look like an independent journal or media product but is actually a vehicle for brand promotion.

**Concern:** This type of publication is considered an advertorial [an advertising message, product promotion or endorsement presented in the format of objective opinion or editorial]
by commercial arrangement] and can mislead the intended audience who may believe that the information contained within is unbiased.

**Management:** Baker IDI has publically stated that it will not participate in advertorials. If the activity is not considered an advertorial and involvement may, on the whole, be considered beneficial the staff member may get involved on the basis that: 1) they have disclosed the potential competing interest; 2) their presentation includes a disclaimer that acknowledges the source of financial support; 3) care is taken to ensure that the presentation and the views presented are well balanced and based on scientific evidence.

**D. Procurement**

**Scenario:** A staff member wishes to contract an outside company to develop a custom database to manage contact information. A company run by the staff member’s husband is selected to provide the service.

**Concern:** Selection of the service provider has been influenced by the close personal relationship and personal benefit.

**Management:** An alternative service provider should be identified. If that company is the only provider the staff member should remove themselves from aspects of the project.

**E. Clinical Practice Guidelines**

**Scenario:** A staff member is asked to be on a drug company sponsored panel for development of a clinical practice guideline for treatment of a specific condition. The staff member has also received payment from the drug company to provide advice on the clinical development of a drug that is useful in treatment of the condition.

**Concern:** Given the importance of clinical practice guidelines in assisting healthcare professionals make treatment decisions it is important that guideline development is free from industry influence.

**Management:** The individual must disclose to the chair of the panel their conflicts of interest and may be asked to excuse themselves from the panel. Participation on the panel should be reported to CI Officer.

**F. Sponsored Research and Clinical Trials**

**Scenario:** A large pharmaceutical company has approached a staff member to develop the protocol for and run a clinical trial. The funds generated from the trial will give the staff member’s lab a significant boost and the associated publications will improve the professional standing of the individual. Negative results may terminate the relationship prematurely.

**Concern:** Systematic reviews have provided substantial evidence that clinical trials with industry ties are more likely to have results that favour industry. While there is no clear evidence as to why this is the case there is a real risk of damage to public confidence in these types of activities.

While there may be no direct financial benefit to an individual in this scenario, the professional benefit is real and is likely to be a driver in decision making.

**Management:** It is important that the staff member involves other personnel in the Institute (without a vested interest in the outcome) in the negotiation of appropriate contractual arrangements that include requirements for publication in a timely manner and limit undue influence on the reporting of results. Ongoing management of the project should also include unrelated individuals.
**Scenario:** A staff member has agreed to undertake a preclinical study for a company in which he holds equity.

**Concern:** The staff member’s personal gain is linked to the success of the company through his shareholding. This may lead to intentional, or unintentional, bias in interpretation of experimental findings in favour of the company. Furthermore the staff member may be influenced or expected to undertake the studies at below cost to support the ongoing viability of the company.

**Management:** The staff member is required to disclose to the Institute his interest in the company and may either be required to forgo involvement in the study or develop a clear management plan to ensure transparency in decision making and interpretation of results by involving another staff member who has no vested interest. Negotiation of appropriate costings and contractual arrangements should be undertaken by alternate personnel who have no vested interest in the outcome.

**G. Start-up Company**

**Scenario:** The Institute has established a start up company to commercialise IP developed by a staff member. In accordance with the Institute IP Policy the staff member will receive equity in the start-up and has requested that she be on the board of the company. Ongoing development of the product being commercialised will need further refinement and this activity is consistent with the ongoing activities within the staff member’s laboratory.

**Concern:** For young technology companies it is essential that the inventor is engaged with and supportive of the new company’s activities. However, while the staff member may gain a personal benefit from the success of the company there is a concern that their decision making, with respect to research findings and reporting of results, will be influenced to maximise that benefit. In addition, the multiple roles described for the staff member in this scenario will lead to real questions regarding “which hat” she is wearing at any given time and in who’s interests decisions are being made: whether the Institute, the company or the individual.

**Management:** While the Institute or the CI Officer may be aware of the conflicts of interest it is a requirement that the staff member submit a disclosure form. A management plan with respect to the staff member’s conflicts of interest will need to be developed to take into account the specific circumstances however in principle it would be appropriate that: 1) the staff member is not appointed to the board of the company but rather is represented on a company scientific advisory board; 2) a clear management plan for ongoing research should be developed to ensure transparency in decision making and interpretation of results by involving another staff member who has no vested interest; and 3) appropriate agreements should be developed between the Institute and the start-up company to cover any ongoing sponsored research and ensure that there is no inadvertent leakage of IP from the staff member’s laboratory to the company.

**H. Close personal relationships**

**Scenario:** A staff member has begun dating one of their subordinates. The subordinate is up for an incremental increase in their classification, which will also result in a pay increase. HR has requested that the staff member advise them if the increment is to be approved.

**Concern:** Due to the personal relationship between the staff member and their subordinate there may be the perception that the staff member will not make an objective decision as to whether the increment is warranted.

**Management:** The personal relationship must be disclosed to the Institute and the staff member removed from any decision making with respect to the subordinates performance.
I. Time

Scenario: A busy, successful staff member has been asked to undertake a teaching role at a university. The staff member supervises a number of graduate and post graduate students and holds the maximal number of grants.

Concern: Baker IDI staff owe their primary professional allegiance to the Institute, and their primary commitment of time and intellectual energies should be to the education and research of Baker IDI. The balance of specific responsibilities within the Institute and the scope for outside activities will differ for individuals and should be based on agreement between the staff member and their supervisor.

Balancing Institute responsibilities with external activities - such as consulting, public service or pro bono work - can result in conflicts regarding allocation of time and energies. Conflicts of commitment usually involve issues of time allocation and in extreme cases both individual performance and any students will suffer.

Management: Paid outside work activities must be disclosed to the Institute in accordance with the Paid Outside Work Policy. While Baker IDI has not set limits on the amount of outside work that can be conducted individual staff members should discuss the extent of their activities with their supervisors to ensure that a fair balance is being achieved and performance or students are not being affected.

3. Institutional Conflicts of Interest

A. Gifts & Donations

Scenario: A large medical device company has agreed to donate to the Institute a significant gift.

Concern: The link to the company may raise concern by the public about the influence of the company on the Institution’s scientific independence.

Management: Any transactions of this kind would need to be reported to the CI Officer prior to sign off and reviewed by the Commercial Issues Committee and/ or the Conflict of Interest Review Committee. The contractual arrangements for the gift would be required to stipulate that the company gift was not tied to any expectations with respect to the Institute’s research activities.

B. Start-up Companies

Scenario: The Institute has established a start up company to commercialise IP developed by a staff member. The Institute retains equity in the start up and considers investing cash to support the company in its early stages. Without the investment the company will struggle to exist.

Concern: Given the complexities of the relationships in this scenario there are a number of areas where actual or perceived conflicts of interest may result in biased decision making:

- company success may realise a financial benefit for the Institute;
- successful commercialisation activities may result in increased funding from government agencies;
- company success will support achievement of performance metrics by the Commercialisation team
- inventors may realise a personal financial benefit from company success.

Management: Any transactions of this kind would need to be reported to the CI Officer prior to sign off and recommendations reviewed by the Commercial Issues Committee and the Conflict of Interest Review Committee.
C. Medical Education Programs

Scenario: The Institute runs diabetes educational programs for physicians to assist them to stay current with best practice treatment approaches. Sponsorship is obtained to defray the cost of the workshops from pharmaceutical companies that market diabetes drugs. Without the support the

Concern: Support by the pharmaceutical company will lead to bias in the information that is provided to participants.

Management: The sponsorship should be disclosed to the CI Officer and to potential or actual participants. Any materials provided to the participants should include a notice of the sponsorship and content should be prepared with particular care to eliminate any real or perceived bias.

4. Public Disclosure of Conflicts of Interest

Baker IDI’s Institutional values state openness, honesty and best practice as clear commitments in our daily dealings. Public disclosure of conflicts of interest by Baker IDI demonstrates to stakeholders (including government and the public) that Baker IDI is acting in line with its stated values and that the Institutions interactions with industry do not affect the integrity and objectivity of the research outputs we generate.

A recent report by the AAMC-AAU Advisory Committee on Financial Conflicts of Interest In Human Subjects Research draws a separation between “reporting” conflicts of interest and “disclosure” of conflicts of interest. Reporting means provision of the relevant information to the authorised Institutional officials in accordance with Institutional policies and disclosure means release of relevant information about significant conflicts to parties outside the Institution’s COI review and management processes e.g. to research subjects, journal editors or prior to presentations. The report goes on to recommend that:

"Disclosure should be extended both in scope and in audience, to assure full awareness of potential conflicts and Institutional efforts to address them. Specifically, an Institution’s policy should require that, with respect to any human subjects research project, disclosure of the existence of all financial interests of a covered individual that are related to that human subjects research project as follows: to state and federal officials, as required by statute or regulation; to research funders or sponsors; to all of the researchers, students, and trainees at the Institution working with the covered individual on the research project in question; to the editors of any publication to which a covered individual submits a manuscript concerning the research; in any substantive public communication of the research results, whether oral or written; and to the human subjects of the research project, as specified below. Substantive public communication of the research results includes presentations to or interchanges with the media, and applies whether the audience is lay persons or other professionals."

Outlined below are some suggestions as to how staff members should acknowledge their conflicts of interest to the public and their peers.

A. Participant Information

Kevin Weinfurt et al have developed model language to assist researchers with competing interest disclosure for participant information statements. A number of scenario’s are

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2. "Developing Model Language for Disclosing Financial Interests to"
covered in their paper including specific disclosures where the researcher received salary support, per capita payments, and the researcher holding a patent, the Institution holding a patent, the researcher owning equity and the Institution owning equity. Included below is the general disclosure, adapted for Baker IDI, which they have proposed and the specific ones can be found at [http://opa.faseb.org/pages/advocacy/coi/Disclosure_to_patients.pdf](http://opa.faseb.org/pages/advocacy/coi/Disclosure_to_patients.pdf)

**Generic Disclosure**

The person leading this medical research study might benefit financially from this study. The HRECS and the Conflict of Interest Review Committee at Baker IDI have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

B. Publications and Seminars

In 2008, the International Committee of Medical Journal Editors proposed “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” however there is significant variation in how individual journals require and deal with conflict of interest disclosures.

Below is sample text provided by Wiley-Blackwell Publishing:

[Name of individual] has received fees for serving as a speaker, a consultant and an advisory board member for [names of organizations], and has received research funding from [names of organization]. [Name of individual] is an employee of [Name of organization]. [Name of individual] owns stocks and shares in [name of organization]. [Name of individual] owns patent [patent identification and brief description].

A similar approach should be adapted for seminars and presentations.

C. Education Sessions

In general, industry provides significant support for accredited continuing medical education and the Baker IDI education programs are often supported from industry funded educational grants. Studies in the United States on bias as a result of industry support for medical education, has lead to close scrutiny of the practice and a call for greater transparency.

All Baker IDI education sessions should include a disclosure statement to make participants aware of any industry support that has been received for that course.

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Potential Clinical Research Participants” IRB Ethics & Human Research 2007: 29(1) p1


4 [http://www.icmje.org/#conflicts](http://www.icmje.org/#conflicts)