

**Baker Heart and Diabetes Institute**

ACN 131 762 948

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# Conflicts of interest policy

For the disclosure and management of personal  
interests and private outside work

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## Section 1: Introduction

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The Baker Institute's mission is to reduce death and disability from cardiovascular disease, diabetes and other health disorders, through research, clinical care, education and advocacy. Fostering relationships with the partners in both the public and commercial sectors is crucial to achieving our objective.

While there are significant benefits of research partnerships, it is essential to preserve the confidence of government and commercial partners, donors and members of the public in the trustworthiness of the Baker Institute's Personnel and their dedication to excellence and integrity in the scientific enterprise. Crucial to this is the establishment of a process of identifying, disclosing and managing any potential sources of conflict that may, or may be perceived to, create bias in the research being performed at the Baker Institute.

While the primary duty of all Staff is to the Baker Institute, the institute also recognises the value, to both the institute and the community, for Staff members to have the opportunity to undertake an amount of private outside work, especially where this can:

- (a) Improve the quality of teaching and research;
- (b) Establish or continue good relations between the Baker Institute and the community;
- (c) Maintain professional skills and standing; or
- (d) Provide the benefits of academic research and professional expertise to the community.

### 1.1 Purpose

- (a) To facilitate research collaborations and consultancy activities.
- (b) To provide a procedure for disclosure of personal interests that is based on the guiding principles of objectivity, transparency and accountability.
- (c) To provide a procedure for the identification and management of potential, perceived or actual conflicts of interest.

### 1.2 Scope

This Policy applies to all Personnel including members of the Board of the Baker Institute.

For the purposes of this Policy, unless otherwise stated:

**Affiliates** means clinical title holders, honorary appointees, visiting scientists, consultants and contractors to the Baker Institute, volunteers, visitors and any persons appointed or engaged by the Baker Institute to perform duties or functions on its behalf, or who use Baker Institute Resources, including those funded by external sponsors.

**Staff** means employees of the Baker Institute.

**Resources** means any form of funds, facilities, services, or resources, including Background IP, equipment, consumables and human resources of, or awarded or donated to, the Baker Institute.

**Personnel** means Staff, Affiliates and Students.

**Student** means under-graduate and post-graduate students of a university or other academic institution including but not limited to honours, masters and PhD students who are conducting research at the Baker Institute as part of their degree.

**Close Associates** means family, relatives, friends, business associates and household members.

**Conflict of Interest** includes both Individual Conflict of Interest and Institutional Conflict of Interest.

An **Individual Conflict of Interest** exists where there may be a divergence between the personal interests of an individual and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests.

An **Institutional Conflict of Interest** can arise where the interests of the institution itself or any of its senior management or board, appear to affect institutional activities. Such conflicts may result in choices or actions that are incongruent with the missions, obligations, or the values of the Baker Institute.

The perception of a Conflict of Interest can be as significant as an actual conflict as it raises concerns about the integrity of the individual or the Baker Institute and on this basis a perceived Conflict of Interest should be managed as if a conflict actually existed.

## 1.3 Guiding principles

The Baker Institute has established a set of guiding principles to assist the institute as a whole and individual Personnel in disclosing and managing potential, perceived or actual Conflicts of Interest.

### 3.1 Objectivity

Objectivity is maintained by ensuring integrity in manner in which we undertake our business activities. This requires conducting and publishing and reporting on activities in a manner that ensure they are uninfluenced by Conflicts of Interest.

### 3.2 Accountability

Accountability implies that there is an obligation to take responsibility for one's actions in accordance with agreed expectations. Acceptance of funds from all sources carries with it an obligation to be accountable both to the funding body and the public.

### 3.3 Transparency

Subject to existing confidentiality obligations, transparency should be upheld both internally and externally, in all our dealings to ensure public confidence in institutional and individual Personnel decisions regarding our activities.

## Section 2: Policy

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### 2.1 Disclosure and management of personal interests

Personnel have obligations of good faith, trust and confidence to the Baker Institute.

All Personnel must **not**:

- (a) allow an actual, perceived or potential Conflict of Interest, or
- (b) allow duties to an external entity come into actual, perceived or potential conflict with duties to the Baker Institute, unless in accordance with the procedure detailed in this Policy.

The obligation to avoid Conflicts of Interest applies across all Baker Institute activities, including research, intellectual property, commercialisation and employment.

Personal interests must be disclosed in accordance with Section 3 regardless of whether there is a Conflict of Interest. In addition, all Personnel should consider potential Institutional Conflicts of Interest that may arise as a result of their specific activities and should make these known to the Conflict of Interest Officer.

### 2.2 Private outside work

Staff's primary commitment of time and intellectual effort should be directed to research, or professional and operational services to support research, conducted for the Baker Institute.

However, subject to the provisions of this Policy, Staff may undertake certain activities as private outside work if:

- (a) the work is of a character that will not damage the good relationship between the Baker Institute and the community
- (b) the nature of the work does not constitute an actual, perceived or potential Conflict of Interest (or has been disclosed and managed in accordance with the procedure detailed in this Policy), and
- (c) the outside activities do not interfere with their professional duties on behalf of the Baker Institute.

Research Staff can utilise a maximum of 52 days per year for full time private outside work (or pro-rata for a part time Staff). Such a limit recognises that some of this time is actually taken from the researcher's time required to discharge duties according to employment with the Baker Institute. Therefore, it is critical to guarantee that responsibilities and obligations to the Baker Institute take priority and researchers must discuss and obtain approval of their Domain Head and Laboratory Head (even where the commitment is less than the maximum number of 52 days per year) before engaging in private outside work.

Administration Staff (including in an education role) are required to work for the Baker Institute in accordance with the ordinary hours of work set out in their contract of employment. Private outside work beyond these hours may be undertaken provided it does not compromise the administration Staff member's commitment to the Baker Institute. In exceptional circumstances, private outside work within normal working hours may be approved. However, administration Staff **must not** undertake private outside work where:

- (a) the nature of the work includes the application for personal profit of specialist skills and knowledge developed and owned by the Baker Institute, or
- (b) use of Baker Institute equipment or services is contemplated.

If there is doubt about whether a particular activity is part of normal institute duties, the Staff member will clarify the matter in consultation with their Domain Head, Deputy Director Administration and the Conflict of Interest Officer.

In the course of consulting or research, Staff may provide a professional evaluation of products or services, based on evidence. However, publicly advertised endorsement of commercial products or services is not, in general, consistent with the independence and objectivity expected of Staff and may not be given in the name of the Baker Institute.

All Staff must disclose their private outside work in accordance with Section 3.

Where the activities undertaken are within the Baker Institute's areas of interest, relevance or expertise, institute-sponsored outside work is preferred.

Institute-sponsored outside work is preferred because it:

- (a) Ensures that there are contractual arrangements in place to deal with the private interests of Staff and the interests of the Baker Institute.
- (b) Ensures that contractual arrangements clearly and unambiguously address issues of confidential information, intellectual property and unintended reach through.
- (c) Enables additional revenue to be generated for discretionary use by Staff at the Domain or Laboratory level.
- (d) Ensures that projects are evaluated for reporting as research income with financial benefits to the Staff member and recognition for the Baker Institute, raising the profile of interactions with industry, government and the community.

Advantages for Staff of undertaking institute-sponsored outside work rather than private outside work include:

- (a) There is no requirement to disclose institute-sponsored outside work using the procedure described in Section 3.
- (b) Baker Institute, not the individual, is liable for performance and compliance.
- (c) Baker Institute name, address and affiliations can be used, including in press releases and other promotional activities (as appropriate).
- (d) Use of Baker Institute facilities and resources, with appropriate cost recovery from the external client.
- (e) Use of Baker Institute title and Baker Institute letterhead, stationary, postal address, phone number, and e-mail address.
- (f) Access to Baker Institute administrative, legal, financial and professional support needed to undertake the activity, including contract development, invoicing, collection and remuneration of the Staff member by the Baker Institute.
- (g) Coverage by professional and public liability insurances maintained by the Baker Institute.

Staff may only receive the income from institute-sponsored outside work by way of Payroll where Finance confirms that their Cost Centre is not in deficit.

Any negotiations in relation to institute-sponsored outside work must involve both the Business Development and Commercialisation, and Legal Services teams.

## Section 3: Procedures: disclosure of personal interest or outside work

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### 3.1 Full disclosure

All Personnel must make full, current and accurate disclosure of any personal interests or private outside work, including relevant interests of any Close Associate who has a direct or indirect interest and may be in a position to decide or influence the Personnel member's objectivity.

### 3.2 When to disclose

Personnel (not including members of the Board<sup>1</sup>) are required to submit an online Disclosure Form (or any other form reasonably requested by the Conflict of Interest Officer):

- (a) On commencement of employment.
- (b) Annually on a designated date (to be advised) for all persons covered in this Policy even if there is nothing to declare.
- (c) Upon recognition of a new personal interest.
- (d) Prior to commencement of new private outside work.
- (e) If there has been any material change to the nature or quantum of a personal interest, or
- (f) If there has been any material change to the nature of the private outside work, the amount of time- release required, insurance or indemnity arrangements.

Personnel must make disclosures and amendments promptly.

Disclosure must be made **immediately** if Personnel become aware that there may be an actual, perceived or potential Conflict of Interest.

Disclosure only occurs on submission of the Disclosure Form. The fact that a personal interest or private outside work is known by others or considered public knowledge does not constitute a disclosure with respect to this Policy.

### 3.3 Information to be disclosed

The Disclosure Form includes sufficient information reasonably required to enable a decision to be made regarding management of the situation, including:

- (a) The type and details (including if applicable, monetary value) of personal interest (e.g. financial interest, professional affiliation, conflicting duties, gifts or other benefit).
- (b) The nature of the private outside work activity.
- (c) A description of all parties involved.

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<sup>1</sup> A board-specific disclosure form applies for board members.



(d) Circumstances giving rise to concerns.

(e) Any other relevant information.

Financial interests involve potential financial gain, including shares, share options or similar ownership interest. It may be an interest in a company asset or intellectual property such as inventions, discoveries, patents, copyrights, and licenses as a result of research. It may be that you receive or have an expectation to receive income, for example, a consulting fee, salary, allowance, dividend, royalty derived from the licensing of technology, capital gain, or some other form of compensation.

However, a financial interest does **not** include:

- diversified financial holdings that are not directly controlled by Personnel individually (e.g. mutual funds, blind trusts, superannuation funds or other retirement accounts), or
- financial interests held by a Close Associate but not known to Personnel (except for interests held by a spouse, domestic partner or dependent children, which are deemed to be known to Personnel).

Professional affiliations may include executive positions, serving on a board of directors/trustees, membership of a committee, scientific advisory group or selection panel.

Gifts include cash, electronic devices, services, promotional items, souvenirs, and hospitality (such as meals and tickets to sporting events or other forms of entertainment).

If further detail is requested by the Conflict of Interest Officer, that information must be provided.

If the Conflict of Interest Officer is concerned that there may be a potential or actual competing interest that Personnel have not disclosed, the Conflict of Interest Officer has the authority to request that Personnel submit a Disclosure Form with respect to the matter.

### **3.4 Confidentiality and public disclosure**

The confidentiality of disclosures will be respected; the information will only be known within the Baker Institute by those with a need to know. The persons to whom the disclosure has been made must keep a written or electronic record of the disclosure and all subsequent related actions and decisions.

In some situations disclosure to other individuals or entities may be necessary in order to appropriately manage the Conflict of Interest. The Baker Institute reserves the right to make such a disclosure if the Conflict of Interest Officer deems it necessary, however the Conflict of Interest Officer will discuss the matter with you prior to that disclosure.

To facilitate transparency to its stakeholders the Baker Institute will maintain a public website that:

- (a) identifies the entities the Baker Institute engages or is engaged by, and
- (b) contains a public link to this Policy.

### **3.5 Gift or Loan of equipment, medicines or other materials**

Any gift or loan accepted by Personnel because of their work at the Baker Institute becomes the property of the Baker Institute, unless there are Baker Institute policies to the contrary.

## Section 4: Procedure: identifying, evaluating and managing conflicts of interest

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The Institute Director has institutional oversight with respect to the reporting and management of institutional and individual conflicts of interest.

The Conflict of Interest Officer manages the day-to-day identification and management of Conflicts of Interest, including management of the Baker Institute's Conflict of Interest Register. The Conflict of Interest Officer may be assisted in these responsibilities by the Research Conduct Officer.

### 4.1 Identifying conflicts of interest

The Conflict of Interest Officer will initially determine in confidence whether the declared personal interest is "significant", that is, may compromise, or have the appearance of compromising, professional judgment and integrity.

A Conflict of Interest can arise when Personnel (or their Close Associates) have a significant interest in a company that:

- (a) funds the individual's research in whole or in part, whether through a research agreement, gift, or other arrangement
- (b) supplies drugs, devices or other goods that are the subject of their research, or services or other deliverables in connection with the research, pursuant to a material transfer agreement, a research agreement or otherwise
- (c) sponsors a clinical trial for drugs, devices or other goods
- (d) owns, licenses or has any other contractual interest in a technology being investigated in such research, or
- (e) acts for, or on behalf of, another company engaged in activities (a) to (d).

A **significant interest** is:

- A salary or other income, whether for consulting, lecturing, travel, service on an advisory board or for any other purpose paid by such company that in the aggregate has in the prior twelve months exceeded the Minimum Threshold or is expected to exceed such amount in the next twelve months.
- For a publicly held company, an equity interest that exceeds the Minimum Threshold, or represents 5% or more ownership in the company.
- For a privately held Affected Company, any equity interest in the company, regardless of the amount.
- Royalty payments, including those received under a Baker Institute agreement, that in the aggregate have in the prior twelve months exceeded the Minimum Threshold or are expected to exceed such amount in the next twelve months.
- Service as an officer, manager, member of a board of directors, or in any other fiduciary or managerial role for such a company, whether or not remunerated.
- Any intellectual property or other property right that would reasonably appear to be affected by the research at issue.

- Any financial or equity interest with any company that owns or has licensed or has rights to licence the product or novel treatment being evaluated in the research that exceeds the Minimum Threshold.
- Service in an executive position in any company that owns or has licensed or has rights to licence the product or novel treatment being evaluated in the clinical research at issue.
- Service as a board member of any company that owns or has licensed or has rights to licence the product or novel treatment being evaluated in the clinical research at issue.

The **Minimum Threshold** permits Personnel to:

- Receive up to AU\$10,000 annually from the company.
- Have an equity interest of 5% or less in a public company limited by shares, so long as the equity was not given in connection with the research at issue.
- Have an equity interest in company (other than a public company limited by shares) provided any such equity is disclosed, or
- Receive royalties under the Baker Institute's Intellectual Property Policy.

Such permission is subject to the disclosure of personal interests that Close Associates may have that in aggregate reach the Minimum Threshold.

Where a funding body has different rules on a minimum threshold for disclosure, those rules take precedence.

## 4.2 Evaluating conflicts of interest

If deemed to be a significant interest, the Conflict of Interest Officer must report to and discuss the issue with the Institute Director in order to formulate the Conflict of Interest Management Plan. If the Conflict of Interest Officer deems that there is no significant issue, but that management beyond disclosure is required, an appropriate Conflict of Interest Management Plan will be developed.

Where a matter is unresolved, or there is disagreement with respect to an appropriate procedure, the matter will be referred to the Institute Director for a final decision.

Throughout the period where the Conflict of Interest is under review, normally 30 working days, Staff members must not commence work on the project at issue or cease involvement in the project where possible.

Factors that will be taken into account when determining whether a Conflict of Interest exists include, but are not limited to:

- (a) The nature of the personal interest.
- (b) The likelihood of real interests actually coming into conflict.
- (c) The likelihood of Conflict of Interest being perceived.
- (d) The potential impact of Conflict of Interest on human subjects.

In the event that the Conflict of Interest Officer has an actual, perceived or potential Conflict of Interest in the respect of the Personnel member or research they are reviewing, the matter will be referred to the Institute Director, and the Conflict of Interest Officer shall:

- (a) be excluded from involvement in the decision making process

- (b) leave the meeting during the discussions (the minutes must document the fact that the Conflict of Interest Officer left the meeting).

In the event that the Institute Director has an actual, perceived or potential Conflict of Interest in the respect of the Personnel member or research they are reviewing, the matter will be referred to the Board.

### **4.3 Conflict of Interest Management Plan**

Where the Conflict of Interest Officer or Institute Director makes a determination that it is possible to manage a Conflict of Interest, and if a management plan is appropriate, the Conflict of Interest Officer or Institute Director (as applicable), with the assistance of the Personnel member involved, will develop a Conflict of Interest Management Plan.

A **Conflict of Interest Management Plan** will provide for, amongst other things:

- (a) The circumstances in which the Conflict of Interest will be further disclosed.
- (b) The persons to whom the disclosure of a Conflict of Interest be further disclosed.
- (c) The recommendations and actions that must be taken by reason of the Conflict of Interest.

Possible recommendations and actions can include, but are not limited to:

- (a) Divestiture of relevant personal interests (e.g. placing equity into a blind trust).
- (b) Public disclosure of the personal interest (e.g. to clinical trial participants, in reports, presentations, or publications).
- (c) Independent review of the research proposal (including data safety monitoring process).
- (d) Monitoring of research by independent reviewers.
- (e) Modification of the research proposal or plan.
- (f) Exclusion of the relevant individual from discussions of certain matters.
- (g) Decisions on certain matters referred to others.
- (h) Reduction of the individual's activity in the research.
- (i) Removal of individual as principal investigator.
- (j) Enrolment of clinical trial participants by another person.
- (k) The research not to be conducted.

The Conflict of Interest Management Plan must be:

- (a) Signed by the Personnel member, Laboratory Head, Domain Head/Deputy Director Administration and Institute Director.
- (b) Included in the personnel records of the individual and the individual's supervisor/manager will be responsible for ensuring compliance with the management plan.
- (c) Included in the Conflict of Interest Register.

## **4.4 Compliance with Conflict of Interest Management Plan**

From the date on which a Personnel member is notified of the Conflict of Interest Management Plan, they have ten (10) working days to implement actions towards compliance. At the end of this period, the Conflict of Interest Officer will verify that corrective measures have commenced. Once recommendations have been completely fulfilled, the Personnel member must report back in writing to the Conflict of Interest Officer.

## **4.5 Appeal**

From the date on which a personnel member is notified of the Conflict of Interest Management Plan, they have ten (10) working days to submit an appeal in writing to the Conflict of Interest Officer. In light of new and relevant information, the Conflict of Interest Officer or Institute Director (as applicable) may reconsider their conclusions and recommendations contained in a Conflict of Interest Management Plan.

## **4.6 Review**

On a quarterly basis, the Conflict of Interest Officer will review whether the Conflict of Interest Management Plan has been adhered to. These reviews will occur for the duration of the research.

# **Section 5: Procedure: management of private outside work**

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## **5.1 Agreement with third party**

Where Staff elect to undertake private outside work they must have an agreement in place that clearly defines the scope, intellectual property commitments (if any), financial terms of the consulting activity, is consistent with their Baker Institute employment obligations and makes it clear that the activity is not sponsored or endorsed by the Baker Institute. This is a personal agreement between the Staff member and client for which the Staff member is personally responsible.

The Conflict of Interest Officer can provide input as to whether a private agreement is consistent with Baker Institute employment obligations and if conflicts may arise, how these may be managed. The Baker institute is unable to provide legal advice to Staff entering into private agreements and such individuals are advised to seek independent professional legal advice.

## **5.2 Use of Baker Institute name and resources**

In general, the Baker Institute name, trademarks and logos, including (but not limited to) letterhead, business cards and other stationery must not be used in connection with private outside work. The Baker Institute office and email address of the consulting Staff member may be used for reasonable communication.

Staff should not:

- (a) Solicit private outside work by advertisement in the media, the web, billboards, direct mail or marketing equivalents that mention the Baker Institute.
- (b) Correspond with their clients in their capacity as an employee of Baker Institute (i.e. using their employment designations).
- (c) Name their private company or activities in a similar way to projects or activities within the Baker Institute.

Private outside work may not confer upon an external client any rights to the Baker Institute's research or any preference for access to proprietary information or inventions resulting from the Baker Institute research. A client may license the results of the Baker Institute research but must do so by formal technology transfer means organised through Legal Services.

Confidential information acquired through conduct of the Baker Institute business or research activities may not be used or disclosed for personal gain, or for any purpose other than the permitted disclosure. Confidential information includes any information that comes into Personnel's possession as a result of employment by the Baker Institute that is not available to the general public.

If use of Baker Institute facilities or other resources, including confidential information and intellectual property, is essential to the undertaking of the private outside work, it is a matter for the judgment of the Conflict of Interest Officer who may refer the matter to the Institute Director, as to whether the work constitutes core Baker Institute business which would be more appropriately carried out as institute-sponsored outside work under contract with the Baker Institute.

Generally administrative Staff support should not be used to support private outside work as:

- (a) The Baker Institute is a not-for-profit institute and its resources should not be diverted for personal gain.
- (b) Any contact external clients have with individuals at the Baker Institute will make it likely that the client will consider that the institute is standing behind the private outside work.

Staff engaged in private outside work are responsible for all of their own financial arrangements, and must not use Baker Institute financial systems and facilities, including business activity accounts, or the Baker Institute Staff to invoice, pursue debtors, pay tax or in any way manage funds associated with private outside work.

### **5.3 Indemnity and insurance**

Staff undertaking private outside work:

- (a) Must indemnify (or procure an indemnity from their outside employer / contracting entity) the Baker Institute against any claims arising from private outside work activities (a standard form personal indemnity is available on request from the Conflicts of Interest Officer).
- (b) Is responsible for his/ her own legal liability, professional indemnity and worker's compensation as appropriate in respect of that private outside work.
- (c) Must ensure that all other parties and interested persons understand and acknowledge that the Baker Institute is not responsible for nor does it provide any implied or expressed warranty or guarantee in respect of the work.

- (d) When deemed necessary by the Conflict of Interest Officer, must obtain a signed release from the other party(s) to a contract for private outside work.

## **5.4 Use of funds from private outside work**

Staff may wish to use their funds from private outside work for the Baker Institute purposes. In such a case arrangements based on institute-sponsored outside work are preferable to eliminate the need for personal tax. Otherwise Staff can consider a donation to the Baker Institute on a tax deductible basis, specifying the area in which the funds can be applied.

## **5.5 Waiver**

The Conflict of Interest Officer or Institute Director may waive part or all of the provisions of this Policy in respect of private outside work in circumstances deemed to be exceptional.

## **Section 6: Consequences of non-compliance**

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If Personnel are suspected to have consciously ignored this Policy or disregarded recommendations or not adhered to recommendations in a timely manner, the Conflict of Interest Officer will inform the Personnel member, their manager/supervisor, the Domain Head/Deputy Director Administration and the Institute Director.

The individual will be given the opportunity to respond in writing or in person to the Conflict of Interest Officer within ten (10) working days of being notified.

If it is concluded that the Staff member is in breach of this Policy, sanctions or disciplinary actions will be enforced, including but not limited to:

- (a) Further education or training on the requirements of this Policy.
- (b) Correction of disclosure information published by the individual concerned.
- (c) Restrictions on external professional relationships.
- (d) Restrictions on supervision of staff and/or students.
- (e) Ineligibility to conduct research.
- (f) Non-renewal of appointment.
- (g) Recommendation for dismissal.
- (h) Termination of employment.