

THE UNIVERSITY OF MELBOURNE

DISCLOSURE AND MANAGEMENT OF CONFLICT OF INTEREST IN RESEARCH

Background

The University of Melbourne encourages staff to participate in sponsored and contract research, consultancies and outside activities that are of benefit to researchers, the university and the broader community. However, the conduct of such activities must be consistent with the obligation of staff members to act in the best interest of the university in the discharge of their professional duties. Obligations which have the potential to compromise this position represent a conflict of interest that must be disclosed and managed in ways acceptable to the university.

Situations such as the following represent conflicts of interest in research (either real, perceived or potential) which must be disclosed by members of staff and managed according to an agreed procedure.

- Any form of affiliation with an organisation which sponsors University research conducted by the staff member or the staff member's students.
- Conducting University research benefiting an organisation in which the staff member has a direct or indirect financial interest.
- Delaying or restricting of the publication of results or inappropriate dissemination of results arising from sponsored University research for personal gain.
- Use of University resources or expenditure of University time for personal gain or for external bodies.
- Involvement in contractual negotiations between the University and an organisation in which the staff member has a direct or indirect financial interest or through which personal financial gain could result.
- Being in a position of influence over the direction of research which could lead to personal financial gain.

Current University Policy

The University policy on conflict of interest in research is outlined in Regulation 17.1.R8 - *Code of Conduct for Research* (<http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.htm>) and Section 22-1 of *The University of Melbourne Personnel Policy and Procedures (PPP) Manual*.

Compliance with other types of conflicts of interest is also required as described in varying sections of the *PPP Manual*, in particular Chapter 10 (Employee Relations) and Chapter 13 (Outside Work, Consultancies). Failure to disclose a conflict of interest in research may be subject to the misconduct or serious misconduct rules described in Section 10-3 (Misconduct and Disciplinary Arrangements - Academic Staff) of the *PPP Manual*.

Some refinements of the University Policy on disclosure and management of conflict of interest in research are required. It is proposed that amendments be made to the *Code of Conduct for Research*, the *PPP Manual* and the *Human Resources (HR) 34 Form (Declarations - Academic Staff)* as outlined in the following recommendations.

Sponsored or Contract Research Agreements

For all documents concerned with sponsored or contract research which require the signature of the Deputy Vice-Chancellor (Research), a cover sheet containing information on a number of standard items (*inter alia* related to Intellectual Property, conflict of interest management, financial, legal and other risk issues) will be provided to the Deputy Vice-Chancellor (Research) through the Melbourne Research and Innovation Office.

This cover sheet will contain the following two questions which must be answered by the chief investigator of the research program and the Head of Department or other responsible officer.

Conflict of Interest Management: Will this project result in a conflict of interest in research for the researcher? Yes/No

If Yes, has the researcher complied with the provisions of The University of Melbourne Code of Conduct for Research? Yes/No

Recommendations

It is recommended that:

1. Regulation 17.1.R8 (*The University of Melbourne Code of Conduct for Research*) **be amended by replacing** Part 5 (Conflict of Interest) of Section 2 (Specific Requirements) by the following:

5. Conflict of Interest

- a. A member of staff, a student or any other person engaged in University research has a conflict of interest in any circumstances where that person has a real, perceived or potential opportunity to prefer their own interests, or those of any other person or organisation, to the interests of the University. Examples of conflicts of interest in research include:
 - i. Where the research is sponsored by a related body.
 - ii. Where the researcher or a related body may benefit, directly or indirectly, from any inappropriate dissemination of research results (including any delay in or restriction upon publication of such results).
 - iii. Where the researcher or a related body may benefit, directly or indirectly, from the use of University resources.
 - iv. Where the researcher conducts a clinical trial which is sponsored by any person or organisation with a significant interest in the results of the trial.

A related body is any person or body with which the researcher has an affiliation or a financial involvement. A financial involvement includes a direct or indirect financial interest, provision of benefits (such as travel and accommodation) and provision of materials or facilities. An indirect benefit or financial interest is one derived by the researcher's relatives, personal or business associates, or research students.

- b. The responsibility for managing a conflict of interest rests, in the first instance, with the individual.
 - i. A researcher must make a full disclosure of a conflict of interest to the Head of Department, Dean of Faculty or Deputy Vice-Chancellor (Research) as soon as reasonably practicable. For the conduct of clinical trials, full disclosure must include the nature of the sponsorship and the relationships between the sponsor, trial subjects and the clinical investigator.

- ii. The officer in receipt of the declaration must discuss the matter with the staff member concerned and determine a procedure for the management or elimination of the conflict of interest. The procedure must be documented and the researcher advised in writing.
- iii. A researcher must comply with the direction of the officer in relation to the management of the conflict of interest.
- iv. Unless involved directly, it is the responsibility of Heads of Departments to ensure that conflicts of interest in research involving their staff members are managed appropriately.
- v. When a Head of Department has a conflict of interest in research, the Dean of the Faculty will be responsible for recommending to the Vice-Chancellor appropriate management arrangements.
- vi. When a Dean of Faculty has a conflict of interest in research, the Deputy Vice-Chancellor (Research) will be responsible for recommending to the Vice-Chancellor appropriate management arrangements.
- vii. All members of academic staff are required to complete annually a declaration regarding their academic activities (Form HR 34) including conflict of interest management.
- viii. A Head of Department must not be a Director of any organisation sponsoring research in that Department or have a direct or indirect financial interest in excess of 5% equity in such an organisation unless full disclosure has been made and the Vice-Chancellor has approved an exception to this policy.
- ix. The Deputy Vice-Chancellor (Research), when deciding whether to accept sponsored research or contract research funding on behalf of the University, may seek information regarding disclosure and management of any conflict of interest that may result.

2. Form HR 34 **be amended by including** a new section on conflict of interest management as follows:

Conflict of Interest Management

I have disclosed my involvement in any activities that represent a conflict of interest in relation to my obligations to the University and have managed the conflict in accord with the direction provided by the University.

3. Section 13-1.3.8 (Directorships (All Academic and General Staff)) of *The University of Melbourne Personnel Policy and Procedures Manual* **be amended to include** the following qualification:

A Head of Department must not be a Director of any organisation sponsoring research in that Department or have a direct or indirect financial interest in excess of 5% equity in such an organisation unless full disclosure has been made and the Vice-Chancellor has approved an exception to this policy.

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