
ALFRED ETHICS COMMITTEE POLICY: CONFLICTS OF INTEREST

INTRODUCTION

A conflict of interest, in the context of research, exists where the interests or responsibilities of an individual or an institution have the potential to influence the way they carry out their institutional role or professional obligations in research. A conflict may relate to financial interests and/or private, professional or institutional benefits that depend significantly on the research outcome. In addition to affecting the integrity of a researcher, a conflict of interest may compromise the research process itself, as well as the institutional governance of research.¹

The Alfred Ethics Committee is aware of the increasing complexity of commercial involvement in clinical research activities. Until recently such activities mainly involved hospital or university based researchers undertaking contract research for the pharmaceutical industry. More recently it has become common for researchers to own shares or be offered options in sponsoring companies or to hold paid positions with these entities.

The Ethics Committee is also aware that such arrangements may be beneficial in providing incentives for innovation and assisting in the protection of intellectual property. Various Government and institutional policies act to promote such involvement.

The various forms of interests relating to personal, professional or institutional benefits add to the need for careful ethical scrutiny of projects to ensure the well being of participants, the integrity of the researcher and the reputation of the institution. This involves ensuring that any incentives or benefits do not influence:

- the rigour of the approval process
- the appropriateness of selection of participants in research
- the conduct of research including the protection of the privacy and other rights of participants
- the interpretation of results of the research project.

To achieve these goals the Ethics Committee wishes to reiterate the key principles that will guide its approach to such projects. These principles focus on two issues:

1. Full disclosure
2. Avoidance of conflict of interest.

For these reasons:

- The Committee requires full disclosure of all aspects of the funding of research projects, as well as information pertaining to any personal, professional or institutional benefits that depend significantly on the research outcomes. Full details are required of any financial involvement between a sponsoring company and those involved in a research project. Such financial involvement would include shares, options, payments or other direct benefits such as gratuities or sponsored travel to researchers or to the institutions involved in the research.
- The Committee must be notified of any significant change in either the funding of a study or the financial involvement of investigators during the course of a study up until finalisation of the last publication derived from the study.
- The Committee will generally not approve studies in which those with financial or other personal interests in the outcome are involved in selection of study participants or in the evaluation of outcomes of the investigation.
- Plain language information provided to patients as part of such studies must make explicit reference to commercial arrangements involving investigators.

- The Committee will provide reports to the hospital management on projects involving significant commercial involvement.

Conflict of interest provisions also apply to the evaluation of research projects, with the requirement that any member of the Ethics Committee or its subcommittees with a direct financial interest in a particular project declares that interest and absents him/herself from the relevant deliberations. (A direct financial interest includes ownership of shares, options or holding of a paid position in the sponsoring company).

FURTHER INFORMATION

Any enquires regarding submission forms and processes, documentation, or variations to the procedures outlined above should be directed to the Ethics Manager.

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NOTES

1. National Statement on Ethical Conduct in Human Research, 2007
www.nhmrc.gov.au/publications/synopses/e72syn.htm