

Policy Statement



Trans Tasman Radiation Oncology Group

ABN: 45 132 672 292

Calvary Mater Newcastle, Locked Bag 7, HRMC, NSW 2310, Australia

Telephone: +61 (0)2 401 43911 Fax: +61 (0)2 401 43902

trog@trog.com.au

www.trog.com.au

Conflict of Interest Guidelines

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Summary: The aim of this policy statement is to define conflicts of interest and how TROG will document, review and manage potential conflicts of interest of committee members.

Author: TROG Central Operations Office

Applies to: This policy relates to all TROG committee members, including the Board of Directors, Scientific Committee, Publications Committee, Independent Data Safety Monitoring Committees and Trial Management Committees including Trial Chairpersons.

Approved by: TROG Scientific Committee and TROG Board

Review date: June 2014

Revision Chronology:	Vs 1	New Policy
	Vs 2, 24 Sep 2008	Update to Corporations Act & relevant processes
	Vs 3, 09 Aug 2013	Update to reflect change in internal TROG procedures for managing conflicts of interest.

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1.0 BACKGROUND

The scientific credibility and acceptance of TROG's clinical trial results are dependent on the integrity of TROG's governance processes and all individuals involved in TROG activities. A real or perceived bias of an individual involved in a committee overseeing a TROG trial or other TROG activity may cast doubt on the validity of TROG's research results. In accordance with the requirements of the Australian Code for the Responsible Conduct of Research¹ and the National Statement on Ethical Conduct in Human Research (The National Statement)², this policy defines conflicts of interest and how TROG will document, review and manage potential conflicts of interest of committee members.

2.0 CONFLICT OF INTEREST DEFINITION

The National Statement defines a conflict of interest as follows:

"A conflict of interest in the context of research exists where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research. While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes."

This definition of conflicts of interest has been provided to assist in identifying potential conflicts of interest. However, the overriding principle is that full disclosure is the appropriate course of action if there is any doubt as to whether a conflict of interest exists.

3.0 CONFLICT OF INTEREST EXAMPLES

In TROG clinical trials, potential for conflict of interest may arise when the investigator:

- is remunerated for participant recruitment (eg, with per capita payments)
- has a commercial interest in the intervention or financial links to the study sponsor
- will benefit in professional or academic terms from involvement in the study.

3.1 Proprietary conflicts of interest

The individual has financial interest in the intervention being trialled because the individual or an immediate family member has a material interest in the intervention that may result in financial gain, e.g., where the individual may receive royalties or other compensation following the commercial sale of the intervention being trialled. Such royalties may be in the form of personal compensation to the individual or may be used in support of the individual's research.

The individual has financial interest in the intervention being trialled because the individual or an immediate family member has an equity interest or option of \$5,000 or more in a commercial enterprise that will benefit from the sale of the product or technology.

3.2 Professional conflicts of interest

The individual has played a substantial role in the previous development of the intervention being trialled; or

The individual has a substantial ongoing affiliation with an organisation having a role in the development or sale of the intervention including organisations holding patents or licenses for the development or sale of research products. This would include instances in which the individual serves as an officer, director, trustee, general partner, scientific advisor or as an employee. Such organisations would also include those with which the individual is negotiating for or has an arrangement concerning prospective employment or affiliation. The significance of the conflict will depend, to some degree, on whether reimbursement for professional activities involves compensation limited to that normally required to support the scientific process, or is substantially larger, leading to actual or potential personal financial gain to the individuals or an immediate family member (a spouse, parent, sibling, dependent child, or other dependent).

4.0 PROCESS FOR DISCLOSURE OF CONFLICT OF INTEREST

The first item agenda item for each the following meetings must be ‘Declaration of Conflict of Interest’:

- a) TROG Committee meetings: Board, Scientific Committee and Publications Committee
- b) Trial Chairpersons: Initial Trial Development meeting
- c) Trial Management Committee meetings
- d) Independent Data Safety Monitoring Committee meetings

Members must give other members notice of any conflict of interest including the nature and extent of the interest, at the first meeting held after the member becomes aware of their interest in the matter and the details must be recorded in the minutes of the meeting.

As general rule, TROG recommends that a member with a COI in a matter that is being considered at a meeting must not be present while the matter is being considered or vote on the matter.

A committee member who leaves a meeting due to a declared conflict of interest will not adversely affect the quorum of the meeting.

5.0 PROCESS FOR MANAGING POTENTIAL CONFLICTS OF INTEREST

5.1 TROG Board

Directors with a material personal interest must not be present while the matter is being considered or vote on the matter unless the other directors who do not have a material personal interest in the matter pass a resolution that identifies the director, the nature and effect of the director's interest in the matter and its relation to the affairs of TROG and a statement that the directors are satisfied that the interest should not disqualify the director from voting or being present (as per s195 (2)-(4) of the Act) .

However, in most cases it is far easier if the interested director leaves the meeting while the issue is resolved.

If there are not enough directors to form a quorum without including the directors who have a material personal interest, then the directors (including those with a material personal interest) may call a general meeting and deal with the matter at that general meeting (as per s195 (2)-(4) of the Act).

5.2 Other Committees

If an individual declares a potential conflict of interest at the beginning of a meeting, the following options may be considered by the chairperson of the committee:

- The individual may be requested to leave the meeting for all discussion regarding the issue in question;
- The individual may be present during the discussion but will absent themselves from the meeting for any votes on the issue;
- The individual may be present during the discussion and may be present for the vote, although they will not be permitted to vote on this issue; or
- The individual may be requested to resign from the committee.

A committee member who leaves a meeting due to a declared conflict of interest will not adversely affect the quorum of the meeting.

In the event of any disagreement as to the appropriate course of action to address a potential conflict of interest, the matter is to be held in abeyance and referred to the Board.

The conflict of interest declared and all decisions made by the committee related to conflict of interest will be documented in the minutes of the meeting. A copy of the meeting minutes will be provided to the TROG Central Operations Office who shall in turn forward the minutes to the TROG Board. The TROG Board will review the conflict of interest and decisions made by the committee and, if satisfied that it does not preclude the individual from participating in TROG activities, will notify the individual that their involvement can proceed.

8.0 REFERENCES

1. Australian Code for the Responsible Conduct of Research, 2007. Available at <http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>
2. National Statement on Ethical Conduct in Human Research, NHMRC, Australia, 2007. Available at http://www.nhmrc.gov.au/guidelines/ethics/human_research/index.htm