



Trans Tasman Radiation Oncology  
Group Limited  
ACN 132 672 292

# TROG POLICY AND PROCEDURES

## Conflict of Interest Policy

### TPP C5

**Version 2: 24<sup>th</sup> September 2008**

(Always refer to the TROG website to check for the current version of this policy)

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## **1 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. This policy defines conflicts of interest and how TROG will document, review and manage potential conflicts of interest of committee members.

## **2 Scope**

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

## **3 Legislative requirements - Corporations Act 2001**

As a public company limited by guarantee, TROG is governed by the Corporations Act 2001, which prescribes the following procedures in relation to conflicts of interest of the Board of Directors:

### **3.1 Disclosure of interest**

Section 191(1) of the Act states that a director who has a material personal interest in a matter that relates to the affairs of the company must give the other directors notice of the interest except in the following circumstances:

- a) if the interest arises because the director is a member of the company and is held in common with other members of the company
- b) if the interest relates to a contract the company is proposing to enter into that is subject to approval by the members and will not impose any obligation on the company if it is not approved by the members

The director must give the other directors notice of the interest including the nature and extent of the interest, and the relation of the interest to the affairs of the company at the first Board meeting held after the director becomes aware of their interest in the matter or after appointment as a director (whichever is later) and the details must be recorded in the minutes of the Board meeting.

### **3.2 Restrictions on voting**

Section 195(1) of the Act states that a director who has a material personal interest in a matter that is being considered at a directors' meeting must not be present while the matter is being considered or vote on the matter unless the provisions of s195 (2)-(4) apply.

## **4 Definitions and examples of conflict of interest**

The definitions and examples of conflicts of interest below are 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.

### **4.1 Professional and proprietary conflicts of interest<sup>1</sup>**

#### **4.1.1 Professional interest**

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

The individual has a substantial ongoing affiliation with an organisation having a role in the development or sale of a product or technology 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.

#### **4.1.2 Proprietary interest**

The individual has financial (pecuniary) interest in the research product being evaluated because the individual or an immediate family member has a material interest in the product or technology that may result in financial gain, e.g., where the individual may receive royalties or other compensation following commercial sale of the product or technology. 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 drug, technique, or technology being evaluated because the individual or an immediate family member (a spouse, parent, sibling, dependent child, or other dependent) 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.

#### **4.2 Examples of conflicts of interest involving researchers<sup>2</sup>**

- a) A researcher has a direct financial interest in the outcome of a trial in which he/she is engaged, in the form of shares, share options, and bonuses.
- b) A researcher is paid for conducting a trial by a pharmaceutical company.
- c) A researcher is employed directly by pharmaceutical company.
- d) A researcher is asked to review a paper or grant application that bears on his/her own work.
- e) A researcher has to make a decision about whether to publish unfavourable or negative results, as a result of which his/her career may be damaged and financial benefits may be lost.

## **5 Process for obtaining conflict of interest information**

### **5.1 Appointment of committee members**

- a) TROG Committees: All members of TROG governing committees (Board, Scientific Committee and Publications Committee) will be required to complete a Conflict of Interest (COI) Declaration Form when they take up their appointment. This will be coordinated by the TROG Central Operations Office (TCOO).
- b) Trial Chairpersons: All potential Trial Chairpersons will complete a Conflict of Interest Declaration Form when they submit a New Proposal Form for presentation of a new trial at an Annual Meeting. This will be coordinated by the TCOO.
- c) Trial Management Committees (TROG-led trials): members will be required to complete a Conflict of Interest Declaration Form when they take up their appointment. This will be coordinated by the relevant Trial Chairperson/Trial Coordinating Centre who will forward completed forms to the TCOO.

- d) Trial Management Committees (Non TROG-led trials): in cases where TROG is collaborating but is not the lead trials group, only the TROG members are required to complete a declaration form. This will be coordinated by the TCOO.
- e) Data Monitoring Committees: members will be required to complete a Conflict of Interest Declaration Form when they take up their appointment. This will be coordinated by the relevant Trial Chairperson/Trial Coordinating Centre who will forward completed forms to the TCOO.

## **5.2 Updating conflict of interest information**

If the interest has arisen after completion of the initial COI Declaration Form (i.e. on appointment to the committee), the member must give the other members notice of the 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.

In addition, all TROG committee members will be required to provide a COI Declaration Form annually.

# **6 Process for managing potential conflicts of interest**

## **6.1 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).

## 6.2 Other Committees

The TCOO will forward any forms indicating potential conflict of interest to the TROG Board who will review the form and if satisfied that none of the interests listed should preclude the individual from participating in TROG activities, will notify the individual that their appointment can proceed.

If an individual has a potential conflict of interest in a meeting agenda item or in respect of an individual trial, 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.

If the potential conflict of interest is not notified by the individual until the meeting itself, the relevant committee (Board, Scientific Committee, Publications Committee, Trial Management Committee, Data Monitoring Committee) may decide one of the options as detailed above at the meeting.

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

All decisions by the committee related to conflict of interest will be documented in the minutes of the meeting, with a copy to the Board.

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.

## **7 Failure to observe TROG conflict of interest policy**

### **7.1 TROG Board**

As per the TROG Constitution, if a director who is a TROG member fails to declare any material personal interests in a matter that relates to the affairs of TROG, they will automatically cease to be a member of TROG.

In the case where the other directors who are not TROG members (ie. consumer and independent director) fail to declare any material personal interest, the other Board directors will be responsible for any action, including the removal of that person from the Board position.

### **7.2 Other Committees**

Failure to disclose a conflict of interest could result in a loss of privileges to participate in TROG activities including loss of TROG membership. Breaches of policy will be notified to the TROG Board who will be responsible for any further action.

## **8. References**

1. EORTC Conflict of Interest Policy (POL001) Version 3.3, Oct 16, 2006.  
Available at <http://www.eortc.be/Services/Doc/policies/pol001.pdf>
2. The Royal Australasian College of Physicians. Ethical aspects of conflicts of interests. January 2004. RACP, Sydney.  
Available at [http://www.racp.edu.au/public/Ethics\\_conflict.pdf](http://www.racp.edu.au/public/Ethics_conflict.pdf)

# Conflict of Interest Declaration Form



**NAME** (please print) \_\_\_\_\_

**TROG POSITION/ROLE** \_\_\_\_\_

**TRIAL** (if applicable) \_\_\_\_\_

I have no interest or benefits to declare that could potentially cause a conflict with my role in TROG.

**OR**

**PLEASE LIST ALL YOUR INTERESTS** (including positions held on the Board/other committees of other organisations/pharmaceutical companies, and equity, shareholdings, travel, grants greater than \$5000). Please note that this also includes immediate family members. Please refer to the TROG Conflict of Interest Policy for further information.

Company/Organisation	Description of interest, role or benefit received (if financial include dollar amount)

I certify that I have read the TROG Conflict of Interest Policy (Version 2.0, September 2008) and agree to abide by the principles and provisions in that document.

I have disclosed above all interests relevant to my role in TROG.

If my interests change, I undertake to update this information by notification in writing to the TROG Central Operations Office.

Signed \_\_\_\_\_ Date: \_\_\_\_\_

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