Conflict of Interest and Confidentiality

POL001
Version 4.2
ALWAYS REFER TO THE EORTC INTERNET WEBSITE TO CHECK THE VALIDITY OF THIS DOCUMENT

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<th>Authorized by:</th>
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<tr>
<td>Director General on Behalf of the Board</td>
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<td>Denis Lacombe</td>
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Table of Contents

1 PURPOSE .................................................................................................................................................. 3
2 BACKGROUND ......................................................................................................................................... 3
3 SCOPE ...................................................................................................................................................... 3
4 CONFLICT OF INTEREST .......................................................................................................................... 3
4.1 Definitions .............................................................................................................................................. 4
4.2 Disclosure .............................................................................................................................................. 5
4.2.1 EORTC investigators ....................................................................................................................... 5
4.2.2 EORTC Study Coordinators .......................................................................................................... 5
4.2.3 EORTC Headquarters staff ........................................................................................................... 5
4.2.4 EORTC Officers and members of committees ............................................................................. 5
4.2.5 Specific scientific experts ............................................................................................................... 6
4.3 Review of disclosure statements & actions on conflict of interest ......................................................... 6
5 CONFIDENTIALITY ................................................................................................................................... 6
6 PENALTIES FOR FAILURE TO OBSERVE THIS POLICY ...................................................................... 6
7 DOCUMENT HISTORY ............................................................................................................................. 7
1 PURPOSE

This policy defines areas of conflict of interest and identifies when disclosure should be provided to eventually place limitations on participation in EORTC activities.

2 BACKGROUND

A situation may occur in which an individual participating in EORTC activities has more than a purely scientific interest in the outcome of a clinical investigation. This interest may be a professional one, due to the fact that this individual has played a substantial role in the development of the product or technology being evaluated, or because he has an ongoing affiliation with the organization holding the patent to, or license for development or sale of the research product. The interest may also be proprietary or pecuniary, if this person or a member of his or her immediate family has a material interest in the product or technology that may result in financial gain, e.g., where he may receive royalties or other compensation following the commercial sale of the product or technology, or where this individual and/or close family members have a substantial equity interest in a commercial enterprise that will benefit from the sale of the product or technology.

The scientific credibility and the general acceptance of the results of a clinical investigation clearly depend on the integrity and objectivity of all individuals involved in EORTC activities. Even the perception that an individual has a bias may cast doubt on the validity of the results. This policy was established to address such concerns.

This statement will define areas of conflict of interest and will identify when disclosure should be provided. Following disclosure, it will be determined on a case by case basis whether any limitations will be placed on participation in EORTC activities.

3 SCOPE

This policy is applicable to EORTC Headquarters staff, investigators, Study Coordinators, scientific experts (reviewers), Officers and members of committees participating in EORTC activities. It aims at covering all forms of conflicts of interest and bribes that may affect the performance of an EORTC activity. Bribery is defined as the offering, giving, receiving, or soliciting of something of value for the purpose of influencing the action of an official in the discharge of his or her duties.

4 CONFLICT OF INTEREST

Participation includes having an active role in the development and conduct of the protocol, as well as reporting of study results (investigators, EORTC Headquarters staff, Study Coordinators). Participation also includes having an active role in the decision making process within the EORTC.

Individuals declare all interests within the last three years that are relevant to the activity performed and EORTC evaluates whether declared interests constitute a conflict.

Individuals having a possible conflict of interest may be allowed to participate in EORTC activities after providing formal disclosure. However, in some instances certain activities may be prohibited.

Because of the potential of a conflict of interest to bias conclusions either intentionally or unintentionally, and because even the perception by others of a conflict of interest could compromise research credibility, EORTC staff, scientists, Officers, members of committees, Study Coordinators and investigators should make reasonable efforts to avoid the occurrence of such conflicts.
Following completion of a study, individuals providing leadership in the design or conduct of the study should refrain from activities primarily targeted at marketing of the product. Scientific activities such as authorship of scientific articles or book chapters, and presentations at academic institutions or professional meetings do not require disclosure unless compensation exceeds standard honoraria and travel expenses.

### 4.1 Definitions

**Research Product:** A research product includes a drug, technique, or technology.

**Immediate Family Member:** Immediate family member includes a spouse, parent, sibling, dependent child, or other dependent.

**Conflict of Interest:** There are several aspects to conflict of interest.

- **Professional Interest**
  The individual has played a substantial role in the previous development of the product or technology.

  The individual has a substantial ongoing affiliation with an organization having a role in the development or sale of a product or technology including organizations 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 or as an employee. Such organizations 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.

- **Proprietary Interest**
  The individual has financial 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 the 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 research product being evaluated 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.

- **Relations with pharmaceutical/medical device firms**
  All industry sponsored EORTC activities must be negotiated, approved, and implemented in accordance with EORTC procedures. No EORTC members will convey information to the firms, except as permitted and approved in the contract negotiated with the firm and EORTC. Members of the EORTC agree that knowledge of confidential information that comes from their participation in EORTC studies will not be used for personal gain, nor should such information be conveyed so as to possibly benefit family or friends and, in general, to anyone who does not have a specific need to know.

- **Other conflicts of interest**
  There may be other instances in which an individual or an immediate family member has an affiliation or relationship such that objective impartiality could be questioned. In any such instance, the individual should disclose the nature and extent of such affiliation or relationship.
4.2 Disclosure

4.2.1 EORTC investigators
Study participants must not have or appear to have a financial interest in the study outcome and may not have equity interests in firms providing pharmaceutical agents or medical devices for the EORTC study in which they are participating.
If a possible conflict of interest exists it should be mentioned before any new study is activated.

4.2.2 EORTC Study Coordinators
They must not have or appear to have a financial interest in the study outcome and may not have equity interests in firms providing pharmaceutical agents or medical devices for their EORTC protocol.
Prior to developing the full protocol the Study Coordinator is also requested to disclose any possible conflict of interest. Conflicts which develop during the conduct of the study of the research product or during the dissemination of results must also be disclosed.

4.2.3 EORTC Headquarters staff
All staff members of EORTC Headquarters will be requested to declare possible conflict of interest when they first start to work with the EORTC (whether employed by the EORTC or not, such as fellows) and when significant changes in financial interests occur. A request to check the current status of conflict of interest will be sent to the staff every three years.
EORTC staff may be invited to scientific events such as but not limited to advisory boards, driven by the commercial sector. While participation to these events may be considered, pending all types of conflicts of interest are duly disclosed and assessed as not interfering with any of the EORTC activity according to this policy, financial or any valued benefit is not possible at any time. EORTC staff can only perform such punctual activities based on a signed agreement between the event organizer and the EORTC. Agreements are handled by the EORTC Budget and Contract unit which is responsible for ensuring the proper status of EORTC contribution and compensation. Being accountable, the agreement is signed by the Director General.
EORTC website: The EORTC will not advertise directly or through web links for commercial events such as conference. Advertising for events is limited to those that are organized by EORTC, recognized academic partners or events which have been granted under the auspices of EORTC.

4.2.4 EORTC Officers and members of committees
Members of the General Assembly and members of the following EORTC Committees are requested to declare possible conflict of interest at time of taking office.
Independent Data Monitoring Committee (IDMC)
Institutional Review Board (IRB)
Membership Committee (MC)
New Drug Advisory Committee (NDAC)
Quality Assurance Committee (QAC)
Protocol Review Committee (PRC)
Scientific Audit Committee (SAC)
Translational Research Advisory Committee (TRAC)

The Statement must be updated when significant changes in conflict of interests occur and at a minimum every three years if an individual is re-elected for a new term for the same or for a different position.

Permanent members of the PRC have to fill the form when a specific conflict arises for a given project.

Members of the IDMC have also to declare possible conflict of for each protocol they review.

4.2.5 Specific scientific experts

Scientists and experts acting as external advisors or reviewers for EORTC Committees have also to declare possible conflict of interest (as part of routine or to document a potential conflict when it exists).

4.3 Review of disclosure statements & actions on conflict of interest

Declared interests are addressed to the IRB Chair who manages them on an ongoing basis by deciding whether there is a potential conflict and decides on actions to be taken.

IRB Chair convenes the IRB at least once yearly to review conflicts of interest and actions taken during the past year.

It is the responsibility of the individual to notify the Chair of the IRB of any subsequent changes in his conflict of interest(s).

5 CONFIDENTIALITY

All information made available to any EORTC scientists* by a third party** and not already in the public domain should be treated in strict confidence.

Such information is supplied to facilitate scientific discussions and decisions concerning the development and/or the conduct of EORTC protocols and must not be reported outside the framework for which the information has been provided.

By accepting to treat in strict confidence any information provided within the framework of their EORTC activities, EORTC scientists* agree to treat in confidence any information which has been provided within this context.

* in this context, EORTC scientists include all investigators, Study Coordinators, EORTC Committees members, members of Data Monitoring Committee and EORTC Headquarters staff members.

** in this context, a third party includes not only industry but also any other research organization, regulatory authorities and EORTC Headquarters staff members.

6 PENALTIES FOR FAILURE TO OBSERVE THIS POLICY

Failure to disclose a conflict of interest or to respect the confidentiality agreement as required above could result in the loss of privileges to participate in the activities of the EORTC.

Possible breaches of these policies will be brought to the attention of the Chair of the EORTC Institutional Review Board and Director General of the EORTC for action. The IRB and/or the Board of the EORTC will investigate the issue and recommend whatever action it deems appropriate.
## DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Version number</th>
<th>Brief description of change</th>
<th>Author</th>
<th>Effective date</th>
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<tr>
<td>1.0</td>
<td>Initial Release</td>
<td>Richard Sylvester</td>
<td>January 1998</td>
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<tr>
<td>2.0</td>
<td></td>
<td>Patrick Therasse</td>
<td>August 1998</td>
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<tr>
<td>2.2</td>
<td></td>
<td>Patrick Therasse</td>
<td>November 1998</td>
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<td>3.0</td>
<td></td>
<td>Patrick Therasse</td>
<td>November 2002</td>
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<td>3.1</td>
<td>Transfer to new template; no further modifications</td>
<td>Patrick Therasse</td>
<td>14 Feb 2005</td>
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<td>3.2</td>
<td>Minor changes; Change of SOPs author and approver</td>
<td>Denis Lacombe</td>
<td>06 Sep 2006</td>
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<tr>
<td>3.3</td>
<td>Minor changes; Implementation of detailed forms for Conflict of Interest</td>
<td>Denis Lacombe</td>
<td>16 Oct 2006</td>
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<tr>
<td>4.00</td>
<td>Clarification of the disclosure and review process. Adapt version number to two decimal digit.</td>
<td>Françoise Meunier</td>
<td>12 Jul 2012</td>
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<td>4.1</td>
<td>Add participation of EORTC staff to scientific events including those driven by the commercial sector.</td>
<td>Denis Lacombe</td>
<td>4 Jun 2015</td>
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<tr>
<td>4.2</td>
<td>Deletion of the associated documents following update of the related AFs</td>
<td>Anastassia Negrouk</td>
<td>16 Mar 2017</td>
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