## Conflict of Interest and Confidentiality

POL001  
Version 4.00  
ALWAYS REFER TO THE EORTC INTERNET WEBSITE TO CHECK THE VALIDITY OF THIS DOCUMENT

<table>
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<tr>
<th>Author:</th>
<th>Signature:</th>
<th>Date:</th>
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| Director General  
Françoise Meunier | | |

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<tr>
<th>Authorized by:</th>
<th>Signature:</th>
<th>Date:</th>
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| Director General  
on Behalf of the Board  
Françoise Meunier | | |
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1 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.

2 SCOPE

This policy is applicable to EORTC Headquarters staff, investigators, Study Coordinators, scientific experts (reviewers), Officers and members of committees participating in EORTC activities.

3 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 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.

3.1 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.
3.2 Disclosure

3.2.1 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 on the "Confirmation of Interest by Principal Investigator" form circulated before any new study is activated.

3.2.2 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.

3.2.3 EORTC Headquarters staff

All staff members of EORTC Headquarters will be requested to declare possible conflict of interest. This statement must be signed when an individual first starts to work with the EORTC (whether employed by the EORTC or not, such as fellows) and should be updated 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.

3.2.4 EORTC Officers and members of committees

Members of the General Assembly and members of the following EORTC Committees are requested to complete the “Conflict of Interest - Confidentiality Disclosure” form 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.
3.2.5 Specific scientific experts

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

3.3 Review of disclosure statements & actions on conflict of interest

Conflicts are addressed to the IRB Chair who manages them on ongoing basis.

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).

4 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.

5 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.
6 ASSOCIATED DOCUMENTS

<table>
<thead>
<tr>
<th>Document title</th>
<th>Reference (file name or path)</th>
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<tr>
<td>Group / Task Force Chairs: Conflict of Interest - Confidentiality Disclosure Form</td>
<td>QS-002-AF-02</td>
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<td>Officers and members of committees: Conflict of Interest – Confidentiality Disclosure Form</td>
<td>QS-002-AF-03</td>
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<td>Headquarters Staff: Conflict of Interest - Confidentiality Disclosure Form</td>
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<td>Study Coordinator: Conflict of Interest - Confidentiality Disclosure Form</td>
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<td>SAC members: Conflict of Interest – Confidentiality Disclosure Form</td>
<td>QS-002-AF-06</td>
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<td>PRC: Conflict of Interest - Confidentiality Disclosure form</td>
<td>QS-002-AF-07</td>
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<tr>
<td>IDMC: Conflict of Interest - Confidentiality Disclosure Form</td>
<td>QS-002-AF-08</td>
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<td>Confirmation of Interest by Principal Investigator Form</td>
<td>CM-005-AF-04</td>
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7 DOCUMENT HISTORY

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<th>Brief description of change</th>
<th>Author</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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<td>2.0</td>
<td></td>
<td>Patrick Therasse</td>
<td>August 1998</td>
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<td>Patrick Therasse</td>
<td>November 1998</td>
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<td>3.0</td>
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<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>14/02/2005</td>
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<td>3.2</td>
<td>Minor changes; Change of SOPs author and approver</td>
<td>Denis Lacombe</td>
<td>06/09/2006</td>
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<td>3.3</td>
<td>Minor changes; Implementation of detailed forms for Conflict of Interest</td>
<td>Denis Lacombe</td>
<td>16/10/2006</td>
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<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>12/07/2012</td>
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