



EORTC

European Organization for Research
and Treatment of Cancer

International Association under Belgian Law

Conflict of interest

Confidentiality

Policy 001

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Author

Patrick Therasse

Signature: _____ Date: _____

Reviewer

Denis Lacombe, Richard
Sylvester

Signature: _____ Date: _____

Approved by

Françoise Meunier (on behalf of
Executive Board)

Signature: _____ Date: _____

Distribution Everybody

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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 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. Conflict of interest

This policy is applicable to all scientists and investigators participating in EORTC activities.

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

Individuals having a potential conflict of interest may be allowed to participate in EORTC activities after providing formal disclosure. However, in some instances certain activities may be prohibited. The chairman of the EORTC Data Center Institutional Review Board (IRB) will convene the IRB at least once yearly to review possible conflicts of interest of investigators, study coordinators or data center staff members to determine whether there is a sufficient basis to recommend to the EORTC Board the prohibitions defined below. All formal disclosures provided by EORTC officers will be considered solely by the Director General of EORTC to determine whether there is a sufficient basis to recommend to the EORTC Board the prohibitions defined below.

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 scientists and investigators should make reasonable efforts to avoid the occurrence of such conflicts.

Following completion of a trial, 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. Policy

3.1 Disclosure

3.1.1 Study participants

If a possible conflict of interest exists it should be mentioned on the Commitment Statement form circulated before any new trial is activated. Participants expressing a possible Conflict of Interest on the Commitment form must complete the EORTC Conflict of Interest / Confidentiality Disclosure form (EORTC Clinical Investigator/Study Coordinators form) and send it to the chairman of the EORTC IRB at the EORTC Central Office prior to enrolling their first patient in a given protocol. 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 trial in which they are participating.

3.1.2 Study Coordinators

Prior to developing a protocol or serving in a leadership role in the conduct of a study involving a research product for which there is a possible conflict of interest, the study coordinator must disclose any possible conflict of interest by completing the Commitment Statement form. Study Coordinators expressing a possible Conflict of Interest on the Commitment form must complete the EORTC Conflict of Interest / Confidentiality Disclosure form (EORTC Clinical Investigator/Study Coordinators form) and send it to the chairman of the EORTC IRB at the EORTC Central Office. 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. Conflicts which develop during the conduct of the trial of the research product or during the dissemination of results must also be disclosed in the same manner.

3.1.3 EORTC scientific personnel

Members of an official EORTC data center will be requested to complete the Conflict of Interest / Confidentiality Disclosure form (EORTC Scientific Personnel form) and send it to the chairman of the IRB where it will be kept on file. This statement must be signed when an individual first starts to work with the EORTC (whether employed by the EORTC or not) and should be updated when significant changes in financial interests occur and at a minimum every three years when a new EORTC Board is appointed.

3.1.4 EORTC Officers

Members of the general assembly and EORTC Committees (QAC, SAC, NTC, PRC, IRB, IDMC) have to complete a Conflict of Interest / Confidentiality Disclosure form (EORTC Officers form or EORTC Group Chairman form according to the position) and send it to the Director General of the EORTC. This statement must be updated when significant changes in financial 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. The Director General of the EORTC has to complete a Conflict of Interest / Confidentiality Disclosure form (EORTC Officers form) and send it to the President of the EORTC. This statement must be updated when significant changes in financial interests occur and at a minimum every three years when a new EORTC Board is appointed.

3.1.5 Relations with pharmaceutical/medical device firms

All industry sponsored EORTC activities must be negotiated, approved, and implemented in accordance with EORTC procedures described in the policies covering industry sponsored trials. No EORTC members will represent the EORTC except as described in these policies and specifically will not convey information to the firms, except as permitted and approved in the

contract negotiated with the firm by the EORTC. Members of the EORTC agree that knowledge of privileged information that comes from their participation in EORTC trials will not be used for personal gain, nor should such information be conveyed so as to possibly benefit family or friends.

4 Review of disclosure statements/ Actions on conflict of interest

4.1 When the chairman of the IRB receives a Disclosure Form marked with a “possible” conflict of interest, the noted “possible” conflict(s) will be typed onto a preformatted form and sent to the individual investigator for a second signature, allowing the investigator to confirm or disaffirm the disclosure(s). When the second disclosure/signature is received by the chairman of the EORTC IRB, it will be kept on permanent file. It is then the responsibility of the individual investigator to notify the chairman of the IRB of any subsequent changes in his conflict of interest(s).

When the chairman of the IRB receives a Disclosure Form marked with a “no” conflict of interest, the Disclosure Form will be held on file at the EORTC Central Office. Should the conflict of interest status of an individual investigator change, it is the responsibility of the individual investigator to notify the chairman of the IRB of any such change.

The EORTC IRB, meeting not less frequently than once per year, will review disclosure statements and will make recommendations concerning possible conflicts of interest situations to the EORTC Director General. These may include the removal of an individual from those positions which pose a conflict or the appearance of conflict of interest.

4.2 When the Director General of EORTC receives from an EORTC officer a Disclosure form marked with a potential conflict of interest, the same procedure as described above will be applied to obtain confirmation. When the potential Conflict of Interest is confirmed, the Director General will seek the advice of the executive committee of the Board before a final decision is taken by the Board of the EORTC.

5 Definitions of potential conflict of interest

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.

5.1 Professional Interest

5.1.1 The individual has played a substantial role in the previous development of the product or technology.

5.1.2 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.

5.2 Proprietary Interest

5.2.1 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.

5.2.2 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.

6 Miscellaneous

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 using the procedures discussed below.

7 Intergroup trials with US cooperative groups

Some studies conducted by the EORTC are performed in collaboration with US cooperative groups granted by the NCI. In this context, the EORTC accepted to comply with the regulations set by the Office for Protection from Research Risk (OPRR) in the US according to an International Cooperative Program Assurance (ICPA). The ICPA describes in details the measures to be taken to enable such collaboration. Compliance with the ICPA should be acknowledged by each investigator willing to participate in such an intergroup trial. As a consequence, a special commitment form has been created (Commitment statement for intergroup trials with US participants) and should be used (in place of the usual commitment form) to confirm adherence to the ICPA guidelines.

8 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 signing the Conflict of Interest / Confidentiality disclosure form, 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 committee members, members of data monitoring committee and data center staff members

** in this context, a third party includes not only industry but also any other research organisation, regulatory authorities and EORTC data centers

9 Penalties for failure to observe conflict of interest / confidentiality policies

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 chairman of the EORTC Institutional Review Board or Director General of the EORTC for action. The IRB and/or the executive committee of the EORTC will investigate the issue and recommend whatever action it deems appropriate to the EORTC Board of Directors. The Board of Directors will receive this recommendation and take whatever action it deems appropriate, accepting the recommendations or applying a greater or lesser penalty than that recommended.