EORTC
European Organisation for Research and Treatment of Cancer
AISBL International Non-Profit Association under Belgian law IVZW

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Conflict of Interest

Confidentiality

POL001

3.3

(Always refer to the Intranet to check the validity of this document)

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(on behalf of the Executive Board)

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 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. Conflict of interest

This policy is applicable to all EORTC staff investigators and officers 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, EORTC 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 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 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 staff, 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 / Clinical investigators

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 Clinical Investigators - Conflict of Interest / Confidentiality Disclosure Form” (Ref.: FO3103) and send it to the chairman of the EORTC data center IRB 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 EORTC Study Coordinators - Conflict of Interest / Confidentiality Disclosure form

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 Study Coordinators - Conflict of Interest / Confidentiality Disclosure form” (Ref.: FO3105) and send it to the PRC secretariat. 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 staff

All staff members of EORTC will be requested to complete the “EORTC Staff - Conflict of Interest / Confidentiality Disclosure form” (Ref.: FO3104) and send it to the human ressources manager where it will be kept on file after discussion with the DG. 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.

3.1.4. EORTC Officers

Members of the general assembly and EORTC Committees (Quality Assurance Commitee, Translational Research Advisory Committtee, New Drug Advisory Committtee, Institutional Review Board, Sscitific Audit Committee, Indepedant Data Monitoring Committee, Protocol Review Committee) have to complete the “EORTC Officers - Conflict of Interest / Confidentiality Disclosure form” (Ref.: FO3102) and the “EORTC Group Chairmen - Conflict of Interest - Confidentiality - Commitment Statement “ (Ref.: FO3101) and send it to the EORTC Director General. 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 the “EORTC Officers - Conflict of Interest / Confidentiality Disclosure form” (Ref.: FO3102) and send it to the Chairman of EORTC IRB. 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. Specific scientific experts

Scientists and experts acting as external advisors or reviewers for EORTC Committees have also to submit a specific Conflict of Interest form. These are scientists consulted on behalf of the "EORTC Scientific Audit Committee (SAC) - Conflict of Interest / Confidentiality Disclosure form" (Ref.: FO3106) of the "EORTC Protocol Review Committee (PRC) - Conflict of Interest / Confidentiality Disclosure form" (Ref.: FO3107). Permanent members of the PRC may have to fill the form (Ref.: FO3107) when a specific conflict may arise for a given project. Members of the Independant Data Monitoring Committee have, in addition to the "EORTC Officers - Conflict of Interest / Confidentiality Disclosure form" (Ref.: FO3102) to sign the "EORTC Independent Data Monitoring Committee (IDMC) - Conflict of Interest / Confidentiality Disclosure form" (Ref.: FO3108) for each protocol they review.

3.1.6. 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 and, in general, to anyone who does not have a specific need to know.

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. 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 in which possible conflicts of interest are mentioned and will make recommendations 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. 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 EORTC staff members

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

8. 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 breeches 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.