

## Conflict of Interest, Bribery and Confidentiality

POL001

Version 4.3

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## 1 PURPOSE

This policy defines areas of potential conflict of interest and identifies when disclosure of interests should be provided to ensure appropriate level of transparency and 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. For example, where he/she 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. Moreover, it is important to ensure the adequate level of transparency about interests at stake, enabling EORTC to evaluate if interests declared constitute a conflict of interests with the scope of specific activities to be performed. This policy was established to address such concerns.

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

This policy shall be considered together with relevant parts of the EORTC code of ethical conduct.

## 3 SCOPE

This policy is applicable to EORTC Headquarters staff, members (specifically investigators and 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.

## 4 CONFLUICT OF INTEREST

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

Based on the nature and gravity of the conflict, in the view of the activity to be performed and the scope of potential impact, 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.

When required EORTC may share disclosures provided and its conclusions with other organizations, such as EORTC partners, collaborators and subcontractors, ethical committees or competent authorities.

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:** Refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising one's professional judgment in the scope of activities performed
- ◆ **Bribery:** 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.

## 4.2 Types of interests

There are several types to interests due to be disclosed.

### 4.2.1 Professional Interest

The individual has played a substantial role in the previous development of the product or technology (past three years only).

The individual has a substantial ongoing or past ((past three years only) 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 Advisor, 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.

### 4.2.2 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 any ownership interests, salary, stock options, or other financial interests whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded sponsor company that exceeds \$50,000 (€40,000 equivalent).

### **4.2.3 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.

## **4.3 Relations with commercial entities**

All EORTC activities supported by pharmaceutical and/or medical device industries or other commercial entities must be negotiated, approved, and implemented in accordance with EORTC procedures. 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.

## **4.4 Disclosure of interests**

Interests are disclosed prior to any applicable activity upon request of EORTC in compliance with this policy and EORTC procedures. It is the responsibility of the individuals to promptly notify the EORTC of any subsequent changes in the declaration of interest(s).

### **4.4.1 EORTC investigators**

Disclosure of interests is mandatory for all participating investigators before any new study is activated. 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.

### **4.4.2 EORTC Study Coordinators**

Prior to developing the full protocol the Study Coordinator is requested to disclose eventual interests. Conflicts which develop during the conduct of the study of the research product or during the dissemination of results must be spontaneously disclosed.

Study coordinators 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.

### **4.4.3 EORTC Headquarters staff**

All staff members of EORTC Headquarters will be requested to declare interests 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 update the disclosure will be sent to the staff every three years.

EORTC staff may be invited to scientific events or advisory boards, driven by the commercial sector. Participation to these events and activities may be considered, pending prospective disclosure, assessment and confirmation of non-interference with any of the EORTC activity according to this policy.

However, financial or any valued benefit resulting from these activities 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.

The EORTC will not advertise directly or through web links for commercial events such as conferences. 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.

#### **4.4.4 EORTC Officers and members of committees**

Members of the General Assembly and members of all EORTC Committees are requested to declare relevant interests at time of taking office.

The Statement must be updated when significant changes 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 make separate declarations of interests for each protocol they review.

### **4.5 Review of disclosure statements & actions on conflict of interest**

Declared interests are addressed to the EORTC International Policy Office (IPO) who manages them on an ongoing basis by deciding whether interests declared constitute any conflict in the view of activities performed. In case of perception of a conflict, EORTC IPO in consultations with EORTC director general decides on actions to be taken. EORTC IPO maintains the record of interests declared and decisions made and reports it yearly to the EORTC IRB.

## **5 BRIBERY**

EORTC strictly prohibits improper payments in any of its business operations, whether they involve government officials or commercial/personal relationships. Such activities can expose individuals and the EORTC to possible criminal prosecution, reputational harm or other serious consequences. This prohibition applies whether the offer or payment is made directly or through another person.

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

Specifically EORTC members or staff will not convey information or data to the firms, except as permitted and approved in the contract negotiated with the firm and EORTC.

\* 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.

## 7 PENALTIES FOR FAILURE TO OBSERVE THIS POLICY

Failure to disclose a relevant interest or to respect the anti-bribery policy or 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 Director General of the EORTC for action.

## 8 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial Release	Richard Sylvester	January 1998
2.0		Patrick Therasse	August 1998
2.2		Patrick Therasse	November 1998
3.0		Patrick Therasse	November 2002
3.1	Transfer to new template; no further modifications	Patrick Therasse	14 Feb 2005
3.2	Minor changes; Change of SOPs author and approver	Denis Lacombe	06 Sep 2006
3.3	Minor changes; Implementation of detailed forms for Conflict of Interest	Denis Lacombe	16 Oct 2006
4.00	Clarification of the disclosure and review process. Adapt version number to two decimal digit.	Françoise Meunier	12 Jul 2012
4.1	Add participation of EORTC staff to scientific events including those driven by the commercial sector.	Denis Lacombe	4 Jun 2015
4.2	Deletion of the associated documents following update of the related AFs	Anastassia Negrouk	16 Mar 2017
4.3	Clarifications for declaration of interests and confidentiality and crystallization of the anti-bribery policy	Anastassia Negrouk	15 Jun 2018