

## EORTC Publications Involving Headquarters Staff

ST-007-SOP

Version 1.1

ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

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# 1 PURPOSE

To describe the process by which all publications of EORTC study results or other EORTC publications co-authored by EORTC Headquarters (HQ) staff are reviewed by EORTC HQ staff, and how they are documented and archived at the HQ. The document also clarifies how the rules set in EORTC POL009 "Disclosure of Results and Publication Policy" for attributing authorship among HQ staff apply in the event that the staff change position or leave EORTC HQ during the research.

# 2 SCOPE

The present document applies to all publications co-authored by HQ staff.

# 3 POLICY

Each publication involving HQ staff must fulfil the requirements stipulated in Chapters 7, 8 and 9 of EORTC POL009 "Disclosure of Results and Publication Policy".

# 4 DEFINITIONS

- ◆ **Publication:** any public release or dissemination of study results (abstracts, oral presentations, posters, full length article, chapters in books, press release) or disclosure of any confidential information, including but not limited to intellectual property; or when not pertaining to study results any article written on behalf of the EORTC that is intended to be made available to the general public. .
- ◆ **HQ Review Coordinator:** the statistician in charge of the analyses, however, in some circumstances when the paper does not heavily involve a statistician (for example when a publication does not involve trial data at all), the HQ staff with the strongest leadership on the publication in question (under the supervision of his line manager, as applicable).

# 5 PROCEDURE

## 5.1 Review of the manuscript

Upon preparation of a manuscript, the HQ study statistician and CRP review the manuscript, or if the manuscript does not involve statistical analyses, the co-authors from HQ review the manuscript (in case of single author publication, the manuscript is reviewed by the line manager). The manuscript Review Coordinator dispatches the manuscript to the other team members and takes the lead until it is published.

The study team members take the following actions:

### 5.1.1 The HQ Review Coordinator

- ◆ Whenever the study involves results produced at HQ, ensures that the preparation of a draft manuscript by the designated first author is within the timelines specified in EORTC POL009. In case of prolonged delay, informs the EORTC Group Officers to take appropriate actions to ensure that the study results are published.
- ◆ Verifies that the list of authors of a draft manuscript complies with EORTC POL009. When applicable, verifies that it also complies with the Group statutes and the study protocol and verifies that the list of authors is approved by the relevant EORTC Group Officers, if any.

- ◆ Produces the list of acknowledgements of the authors of the study and verifies that it conforms to POL009 (with the help of the HQ team as appropriate)
- ◆ Ensures that the sources of funding and supporting bodies are appropriately acknowledged and conform to the specifications provided by the Communications Office.
- ◆ Submits the draft article (including the publication title, full list of authors, EORTC study number, and the name of the journal to which the article will be submitted) to the Communications Office for review and approval of the acknowledgements. It is also helpful for the Communications Office to know if other article(s) related to the same study/project of the upcoming article, was/were already published in the past (to be consistent with the acknowledgements paragraph).
- ◆ Ensures that "EORTC" is sufficiently visible in the publication (in the title or in the list of authors). Affiliation of authors should be: Author's name, EORTC Headquarters (*no department cited*), Brussels, Belgium
- ◆ Coordinates the review of the draft manuscript by the HQ staff involved and, whenever appropriate, by pharmaceutical company representatives through the Project Manager.
- ◆ Verifies that the first author distributes the manuscript for review and approval by all co-authors. If needed, takes the actions needed for this review to take place.
- ◆ Reviews and approves the final version of all publications.

### **5.1.2 The Statistician**

- ◆ Ensures that the statistical methods used are appropriately described in the "Methods", that the reported results conform to the Final Analysis Report, and that the conclusions of the "Discussion" and the abstract are supported by the data.
- ◆ Reviews and approves the final version of all publications that involve statistical analyses.

### **5.1.3 The Clinical Research Physician**

- ◆ Ensures that the manuscript reflects the study results with particular attention to the safety.
- ◆ Reviews and approves the final version of all publications.

### **5.1.4 The Project Manager**

- ◆ Whenever applicable, submits draft manuscript to pharmaceutical companies or collaborative Groups involved in the study, obtains their comments, and forwards the comments to the HQ Review Coordinator.

### **5.1.5 The Communications Office**

- ◆ Upon receipt of a new manuscript, reviews the acknowledgement section with the EORTC General Director and provides the list of funding bodies to acknowledge in the publication.

### **5.1.6 Other study team members involved in the publication, as appropriate**

- ◆ Review the manuscript and provide feedback to the HQ Review Coordinator.

## **5.2 Submission, acceptance and publication**

### **5.2.1 The HQ Review Coordinator**

- ◆ Informs the Communications Office (mail To: [Communications@eortc.be](mailto:Communications@eortc.be)) of the initial submission of any article to a journal.
- ◆ Immediately upon acceptance of the article for publication informs the Communications Office of the final reference and the expected publication date and provides them with an electronic copy of the publication as soon as it becomes available (proofs, ePub) so that they can prepare press releases as needed.

### **5.2.2 The Project Manager**

- ◆ Communicates the reference of the publication and the electronic copy and full-length article to all study participants and to any third party involved with the study (collaborative Groups or pharmaceutical companies).

### **5.2.3 The Communications Office**

- ◆ Upon effective publication of the article, the Communications Office updates the Bibliography Database by completing the reference for the publication (authors, title, journal, issue number, pages, date, DOI link) and obtains an electronic copy of the publication (via the Statistician, via an online access or via an external library). This process allows the Communications Office to potentially write a Press Release that could appear simultaneously with its online publication.
- ◆ Maintains the central database of EORTC publications and the central EORTC Bibliography.
- ◆ Ensures appropriate central storage of the publication.

## **5.3 Rules for attributing the authorship positions to the HQ staff, when they change position or leave the HQ during the study**

### **5.3.1 The study Statistician is being replaced**

Whenever the study Statistician is replaced while a publication is being prepared or submitted, he/she will keep his/her position as an author on the paper if he/she performed the final analysis, took responsibility for the analysis report, and was involved in the preparation of a least a first draft of the resulting paper. In that case, the staff member taking over the project will contribute to the finalization of the paper and its submission but will not necessarily be an author; he/she will be listed in the acknowledgements section.

Whenever the above conditions are not fulfilled, the Statistician completing the work on the study will be listed as a co-author according to the rules delineated in the earlier chapters, and the former Statistician will not be a co-author. His/her name will be listed in the acknowledgements section.

### **5.3.2 Other staff members are replaced**

Whenever other HQ staff members who would normally be co-authors (e.g. Clinical Research Physician) on a paper are replaced on a project before the paper is accepted for publication, the following rules will apply:

If the staff member was the leader of the project or the leading force behind the project or if he/she contributed to the draft paper, he/she will retain authorship in the position that he/she had been attributed at the time he/she was replaced on the project. The new staff member who takes over will not be included as co-author, especially if he/she did not have a major input to the publication but will be listed in the acknowledgements.

In cases where the replaced staff member did not contribute to the extent listed above (e.g. in case of contribution to only the design of the project), but a new staff member with similar qualifications and position takes over his/her position and becomes the leader of the project or the leading force behind the project, or if he/she makes a major contribution to the publication, that person will be listed as co-author and the replaced staff member will be listed in the acknowledgements section.

In cases where neither the replaced staff member nor the new staff replacing them did not contribute to the extent listed above (e.g. in case of contribution to only the design of the project), both of them will be listed in the acknowledgement section and the authorship position will be attributed to another EORTC HQ staff member, if any, who contributed more extensively to the project (e.g. a fellow who was heavily involved in with the project or the Data Manager or Project Manager of the study).

In case of disagreement, the decision will be made jointly by the Head of the Department to which the staff members belonged and by the first author, with the help of the author of the present policy, in case agreement is difficult to achieve or if the Head of Unit/Department and first author is a same person.

## **5.4 Acknowledgement of sources of funding and supporting bodies**

The following phrases will be used to acknowledge the sources of funding and supporting bodies in EORTC publications

### **5.4.1 Academic studies with no or partial support from industry**

For academic studies, all publications emanating under the EORTC label for an EORTC study should indicate the following acknowledgements:

- ◆ Whenever specific grants were attributed to the study or research, by pharmaceutical companies to the support of the study, these must also be acknowledged:

*“ We are grateful to (PharmaCompany/Other funding source) for supporting this study through an Educational Grant”*

- ◆ Whenever free drugs were offered by a pharmaceutical company, the acknowledgement section should indicate *“We are grateful to PharmaCompany for providing drug name for this study”*.

- ◆ Some studies are supported in full or in part by the EORTC Academic fund or by other EORTC grants. For these, the following acknowledgement should be included:

*“The authors and co-authors acknowledge the financial support to this work provided by the EORTC Board.”*

- ◆ For studies that received NCI funding since 2012 (EORTC 26081 and 40084), NCI must be acknowledged with the following statement, where the NCI grant numbers cover the years during which NCI supported the study (NCI grant numbers are available on EORTC Intranet).

*“This publication was supported since 2012 by grant(s) number ..... (through .....) from the US National Cancer Institute (Bethesda, Maryland, USA) Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Cancer Institute”.*

- ◆ If the National Cancer League from the country of residence of the primary author publication provided core support to the EORTC in the year preceding the publication, it should also be acknowledged. This information is supplied by the Communications Office (List of National leagues supporting EORTC is available on EORTC intranet).

This publication was supported by a donation from the "Cancer League" from "Country of residence of the first author" through the EORTC Cancer Research Fund

*"This publications was supported by Fonds cancer (FOCA) from Belgium"*

Either the Fonds Cancer (FOCA) or the EORTC Cancer Research Fund (depending on who from HQ is a co-author on the publication) should also be acknowledged unless a pharmaceutical company is also acknowledged for having fully supported the study. This information is provided by the Communications Office.

- ◆ If an EORTC fellow contributed to the publication, further acknowledgment is required (see section 5.4.3)
- ◆ If a publication is related to a specific grant or donation, the source of funding should be acknowledged. Communications Office maintains the list of projects and will be able to provide the accurate information.

#### **5.4.2 Academic studies fully supported by the pharmaceutical industry**

For EORTC studies that were fully supported by a pharmaceutical company, only the pharmaceutical support should be acknowledged:

*“We are grateful to PharmaCompany for supporting this independent EORTC study.”*

#### **5.4.3 Publications written or co-authored by EORTC Fellows**

For publications written or co-authored by EORTC fellows, the acknowledgement section must disclose the support from the Fellowship Program. For example:

*“Fellow-name’s work as Fellow at EORTC Headquarters was supported by a grant from Source of the Grant”*

## **6 FILING AND ARCHIVING**

The PDF version of the publication is centrally filed by the Communications Office and follows the regular backup as per EORTC procedure.

## 7 RACI MATRIX

Functions Activities	HQ Review Coordinator	CRP	HQ staff co-author of the publication	Comm Office	EORTC Group co-authors	Stat	PM
Review of manuscript	A	C	R	C	C	C	
Submission, acceptance & publication step	A		R	R			
Distribution of manuscript to co-authors & third parties							A
Central filing				A			
R: responsible; A: accountable; C: consulted; I: informed. Use 'A' when 'A' and 'R' are assigned to the same person.							

## 8 REFERENCES

International Committee of Medical Journal Editors (Vancouver Group) - Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>)

Revised CONSORT statement (<http://www.consort-statement.org>)

## 9 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
Disclosure of Results and Publication Policy	POL009

Policies are available from Intranet, documentation section, Electronic Library of Quality Standard Documents page and from EORTC website.

## 10 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial release; superseding ST-007-WIN-01 v 1.1	Laurence Collette	19 Mar 2015
1.1	Clarification in section 5.2.1. Update “Charitable Trust” into Cancer Research Fund”. Clarification of the PM role in the RACI matrix.	Laurence Collette	20 Apr 2015

1.1	No change	Laurence Collette	24 May 2018
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