



AISBL International Non-Profit Association under Belgian law IVZW

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Release of data from EORTC studies for use in External Research Projects

POL008

Version 2.0

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

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1 PURPOSE

To define the terms and conditions under which individual data from all or a subset of the patients treated within EORTC protocols may be released to academic institutions for the purpose of scientific research projects.

This procedure applies to all academic researchers wanting to use for their research, individual patient data from EORTC studies the primary results of which were already published. Only requests for data existing in the EORTC central database are covered by this document, requests for further data collection and transfer of data from the EORTC Tumor Bank are not covered.

This procedure does not cover the routine transfer of safety information to regulatory authorities, nor the transfer of data to third parties (collaborative group or pharmaceutical company) as these are the object of trial specific agreements or contracts between the EORTC and the third party.

2 DEFINITIONS

Requestor: the person seeking access to data from EORTC trial(s) for the purpose of carrying out an external research project. This person is also the scientific leader of that research project.

External research project (ERP): an academic research project that intends to use data from all or a subset of patients from one or several EORTC trials

External Research Projects Coordinator: the EORTC staff member responsible for reviewing, approving and following up the external research project

3 POLICY

Our policy builds on the central principles of the Organisation for Economic Co-operation and Development (OECD) in its report “Promoting Access to Public Research Data for Scientific, Economic and Social Development”.

Recognizing that access to international data helps produce a better understanding of public health issues and worldwide disease prevention and control the EORTC makes data from its clinical trials available to other academic researchers. Considering that on-going research contributing to the completion of datasets must not be compromised by premature or opportunistic sharing and analysis of data, the EORTC will not release the data of its trial until the primary trial results have been published.

An investigator who wishes to use data from one or more EORTC studies must make a formal request which is reviewed by the EORTC Coordinator for External Research Project. Specifically the scientific merit and feasibility of each request will be evaluated. Requests will only be considered once the primary study analyses have been published. Any release of data will take into consideration individual patients’ rights to privacy.

4 How to request EORTC Data

4.1 Submission of an ERP by a requestor

To submit a request for using EORTC data, the requestor fills out the EORTC data request form that is accessible on the EORTC web site.

The EORTC coordinator will first check the completeness of the form and may ask the requestor further specifications on the research project via e-mail.

4.2 Review and approval of the ERP request

Once the data request form is complete, the document is sent for approval to the chairperson of the relevant EORTC groups, to the study coordinator of the individual EORTC studies involved and to the named scientist leading the research project (usually the requestor)

The Chairperson of the EORTC Group that conducted the EORTC studies involved in the ERP reviews the scientific value and feasibility of the ERP and sends his/her comments or approval by e-mail addressed to the ERP@eortc.be. Likewise, when contacted, the study coordinator(s) of the studies involved in the ERP sends his/her comments if any, or approval by e-mail to ERP@eortc.be

Once all involved parties have confirmed their approval of the project, the ERP coordinator officially approves the project and informs the requestor and the relevant EORTC Headquarter personnel that the project is approved and that the data release is authorized. The EORTC will then proceed to the transfer of the database to the requestor.

4.3 Data Transfer

Only anonymous patient data will be transferred to the requestor.

The data will be preferentially transferred in the form of an ASCII file (with .dat extension), with associated SAS® programs to load the data into SAS. In case data from several trials are requested. One such set of files will be provided for each trial. If another file format is needed or if specific recoding of (a subset of) variables is needed, this should be clearly indicated in the ERP application form and consideration will be given to providing the files in the desired format, whenever technically feasible for the EORTC.

The data files will be sent by e-mail, in a password protected compressed folder. The password will be sent in a separate e-mail.

If necessary, the EORTC may provide one and only one update of the database during the course of the ERP.

4.4 Follow-up of the project

The Requestor specifies in the ERP request form the anticipated timelines of the ERP.

On a yearly basis, the Requestor (or his/her designee) will inform the EORTC of the progress of the ERP and will update the anticipated timelines whenever required, by e-mail sent to ERP@eortc.be. The update is expected at latest on the anniversary date of the ERP approval. The Requestor will in particular inform the ERP of any publication resulting from the ERP (presentation at scientific congresses, abstracts, full-length articles).

In case full-length articles are prepared, the Requestor will send the draft version by e-mail to ERP@eortc.be within 10 working days before the effective submission to a journal, in order for the ERP coordinator to check the conformity of the publication with the present policy.

In case the Requestor delegates the follow-up of the ERP to one of his/her collaborators, the name and e-mail address of that person must be indicated on the ERP request form.

5 Terms and Conditions

By completing and submitting the ERP request form, the Requestor and his team agree with present EORTC Policy and accept the following responsibilities

5.1 Publication of ERP results, authorship, acknowledgement to EORTC

The following acknowledgement to EORTC will appear in the publication: *“The authors thank the European Organization for Research and Treatment of Cancer for permission to use the data from EORTC trials [list of trial numbers] for this research. The contents of this publication and methods used are solely the responsibility of the authors and do not necessarily represent the official views of the EORTC.”*

Inclusion of EORTC representative(s) (from the group or from the Headquarters) as co-author will be considered for each ERP on a case by case basis. If such an authorship is considered, it will be prospectively mentioned in the ERP request form.

The Requestor should send a PDF copy of the article to ERP@eortc.be within 3 months after publication.

5.2 Confidentiality of data

The EORTC data shared for an ERP are confidential and can only be used for the research described in the approved ERP. The copy of the EORTC data at the Requestor's site must be destroyed after the ERP is completed, except in the case of meta-analyses (for which a permanent meta-analysis database may be maintained and regularly updated).

5.3 Responsibilities of the Requestor

The Requestor takes full responsibility for

- ◆ Submitting the ERP request for data to the EORTC ERP coordinator by completing the (electronic) ERP request form
- ◆ Completing the ERP in compliance with the present procedure
- ◆ Informing the ERP secretary of the progress of the ERP on a yearly basis, with documentation of any publication (abstract, articles). The update is expected at the latest on the anniversary date of the ERP approval.
- ◆ Submitting the draft version of eventual full-length publications to the ERP secretary within 10 working days of the effective submission
- ◆ Ensuring the confidentiality of the EORTC data

- ◆ Destroying the local copy of the EORTC data at completion of the ERP, unless the ERP is a meta-analysis, in which case EORTC may agree not to request data base destruction.

6 REFERENCES

Document title	Reference (file name or path)
OECD Principles and Guidelines for Access to Research Data from Public Funding	http://www.oecd.org/dataoecd/9/61/38500813.pdf (last accessed August 22. 2008)

7 DOCUMENT HISTORY

REVISION HISTORY			
Version N°	Brief Description of Change	Author	Effective Date
1.0	Initial Release	Laurence Collette	
1.1	<p>Changed MA into CP.</p> <p>Clarified responsibilities in first paragraph of 4.2.2.</p> <p>Added references to WP6301.</p> <p>Added exception to database destruction in case of Meta-analysis.</p> <p>Added acknowledgement to EORTC and disclaimer</p>	Laurence Collette	June 2, 2004
2.0	<p>Changed to new template, cleared the document of procedural aspects internal to the EORTC Headquarters (now covered by ST-008-SOP), implemented web-based submission of projects</p>	Laurence Collette	March 2, 2009