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## Data Sharing

POL008

Version 3.0

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 electronic records of individual data from all or from subsets of the patients from EORTC studies may be shared with other organizations or individual researchers for the purpose of scientific research projects or may be posted on data repositories.

## 2 SCOPE

This policy applies whenever electronic records of individual data from all or from subsets of the patients from EORTC studies are shared with individual researchers not employed by EORTC Headquarters or with other academic or non-academic (including for profit) organizations; except for the routine safety reports to authorities and for contractually agreed data transfers to third parties during the course of a trial.

This policy does not apply when data of their own patients are transferred back to an EORTC site or when data of the patients from an academic Group that contributed to an intergroup study managed at EORTC are transferred back to that Group, since this requires no specific approval beyond the study intergroup agreement.

The shared data may include data generated from EORTC translational research projects. However, only requests for data available to the EORTC Headquarters are covered by this policy. Requests for access and use of Human Biological Material (HBM) are covered by a separate policy (EORTC POL020).

Requests for additional data collection usually require further ethical committee and/or other regulatory bodies to review the project and may also require obtaining additional patient consent and/or authorization. Consequently, the information obtained is often incomplete. Retrospective collection of data is expensive and time consuming for the EORTC. Therefore, requests for projects necessitating further data collection must be submitted for review to the EORTC using the appropriate channels (see Policy 016).

## 3 DEFINITIONS

- ◆ **Coded data:** Refers to the result of the process of replacing personal identifiers linked to data or HBM by a code for confidentiality and privacy reasons (also, known as "linked anonymized" or "pseudonymized"). To be distinguished from "anonymized" that refers to when the link between the data and human biological material is irreversibly broken.
- ◆ **EORTC data:** All and any electronic records of human clinical and biological data (included but not limited to genetic, any -omic or other molecular data) or centrally stored imaging data in Digital Imaging and Communications in Medicine (DICOM) file format obtained from patients entered in EORTC studies; i.e. individual patient data. Data does not include human biological material samples. As EORTC works exclusively with coded data, the term "EORTC data" in the present document refer exclusively to coded EORTC data.
- ◆ **Data applicant:** The person seeking access to EORTC data.
- ◆ **External research project (ERP):** A research project that uses EORTC data, the statistical analyses and publications of which are not centralized at the EORTC Headquarters, and thus requires these data to be released outside EORTC Headquarters.
- ◆ **EORTC Research project (EORTC-RP):** An EORTC research project that uses EORTC data and the statistical analyses and publications of which are centralized at the EORTC Headquarters but that may require that data be released outside EORTC Headquarters to partner researchers or research organizations.

- ◆ **Data Sharing Coordinator:** The EORTC staff member responsible for reviewing, approving and following up the data sharing agreements.
- ◆ **Data Access Committee (DAC) Coordinator:** The EORTC Headquarters staff member who is member of the different EORTC DACs. He/she is responsible for executing the decisions of the ODAC regarding EORTC genetic, any -omic and other molecular data stored on access controlled external repositories and approve the posting of data by investigators on public repositories. He/she is also responsible for following-up the decisions of the IDAC regarding the release of EORTC images stored on access controlled imaging platforms in relationship with the EORTC Headquarters expert in imaging translational research.
- ◆ **EORTC OMICS Data Access Committee (ODAC):** The EORTC DAC responsible for making decisions regarding the access to EORTC genetic, any -omic and other molecular data that are stored in access controlled external repositories and for granting authorization to post data on public repositories. Inside the EORTC Headquarters, the ODAC functions under the hierarchical supervision of the Medical Director and it reports to the chair of the Translational Research Committee at the EORTC organization level. The ODAC is composed of at least the DAC Coordinator, the Head of the EORTC Translational Research, radiotherapy, and imaging department (or delegate) and at least one more staff member from the Translational Research, Radiotherapy, and Imaging department of the EORTC Headquarters.
- ◆ **EORTC Imaging Data Access Committee (IDAC):** The EORTC DAC responsible for making decisions regarding the access to EORTC radiological images that are stored in access controlled imaging platforms. Inside the EORTC Headquarters, the IDAC functions under the hierarchical supervision of the Medical Director and it reports to the chair of the Translational Research Committee at the EORTC organization level. The IDAC is composed of at least the DAC Coordinator, the Head of the EORTC Translational Research, radiotherapy, and imaging department (or delegate) and at least one more staff member from the Translational Research, Radiotherapy, and Imaging department of the EORTC Headquarters.

## 4 POLICY

EORTC is committed to ensuring that the data generated from its studies be put to good use by the cancer research community and, whenever possible, are translated to deliver patient benefit.

It is therefore EORTC's policy to consider for sharing upon request from qualified scientific and medical researchers all data generated from its research whilst safeguarding intellectual property, the privacy of patients and confidentiality.

Considering that ongoing 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 study until the primary study results have been published; unless authorization for release has been granted according to the terms of EORTC Policy 009.

Whilst EORTC complies with the OECD Principles and Guidelines for Access to Research Data from Public Funding and with the National Institutes of Health Final Statement on Sharing Research Data released on February 26, 2003; it is committed to do so within the limits needed to guarantee the protection of personal data in accordance with the EU data protection rules and other applicable European legislation.

Upon explicit approval of EORTC, coded individual patient data that were generated in the framework of translational research studies may be deposited in online public repositories or databases with or without restrictions on access. Authorization for posting data will be granted by the ODAC according to the type and

level of the data, and the potential risk associated to the data release. Restricted controlled access to the posted data will then be under the management of the ODAC, unless a specific process/committee exists for the repository to which the ODAC would already have delegated responsibilities. EORTC also reserves itself the right to refuse sharing of data if it judges that the data repository in question does not offer sufficient system protection.

## **5 HOW TO REQUEST EORTC DATA**

Data applicants are required to submit a research proposal to document the legitimacy of the research question and the qualifications of the requestor.

Research proposals should include, and will be evaluated against the following: a description of the data being requested, including the hypothesis to be tested; the rationale for the proposed research; the analysis plan; a publication and posting plan; qualifications and experience of the proposed research team; and the source of any research funding.

Some projects that are performed outside the premises of the EORTC Headquarters and thus require data sharing are however conducted in close collaboration with EORTC Headquarters staff or EORTC Groups, so that the resulting publication(s) will be co-authored by an EORTC staff and/or be published on behalf of EORTC. Such circumstances must be declared upfront in the data submission form so that appropriate terms of use are agreed upon upfront. EORTC may also request to be associated to the research when it finds it relevant.

Whenever this was not agreed upfront, and/or there is no EORTC co-author, but the publication appears 'on behalf of EORTC' or if "EORTC" appears in the title, then the use of that mention will require an additional approval from EORTC to modify the initially agreed terms of use.

Instructions and a request form are available at <http://www.eortc.org/investigators/data-sharing/>. All questions concerning EORTC data sharing should be addressed to [DataSharing@eortc.be](mailto:DataSharing@eortc.be).

## **6 REVIEW AND APPROVAL OF DATA ACCESS REQUESTS**

Review of the requests by the relevant EORTC bodies is coordinated by the Data Sharing Coordinator.

The scientific merit of each specific request will be evaluated as well as its feasibility: whether there is sufficient data to provide adequate information for analysis, the availability of the required data and the potential costs. Any release of data will also consider individual patient's rights to privacy.

The authorization for release will be granted by the Data Sharing Coordinator once all reviewers (detailed in the sections below) have approved the request, and provided legal and contractual agreements allow it. In case of disagreement among study coordinators and/or steering committees of the studies for which data is requested, the chairpersons of the EORTC groups who conducted the trial will arbitrate their positions.

EORTC reserves itself the right to deny access to data if similar research is already being conducted by EORTC itself.

The EORTC will notify the data applicant of the final decision by e-mail within two (2) months of the application and will inform of the reasons for rejection, whenever data access is not granted.

The timing of the data release will be decided by the study statistician for the databases located at EORTC Headquarters.

The timing for granting access to genetic, any -omic and other molecular data stored on access controlled external depositories, and to images stored on access controlled imaging platforms will be decided by the DAC Coordinator in order to maintain the study integrity, in accordance with EORTC POL009.

The possibility of transferring any EORTC data will be checked against the terms of the Patient Informed Consent.

The review process is adapted to the nature of the data that is requested, of the research purpose and of whether the data applicant is from academia as explained below.

## **6.1 Release of data for projects not yet approved by EORTC**

The proposal will be reviewed by the steering committee or study coordinator of the studies for which data is sought and by the chairpersons of the EORTC groups who conducted the trial; by the study statistician(s), and by the EORTC Data Sharing Coordinator, as well as by the EORTC staff or EORTC members that are identified as future co-authors of the resulting publication(s).

Whenever the request concerns data from the quality of life studies (field studies and the like) the proposal will be approved by representatives of the Quality of Life Group through the Quality of Life Unit (see 6.6).

Additionally, when such requests involve EORTC genetic, any -omic or other molecular data stored on access controlled external repositories or EORTC images stored on access controlled imaging platforms, review and approval of the ODAC or IDAC, respectively, is also needed.

Finally, release of data collected in a clinical or translational research study conducted under a binding agreement between EORTC and a pharmaceutical/biotechnology company must be in compliance with the terms of this agreement and must be approved by both EORTC and the company.

The terms of use in Section 7 apply.

## **6.2 Release of data for projects already approved by EORTC**

Specific projects linked to EORTC studies or research projects for example but not limited to translational research projects may involve sending clinical data to other locations, such as to the institution performing the lab work, for analysis. As such, the necessary data exchanges required for conducting such projects may be already approved by the EORTC.

If the specific data required and a summary of the analysis plans were clearly described in the study protocol approved by EORTC then data requests for these projects will be approved without further scientific review. The terms of use in Section 7 still apply.

If the specific data required and a summary of the analysis plans were clearly described in a research project that was already approved by EORTC Translational Research Advisory Committee or if the data request concerns data release related to an EORTC-RP then the data request will be approved without further scientific review. The terms of use in section 7 still apply

Additionally, when such requests involve EORTC genetic, any -omic or other molecular data stored on access controlled external repositories or EORTC images on access controlled imaging platforms, review and approval of the ODAC or IDAC, respectively, is also needed.

The terms of use in Section 7 apply.

If the requested data or the planned analyses go beyond what EORTC has already agreed then the request must be reviewed by the EORTC, as described in Section 6.1 above.

### **6.3 Requests for data sets to use for illustration of statistical methodology**

Requests for data sets to use for illustration of statistical methods in papers intended for publication in the statistical literature follow a simplified path. The Data Sharing Coordinator will assess with the Heads of the statistics department if the data set appears to be appropriate for the project. If so, the Data Sharing Coordinator can approve the request without further review. However, when such requests involve data from studies fully supported by a pharmaceutical company, the necessary approval from the company will be obtained, in accordance with the contractual agreements between EORTC and that company.

The study coordinators of the studies involved and the chairpersons of the EORTC groups who conducted the trial(s) will be informed that the data is being used for that purpose.

The terms of use in Section 7 still apply.

### **6.4 Requests for accessing only genetic, any -omic and other molecular data that are stored on access controlled external repositories**

Such requests will be handled through ODAC which will seek approval of the relevant trial steering committee.

Whenever the request also covers other type of data centrally stored at the EORTC Headquarters, the approval process specified in 6.1 additionally applies.

The terms of use in Section 7 still apply.

### **6.5 Requests for accessing imaging data in DICOM file format**

Such requests will be handled through the IDAC which will seek approval of the relevant trial steering committee.

Whenever the request also covers other type of data centrally stored at the EORTC Headquarters, the approval process specified in 6.1 additionally applies.

The terms of use in Section 7 still apply.

### **6.6 Requests for accessing data of Quality of Life studies**

Such requests will be handled through the EORTC Quality of Life department which will seek approval of the QLG Group steering committee and the study PI.

Whenever the request also covers other type of data centrally stored at the EORTC Headquarters, the approval process specified in 6.1 additionally applies.

The terms of use in Section 7 still apply.

## 6.7 Requests from commercial entities or with commercial purpose

Requests emanating from non-academic researchers or from for-profit organizations will follow the review path described in sections 6.1 to 6.5 above. They will additionally be reviewed by the EORTC Directors. Fees may apply and will be calculated on a case by case basis. The feasibility of transferring the data for non-academic research will also be checked against the terms of the Patient Informed Consent.

## 7 TERMS OF USE

Upon submission of the request, the data applicant must agree to the [Terms of Use](#) specified in the application form

The EORTC must be acknowledged for sharing the data for the research. Unless an EORTC staff is co-authoring the publication or if it was agreed upfront that the publication would be "on behalf of EORTC" or as "EORTC research", the publication must contain the following disclosure "*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*".

Additionally, for all projects, the data applicant commits to provide EORTC with references of any publication resulting from research that used EORTC data within two (2) months of the publication; unless the publication is made "on behalf of EORTC" or if "EORTC appears in the study title" in which case the data applicant must submit the publication to [DataSharing@eortc.be](mailto:DataSharing@eortc.be) prior to presentation and/or submission of the results for publication.

EORTC reserves itself the right to request the establishment of a formal contract in addition to the above terms of use, when sharing particularly sensitive data and/or for requests in the scope of section 6.5.

## 8 TERMINATION OF THE AGREEMENT

The data applicant must notify EORTC of the completion of the project. This is best done by an email addressed to [DataSharing@eortc.be](mailto:DataSharing@eortc.be).

EORTC reserves itself the right to cease data sharing agreements upon breach of the agreed terms and conditions for use.

Requests for extension of existing data sharing agreement must be requested online using the data request form (see section 5). The data request must clearly stipulate that the demand is an extension of an existing agreement and provide reference to that former agreement. Review and approval of extensions follow the rules specified in section 6 above.

## 9 QUESTIONS

Questions regarding the present policy or data sharing should be addressed by email to [DataSharing@eortc.be](mailto:DataSharing@eortc.be).



## 10 REFERENCES

- ◆ OECD Principles and Guidelines for Access to Research Data from Public Funding; <http://www.oecd.org/dataoecd/9/61/38500813.pdf> (last accessed March 26, 2015)
- ◆ [National Institutes of Health Final Statement on Sharing Research Data](#) released on February 26, 2003;
- ◆ [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/) (last accessed March 26, 2015)

## 11 DOCUMENT HISTORY

Version number	Brief description of change	Author	Issue date
1.0	Initial Release	Laurence Collette	October 2001
1.1	Changed MA into CP. Clarified responsibilities in first paragraph of 4.2.2. Added references to WP6301. Added exception to database destruction in case of Meta-analysis. Added acknowledgement to EORTC and disclaimer	Laurence Collette	02 Jun 2004
2.0	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	Laurence Collette	02 Mar 2009
2.1	Included release of data involving biological material and simplified process for projects endorsed by EORTC. Added the statement regarding "breach of policy". Clarified requirements for submission of publications (incl. Abstracts)	Laurence Collette	19 Oct 2010
2.2	Expanded the scope of chapter 4.2.3 to all projects that are part of the objectives of a protocol, irrespective if they involve or not biological material from the patients.	Laurence Collette	15 Nov 2011
2.03	Clarified introduction section. Replace Translational Research Unit by Translational Research Team. Increased time for review of full papers from 10 to 15 days.	Laurence Collette	07 Mar 2012
2.3	EORTC Executive Committee updated into EORTC Board.	Laurence Collette	06 Mar 2015
3.0	Rename the policy "Data Sharing policy", rename ERP coordinator to Data Sharing Coordinator and generalize it to cover all data sharing including genetic, any -omic or other molecular data, imaging data, and data released for IRPs. Update of references to more recent references. Move details of approval to the SOP.	Laurence Collette	03 Oct 2016