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Data Sharing

ST-008-SOP
Version 2.0
ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

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Authorized by: *Director General* Denis Lacombe	Signature:	Date: 3 Oct 2016

1 PURPOSE

To describe the process of review, approval, documentation and release of electronic records of individual data from all or from subsets of the patients from EORTC studies requested by other organizations or individual researchers for the purpose of scientific research projects.

It also describes the follow-up of such projects.

2 SCOPE

This procedure applies whenever electronic records of individual data from all or from subsets of the patients from studies where data are available at EORTC HQ and where they are shared with individual researchers not employed by EORTC Headquarters (HQ) 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 procedure does not apply when data of their own patients are transferred back to that 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 HQ are covered by this policy. Requests for access and use of Human Biological Material (HBM) are covered by 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, Policy 005 as appropriate).

This procedure also covers data posted on public data depositories.

3 POLICY

This procedure follows the EORTC Policy 008 on "Data Sharing".

4 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.

- **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 HQ but that may require data to be released outside EORTC HQ to partner researchers or research organizations.
- **External research project (ERP):** A research project that uses EORTC data, and which is neither a study, nor an EORTC-RP, and thus requires individual patient data to be released outside EORTC HQ.
- **Data Sharing Coordinator**: The EORTC staff member responsible for reviewing, approving and following up the data sharing requests.
- **Data Sharing Secretary**: The EORTC staff member responsible for the filing of the data sharing requests and approvals.
- **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 HQ, 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 Clinical Leader member of the Translational Research, radiotherapy, and imaging team and at least one more staff member from the Translational Research, Radiotherapy, and Imaging team.
- **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 HQ, 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 Clinical Leader member of the EORTC Translational Research, radiotherapy, and imaging team and at least one more staff member from the Translational Research, Radiotherapy, and Imaging team.
- **Data Access Committee (DAC) Coordinator**: the EORTC HQ staff member who is member of the different EORTC DACs. He/she is responsible for executing and following-up the decisions of the ODAC and IDAC.

For each data sharing request, the following is defined:

- **Data Applicant:** The scientific leader of the scientific research project seeking access to EORTC data.
- **Internal Contact:** The person at EORTC HQ responsible for the transfer or release of EORTC data to the data applicant i.e. the EORTC Statisticians for the transfer of data stored in the EORTC clinical database, the DAC Coordinator for providing the access to EORTC genetic, any -omic, other molecular data as well as images stored on access controlled external repositories and for informing the investigators on the decision of ODAC regarding the authorization to post data on public repositories. For scientific research projects specifically involving Quality of Life data, the Head of the EORTC Quality of Life Department is an Internal Contact. Internal Contact provides information that helps the Data Sharing Coordinator to approve or not the ERP.

5 PROCEDURE

5.1 Submission of the data request form

The instructions to submit a data request for an ERP and the data request form are available at http://www.eortc.org/investigators/data-sharing/. The Internal Contacts (study Statistician or DAC Coordinator) may be asked by the Data Sharing Secretary to provide help to the Data Applicant for the completion of the data request form.

Upon submission of the request, the Data Applicant must agree to the Terms of Use specified in the application form [Terms of use for POL008.docx].

5.2 Upon submission of the data request form: Internal review

Once the data request form is submitted, the ERP is first reviewed internally by the Data Sharing Coordinator who together with the Data Sharing Secretary:

- Identifies the scope of the project (clinical research, meta-analysis, translational research, imaging research, statistical or methodological research, other research)
- Identifies the type(s) of data (clinical, genetic, any -omics and other molecular and/or images).
- Identifies if the request involves or not data from trial(s) supported by pharmaceutical or biotechnology company and if the request emanates or not from such a company.
- Identifies if the request emanates from non-academic researchers or from for-profit organizations
- Identifies the Internal Contacts who need to review project.
- Identifies the external persons to EORTC HQ who need to approve the project (depending on the nature of the data requested, on the research purpose and on whether the data applicant is from academia or not) or decides if the simplified approval process is applicable (see below).

Thereafter, the Data Sharing Secretary asks the Internal Contacts, the DAC Coordinator, the Budget and Contract unit (BCU), and the translational research team (as applicable) to review the data request.

- The **Internal Contacts,** after consulting the team(s) responsible for the study (ies) involved in the request, inform (by sending an email to datasharing@eortc.be) of the HQ position regarding:
  - The scientific merit, the methodological strength of the project including whether there is sufficient sample size to realize the objectives of the project (with Statistician, CRP and DAC Coordinator).
  - The feasibility of the project:
    - Effective availability of data and/or images (with Statistician, DM and DAC Coordinator).
  - Ethical and legal feasibility: whether the original Patient Informed Consents allows further distribution of data and/or images; fulfillment of other Ethics Committee or Regulatory requirements); sufficiency of Terms of use for the transfer (e.g. transfer to a party based outside EU may require the execution of a formal contract) (with PM, RA, BCU and DAC Coordinator).

- The workload that the ERP may possibly require from the EORTC staff (with whole team and Heads of Units and/or Directors in case the project induces substantial workload for the HQ)
- Whether there is any contractual agreement with third parties that would require to respect additional formalities or make the share of the data or images impossible (with CRP and PM and DAC Coordinator).
- Whether similar research is already being conducted by EORTC itself which can eventually be a sufficient reason to deny access to data (with Statistician, CRP, PM and DAC Coordinator).

The applicant may be contacted again as needed, through the Data Sharing Secretary, to request additional information or if the application form is incomplete.

- In order to collect the information under his/her responsibility, the **DAC Coordinator** consults the members of ODAC and/or IDAC. If needed, the EORTC Translational Research Advisory Committee can also be consulted for advice. The DAC Coordinator communicates to the Data Sharing Coordinator the decisions of the DACs by sending an email to datasharing@eortc.be.
- In case of an ERP supported by pharmaceutical company or another for profit organization or if there is any contractual agreement with third parties (like in intergroup studies) that would interfere or make the share of the data or images impossible, the Data Sharing Secretary contacts the **Budget and Contract unit** (BCU) which checks if the data release is compliant with the terms of the agreement and if required, obtains the authorizations from third parties. For obtaining them, BCU may ask the support of PM or Intergroup Officer.
- If the request also involves access to Human Biological Material (HBM), it will be managed by the **Translational Research team** according to chapter 3.6.2 on secondary use of HBM of EORTC POL020.

5.3 Approval of the requests

Once the internal review is performed, the Data Sharing Coordinator confirms the completeness of the application form and feasibility of the request then the Data Sharing Secretary asks the external persons to approve the data release.

Requests emanating from non-academic researchers or from for-profit organizations must be approved by the Director General.

5.3.1 Approval process for release of data or images for new projects never approved by EORTC

The proposal must be reviewed and approved by the study (ies) steering committee (s) (if any) and at least by the Study Coordinator of the studies for which data or images are sought, and by the EORTC group Chair; as well as by the EORTC staff or EORTC members that are identified as future co-authors of the resulting publication(s). In case the Study Coordinator is not anymore professionally active or is not responding, the approval of the group Chair will be considered sufficient. The reviewers send their comments and approvals to datasharing@eortc.be. In case of disagreement, the group Chair will arbitrate the different positions.

5.3.2 Approval process for release of data or images for projects already approved by EORTC

If the requested data or images and a summary of the analysis plans were clearly described in the study protocol approved by EORTC protocol review committee and/or by EORTC Translational Research Advisory Committee (TRAC) or if the request concerns data or images related to an EORTC-RP then data or images release for these projects is approved without further scientific review. The feasibility and timelines of the data or images release are evaluated by the Data Sharing Coordinator with the support of Internal Contacts.

5.3.3 Approval process for requests for data sets to use for illustration of statistical methodology

In case of requests for data sets to use for illustration of statistical methodology in papers intended for publication in the statistical literature, a simplified path is followed. The Data Sharing Coordinator assesses with the Head of the statistics department if the data set appears to be appropriate for the project. If so, the Data Sharing Coordinator approves the request without further review. The study (ies) steering committee(s) (if any) and at least the Study Coordinator of the studies for which data are sought, and the group chairperson in charge are informed that the data are being used for that purpose.

5.3.4 Communication of the EORTC decision regarding the data or images release

Once the data release is approved the Data Sharing Secretary informs the Data Sharing Coordinator who decides about the appropriate timing for granting access to the data or images in order to maintain the study integrity, in accordance with EORTC POL009 and documents the approval by signing the Data Sharing approval form (ST-008-AF-01).

The Data Sharing Secretary then informs the Data Applicant and the Internal Contacts that the project is approved and that the clinical data transfer and/or the release of genetic, any -omics and other molecular data or of images is authorized and when the transfer can take place.

If the EORTC decision is to not approve the release of either the data or the images, the Data Sharing Coordinator summarizes the arguments for not granting access to EORTC data or images. The Data Sharing Secretary informs the Data Applicant and the Internal Contacts of the EORTC decision.

5.4 Data Transfer

If data or images release is approved and all required authorizations are in place, the EORTC statistician proceeds to the database transfer and the DAC Coordinator to the release of genetic, any -omics and other molecular data or images. They inform the Data Sharing Secretary of the dates of the data base transfer and/or genetic, any -omics and other molecular data or images release.

Only coded data are transferred to the requestor.

The clinical data are 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 is provided for each trial. If another file format is needed or if specific recoding of (a subset of) variables is needed, the Internal Contact makes due diligence in trying to provide the data in the agreed format, whenever technically feasible for the EORTC.

EORTC transfers clinical data files according to ST-009-SOP. Genetic, any -omics, other molecular data and images are released under the responsibility of the DAC Coordinator.

5.5 Follow-up of the projects by the Data Sharing secretary

The follow-up of the projects is performed by the Data Sharing Secretary. The organization of the follow-up is different if EORTC staff member(s) is (are) planned as co-author(s) of the publication or not and if the publication was released on behalf of EORTC or not.

The Data Sharing Secretary identifies every month the projects for which publications and completion are expected.

If EORTC staff member(s) is (are) planned as a co-author(s) on the publication, the list of projects is circulated to them. They update the Data Sharing Secretary of any news they may be aware of concerning these projects. Upon release of the publication they inform the Data Sharing Secretary and provide the titles and the hyperlink of the publication. The procedure ST-007-SOP is of application.

If no EORTC staff member is planned as co-author on the publication, the Data Sharing Secretary contacts the Data Applicant to enquire on the status of the project. If the project is completed and a draft of publication is in preparation, the Data Sharing Secretary requests to receive a copy of the document. Upon receipt of the draft, he/she informs the Data Sharing Coordinator who checks for compliance with the Terms of Use of POL008.

If the publication is released on behalf of EORTC or if EORTC appears in the study title the Data Sharing Secretary asks the HQ team(s) involved with the study(ies), via the Internal Contacts, to review the publication, Internal Contacts inform the Study Coordinator(s) whenever required. If the publication relates to translational or imaging research, the DAC Coordinator is consulted and is responsible to organize the internal review by ODAC or IDAC respectively. The Data Sharing Coordinator verifies if EORTC has been properly acknowledged using the sentence *"The authors thank the European Organization for Research and Treatment of Cancer for permission to use the data from EORTC studies [list of study numbers] for this research"*.

If the publication is not released on behalf of EORTC or if EORTC does not appear in the study title, the publication is not internally reviewed. The Data Sharing Coordinator only checks the acknowledgments to EORTC (see above) and if the publication contains 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 "*.

5.6 Closure of the project

During the monthly review of projects, the Data Sharing Coordinator identifies with the Data Sharing Secretary those projects that are supposed to be completed. The Data Sharing Secretary contacts the Data Applicant, requests confirmation of the project completion (including meta-analyses) and reminds that data should not further be used and datasets should not be stored beyond what is legally required. Once these have been confirmed, the Data Sharing Secretary turns the project status to "closed", the project is archived and no longer subject to follow-up. In case the investigator plans to re-use the same dataset for a subsequent project with a new objective, a project extension describing future use of the dataset should be submitted online using the data request form. The data request must clearly stipulate that the demand is an extension of an

existing data sharing request and provide reference to that former request. Review and approval of extensions follow the rules specified in section 5 above.

Any breach of agree terms will be reported by the Data Sharing Coordinator to EORTC Director General.

5.7 Posting and release of genetic, any-omic and other molecular data

After consultation of ODAC, the DAC Coordinator informs the EORTC investigators who have generated genetic, any -omic and other molecular data within EORTC studies if they are allowed to post these data on public open access depositories (e.g. ENA,NCBI,…) or if they have to store their data on access controlled external repositories (e.g. EGA,…). The DAC Coordinator provides the codes to EORTC account on the access controlled external repository. By definition, once on open access depositories, data can be directly downloaded by the scientific community. Request for release of genetic, any -omic and other molecular data on access controlled depositories alone or together with other EORTC data are covered by POL008 and executed according to the above process (sections 5).

6 FILING AND ARCHIVING

An electronic registry of all approved ERPs is maintained by the Data Sharing Secretary. This registry identifies the project by project number, short title, EORTC studies involved, approval date, data release date, date of last update, publication data, project status (ongoing, closed), reference of full-length publications resulting from the ERP, internal contacts, name and e-mail of the Requestor (or his/her designee for the yearly updates and communication with the EORTC). For projects approved from January 1st 2009 onwards, the registry contains the full ERP application details, since the requestors fill the application form on-line via the EORTC web-site and directly populate the database. For earlier projects, the database will only contain key summary information listed above.

A paper copy of the approved ERP, paper documentation of approvals (printed e-mails) and of any supportive document (appended protocol, curriculum vitae of responsible Statistician) is kept in the Data Sharing Secretary's office.

7 RACI MATRIX

Functions / Activities	DS Coord	DS Secret	DAC Coord	ODAC IDAC TRAC	Internal contact	DG	RA	BCU^	Data applicant	Study St Comm or SC	Group Chair	Head stat	3rd parties
Submission of the request	C	R	C		C				A				
Internal review of the request	A	R	R	R	R		R	R					C
Approval of new project never approved	I	R			I	C*			I	R	A		C
Approval of project already approved	A	R			C/I	C*			I	I	I		C
Approval of project for illustration of statistical methodology purpose	A	R			I	C*			I	I	I	C	C
Proceed to the EORTC data transfers (all kinds)	A	I	R		R								
Follow-up ERP	A	R	R***		R***				C	I			
Posting data on public depositories			A	C									
Decision if breach of the Terms of Use	C					A							

R: responsible; A: accountable; C: consulted; I: informed.
Use ‘A’ when ‘A’ a nd ‘R’ are assigned to the same person. DS: Data Sharing. Coord. : Coordinator. Secret. Secretary

* For requests from non-academic researchers or from for-profit organizations.

^ For requests from non-academic researchers or from for-profit organizations or if there a contractual agreement with third parties concerning the data requested.

***If co-author on the publication

8 REFERENCES

- 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)

9 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
EORTC data request form	http://www.eortc.org/investigators/data-sharing/
Data Sharing approval form	ST-008-AF-01

10 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.00	Initial release	Laurence Collette	02 Mar 2009
1.1	ERP supported by pharmaceutical company or another for profit organization Transfer of variables really needed versus whole database transfer. ERP extension	Thierry Gorlia	18 Feb 2013
2.0	Extended to the release of any EORTC genetic, -omic and other molecular data or images. and their posting on public access depositories. Function of I/O DAC and DAC Coordinator Data Sharing approval form	Thierry Gorlia	03 Oct 2016