

Terms of Use for using EORTC study data in external non-EORTC research

Acceptance of Terms of Use

1. By accessing and using the dataset(s) provided by the European Organisation for Research and Treatment of Cancer (“EORTC”) in the scope of your specific project, you shall be deemed to have accepted to be legally bound by these terms (hereinafter referred to as “Terms of Use”). If you do not agree to these Terms of Use, you are not entitled to receive and use the EORTC data.
2. In addition, EORTC may require that you comply with additional terms beyond these Terms of Use (if any), which will be notified to you in writing at the time of the approval of your request or which may require a formal agreement to be put in place with you/your institution (for example in the case of accessing human biological material or in case of sharing data with non-EU entities, etc...).

Administrative Fee

3. EORTC will charge an administrative fee for managing and processing approved requests. The academic fee consists of:
 - a. a fixed fee of 2.500€ for a first study dataset
 - b. an additional fixed fee of 500€ per additional study dataset

Any other relevant costs will be estimated in advance and charged to the requestor: e.g. costs for sample logistics, costs for accessing data from external databases (e.g. genetic data), etc.

For commercial requests, specific fees will apply and will be calculated on a case-by-case basis.

4. For the above purpose, EORTC shall address an invoice to you/your institution. EORTC will collect from you the required financial information at the time of request approval. Payments are due, at the latest, within thirty (30) days from the date of invoice, it being understood that the requested data will only be shared after the payment has been received. The fees paid under these Terms of Use are non-refundable.

Conditions of Use

5. Subject to these Terms of Use, EORTC grants you/your institution a royalty-free, non-exclusive, non-transferable, non-assignable license to use the data solely for the following purposes:
 - a. use of the data specifically for the project for which you requested the data in the request form (hereinafter the "Project");
 - b. modification or adaptation of the dataset(s) to suit the needs of the Project;
 - c. publication of the results arising out of the Project.
6. Subject to these Terms of Use, and without prior written authorization by EORTC, you are explicitly prohibited to:
 - a. further copy, distribute or transmit the dataset(s) to any third party that was not declared to and accepted by EORTC at the time of the data request;
 - b. post the dataset on a public data repository/website, unless in a form of results and/or otherwise agglomerated data;
 - c. further share or commercialize any applications or any other material that you might develop using the dataset(s);
 - d. attempt to identify data subjects or any action which is likely to lead to subject identification;
 - e. publish any individual patient data (except when fully anonymized or agglomerated) or any other type of data that puts data subjects under the risk of potential intentional or unintentional identification, unless specifically and explicitly authorized by the data subject;
 - f. use the data for other purposes than the Project;
 - g. use the data for unlawful purposes or present results in a misleading way. Such instances include, but are not limited to:
 - presenting the dataset(s) in a misleading or incorrect manner, or misrepresenting the data; or
 - using the data to promote or support any illegal activities.
7. You must:
 - a. ensure that the Project has received, when applicable, an appropriate ethical approval and / or any other approval(s), and that it is otherwise legitimately performed in compliance with all applicable legislation, including but not limited to any local or national rules applicable to re-use of patient data from in a given country or territory;
 - b. ensure that any third party involved in the Project complies with these Terms of Use, as applicable;

- c. process the data in a way that will make any inappropriate access to the dataset(s) or any breach to data privacy highly unlikely, by (among other measures) using appropriate technical tools;
- d. limit all processing of dataset(s) to entities based within the European Union or inform EORTC about any need to transfer dataset(s) to any party based outside the European Union prior to any transfer or any agreement to transfer as additional constraints may apply;
- e. publish the results arising out of the Project, which shall be done by these Terms of Use and applicable international standards, including but not limited to the recommendations from the International Committee of Medical Journal Editors (ICMJE);
- f. upon EORTC's exceptional prior written request (at the time of approval), submit any intended publication or any other public disclosure of results to EORTC and / or EORTC's designee for its revision at least thirty (30) days in advance (or as otherwise instructed by EORTC), prior to public disclosure;
- g. clearly state in all your communication: "*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*" and "*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*";
- h. cease to use the dataset(s) once the Project is ended and do not store the data any longer than the archiving time legally required by the legislation applicable to your activities and/or to the Project;
- i. provide the information on, modify, correct or destroy dataset(s) or parts of the dataset(s) upon specific request of EORTC at any moment, in particular in relation to data subject rights and requests; such actions shall not generate any costs or liability for EORTC;
- j. immediately inform EORTC about any breach to data privacy in relation to dataset(s) you received from EORTC or any breach of these Terms of Use;
- k. send EORTC (datasharing@eortc.org) the reference of any resulting scientific publication within 2 months of the publication.

Data Protection

8. In relation to the processing of the dataset(s) requested by you and provided by EORTC under these Terms of Use, you become a Data Controller on your own, exclusively for this particular re-use of the data. By agreeing with these Terms of Use you confirm to ensure that any personal data processing activities are compliant with the applicable laws, including but not limited to the General Data Protection Regulation 2016/679 ("GDPR"):
 - a. you ensure that you assess and decide the legal basis and the lawfulness of personal data processing activities performed in the scope of your Project;
 - b. you confirm you will process the shared personal data lawfully, fairly and in transparent manner;
 - c. you will process personal data in a way that ensures appropriately security of personal data and maintains their integrity and confidentiality;

- d. you restrict access to the personal data, so it is limited to those employees that meet the regulatory compliance obligations;
 - e. you are responsible to ensure the data protection and security measures of the environment where you will host the requested data
 - f. you may delegate partially or entirely any of the processing activities to vendors and sub-contractors and in doing so, you shall enter into a written agreement with the processor, as required by the Article 28 of GDPR which imposes the same obligations on the processor to comply to the conditions imposed under these Terms of Use.
 - g. you acknowledge that if the data being used for this research includes genetic data, you shall comply with additional safeguards in connection with the processing of genetic data following GDPR and related applicable national laws. You will implement all necessary administrative, physical, and technical safeguards designed that take into consideration the nature of such data and the privacy and legal risks consequently involved. The additional security measures shall include but not be limited to ensuring a proper controlled access to the data, implementing access management procedures, keeping a record of access to the data, establishing restrictions for cross-border data transfers or any other necessary security measures. You understand that you have a duty to stay informed of possible changes to such laws during the term of this research.
9. Although you are responsible to assess and comply with the formalities requested by GDPR for the data breaches and complains that occurs at your side and in relation to the dataset(s) provided by EORTC, EORTC, as the original controller, would like to be informed (dpo@eortc.org) within the shortest delay possible about any risk or high risk data breaches, as this might have impact on EORTC's reputation or image.
10. In the event of a data subject request, and since you are not in direct contact with the sites from where the patient data shared with you were initially collected nor in the position to identify the data subject, EORTC will provide reasonable assistance so that you complete the data subject request within the timelines and formalities requested by GDPR.
11. For the sake of clarity, these Terms of Use are applicable only when the requester of the data is a person/entity within the European Union entity. When the requester is a non-EU person/entity, the Terms of Use might not be sufficient and EORTC might need to put in place additional contractual clauses to cover this.

Disclaimers

12. The dataset(s) are provided on an "as is" basis without warranties of any kind. EORTC does not make any representations or warranties whatsoever and, to the fullest extent permitted by the law, hereby disclaim warranties, whether express, implied or statutory, to you or any third party in relation to the use of the dataset(s), including but not limited to any warranty as to the accuracy, correctness, reliability, timeliness, non-infringement, title, quality or fitness for any particular purpose of the dataset(s).

13. To the fullest extent permitted by law, EORTC shall not be liable to you or any third party for damage or loss of any kind, including but not limited to direct, indirect, punitive, special or consequential damages, loss of goodwill, loss of business resources, income, revenue or profits, lost or damaged data, or damage to your computer or other property, arising directly or indirectly from your or any third party's use of, or inability to use, the dataset(s) or the results of the Project.

Indemnity

14. You agree to fully indemnify EORTC and to hold EORTC harmless from any and all claims, demands, losses, liabilities, costs and expenses (including but not limited to legal costs) against EORTC arising directly or indirectly from (i) your use of the dataset(s); (ii) your breach of any of these Terms of Use; (iii) your violation of any third party rights; or (iv) any claims made by a third party in connection with the third party's use of the dataset(s)/results or any derived analyses or applications which you have generated.

Ownership and Intellectual Property

15. You acknowledge that you understand and agree that:
- a. You are not the owner of the dataset(s), and their ownership is not anyhow affected by these Terms of Use;
 - b. without prejudice to clause 6.c above, and except for intellectual property rights that may be claimed by a third party that participated in the studies where the data was originally collected and / or generated, you retain the intellectual property rights exclusively and specifically on the results generated in your Project. For the sake of clarity, any intellectual property rights otherwise related to the dataset(s) are not affected by these Terms of Use and remain with EORTC.

Breach of the Terms of Use

16. Without prejudice to any other rights that EORTC may decide to exercise, the breach of these Terms of Use shall result in the cancellation of the license to use the dataset(s) granted to you under clause 5. These Terms of Use (except for clause 5) shall survive the cancellation of the license granted herein.

Governing Law

17. These Terms of Use shall be governed by and construed in accordance with Belgian laws. You irrevocably agree that Belgian courts shall have exclusive jurisdiction in relation to any dispute arising from or relating to these Terms of Use.