



Avenue E. Mounier 83/11
1200 Brussels
Belgium
Tel: +32 2 774 1611
Email: eortc@eortc.be
www.eortc.org

Protection of Personal Data

POL021

Version 1.0

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Author: <i>Head International Policy Office</i> Anastassia Negrouk	Signature:	Date:
Authorized by: <i>Director General on Behalf of the Board</i> Denis Lacombe	Signature:	Date:

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1 PURPOSE

This policy aims to ensure adequate protection of personal data collected, stored or processed or otherwise handled by EORTC staff, its members, experts or any other third party handling personal data on behalf of EORTC.

Objectives of this policy are to ensure a clear understanding of the EORTC strategy to achieve these aims by all concerned persons.

2 DEFINITIONS

- ◆ **Personal data:** any information relating directly or indirectly to an identified or identifiable natural person
- ◆ **Addressograph:** virtual name, means all databases kept by EORTC Headquarters (HQ) staff containing personal data of EORTC members, experts, participants to EORTC events and courses, partners, vendors, contractors and their relevant members or staff including, but not limited to, the accounting details or CVs as applicable
- ◆ **Clinical research subject database:** all databases kept by EORTC HQ containing personal pseudoanonymised data of research subjects, including but not limited to clinical data base, safety data base, sample tracking tool, etc...
- ◆ **Anonymous data:** data which does not relate to an identified or identifiable natural person; or personal data rendered anonymous in such a manner that the data subject is not or no longer directly or indirectly identifiable
- ◆ **Pseudoanonymised data:** data which can no longer directly be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person

3 SCOPE

This policy applies to any personal data collected, stored or processed or otherwise handled by EORTC staff, its members, experts or any other third party handling personal data on behalf of EORTC or otherwise related to its activities, with following exceptions:

- ◆ this policy does not apply to the processing of anonymous data;
- ◆ this policy does not apply to contact details of individuals representing various organizations, journals, government officials or other public personalities as relevant to EORTC activities and as available in public domain or any other type of personal information in public domain;
- ◆ unless otherwise specified by law applicable in a specific cases, this policy does not apply to data of deceased subjects insofar as it does not contain any data about other data of living subjects (e.g. family members)

The policy applies to all staff of EORTC HQ or any EORTC member or executive acting on behalf of EORTC and all other computer, network or information users authorized by the EORTC or any department thereof.

It relates to their use of any EORTC-owned hardware (and those leased by or rented or on loan to EORTC), centrally managed or otherwise; to all EORTC-owned, licensed or otherwise supported data and programs (wherever stored); and to all data and programs provided to EORTC by third parties (wherever stored). The policy also relates to paper files and records created for the purposes of EORTC business.

4 POLICY

Within the scope of this policy any data collection, storage or processing shall comply with the Belgian law on data protection and any relevant recommendation of the Belgian Privacy Commission and relevant parts of the Universal declaration of Human rights, the European Convention on Human Rights, the European charter on patient rights, the Declaration of Helsinki, principles of ICH GCP or relevant recommendations of the Working Party 29 on Data Protection (and the future European Data Protection Board).

In situations where EORTC would handle the data on behalf of another party or work in collaboration with other parties or otherwise collect data from outside EU, the Belgian law may not apply entirely and / or other national (Swiss data protection law, HIPPA etc...) or international legislations may apply. If this is the case, relevant contracts shall specify the law applicable and relevant EORTC staff shall be informed.

5 KEY PRINCIPLES OF PERSONAL DATA PROTECTION

Within the scope of this policy all personal data shall be:

- ◆ processed fairly and lawfully;
- ◆ obtained for specified and lawful purposes;
- ◆ adequate, relevant and not excessive;
- ◆ accurate and up to date;
- ◆ not kept any longer than necessary;
- ◆ processed in accordance with the “data subject’s” (the individual’s) rights:
 - right to be informed
 - right of access
 - right of rectification or erasure
 - right to data portability
 - right of objection to further processing
- ◆ securely kept;
- ◆ not transferred to any other party without adequate protection and/or adequate safeguards in place.

6 NOTIFICATION TO THE BELGIAN PRIVACY COMMISSION

For the purpose of complying with Belgian law, EORTC has declared its treatments finalities to the Belgian privacy commission.

6.1 Data of EORTC staff

On the basis of the art 51 & 52 of the Royal Decree of 13 February 2001, treatments of data of EORTC staff are exempt from this declaration.

6.2 Data of research subjects (“Clinical research subject database”)

Within the scope of its activities, EORTC handles exclusively Pseudoanonymised (or coded) data. EORTC do not process any non-coded data of research subjects.

Data of research subjects are processed exclusively for the purpose of cancer research.

Coded data may be shared with third parties and/or transferred inside or outside Belgium, including to non-EU countries if necessary for the performance of adequately approved research.

EORTC will ensure such a transfer is performed within the scope of data subject's consent and/or will put in place appropriate terms of use or will enter into a contractual agreement with any such third party to ensure appropriate technical and organizational safeguards are in place as relevant to each specific case and in compliance with applicable legislation and/or will anonymize the data to the extent that would enable safe transfer.

This treatment finality is notified to the Belgian privacy commission (VT000512516).

6.3 Personal data other than those of research subjects (“Addressograph”)

Data subjects are informed about the purpose of collection of this data and the law applicable.

Processing of their data is done exclusively for the purpose of performing EORTC professional activities (e.g. contacting its members for the purpose of participation to EORTC events, courses and research).

Personal data may be shared with third parties and/or transferred inside or outside Belgium, including to non-EU countries if necessary for the performance of EORTC international activities. EORTC will put in place appropriate terms of use or will enter into a contractual agreement with any such third party to ensure appropriate safeguards are in place as relevant to each specific case and in compliance with applicable legislation. EORTC will inform data subjects as relevant and when applicable.

This treatment finality has been declared to the Belgian privacy commission (ref VT005013266).

7 DATA SECURITY

EORTC ensures, including by appropriate training and instruction, that:

- ◆ any software, electronic tools or devices are designed, set-up and maintained in a way that provides sufficient level of security to personal data processed by EORTC in compliance with applicable legislation in the domain of data security and any other security norm as applicable to each treatment;
- ◆ any software, electronic tool or devices operates in such a way that ensures personal data are being processed in a way that enables their authenticity, reliability and usability and capable of speedy and efficient retrieval;
- ◆ as personal data will not be retained longer than the periods permitted by applicable legislation and, when no longer required for operational reasons, systems shall ensure data are archived or disposed of securely and confidentially for the entire duration of archiving as required by applicable legislation;
- ◆ appropriate systems are in place to prevent unauthorized access, disclosure and loss.

8 COMPLIANCE AND REPORTING OF DATA BREACH

EORTC staff shall be trained on applicable regulations and this policy.

EORTC staff shall promptly report any suspicion of breach to data privacy or any unauthorized disclosure, deletions, losses or any other type of non-authorized processing of personal data in compliance with standard operating procedures in place.

Negligent loss or unauthorized disclosure of personal data, or failure to report such events, may be treated as a disciplinary matter and could be considered gross misconduct.

EORTC Quality Assurance ensures compliance with this policy while conducting internal audits as per its standard operating procedures.

9 REFERENCES

- ◆ Universal declaration of Human rights (art 12)
- ◆ EU data protection directive 95/46/EC
- ◆ EU data protection regulation 2016/679
- ◆ European Convention on Human Rights (art 8)
- ◆ European charter on patient rights
- ◆ Declaration of Helsinki
- ◆ Guideline for Good Clinical Practice E6 ICH-GCP E6
- ◆ Loi du 26 fevrier 2003 modifiant la loi du 8 décembre 1992 relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel et la loi du 15 janvier 1990 relative à l'institution et à l'organisation d'une Banque-Carrefour de la securité sociale en vue d'aménager le statut et d'étendre les compétences de la Commission de la protection de la vie privée.
- ◆ Royal Decree of 13 February 2001 providing further details to the Act of 8 December 1992 on the protection of privacy in relation to the processing of personal data.

10 DOCUMENT HISTORY

Version number	Brief description of change	Author	Effective date
1.0	Initial release	Anastassia Negrouk	20 Feb 2017