

JRC Central Database for EUROCAT (European network for the surveillance of Congenital Anomalies)

PROTECTION OF YOUR PERSONAL DATA

Table of Contents

- 1. Introduction**
- 2. Why do we process your data?**
- 3. Which data do we collect and process?**
- 4. How long do we keep your data?**
- 5. How do we protect your data?**
- 6. Who has access to your data and to whom is it disclosed?**
- 7. What are your rights and how can you exercise them?**
- 8. Contact information**
- 9. Where to find more detailed information**

1. Introduction

This privacy statement explains the reason for the processing, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you may exercise in relation to your data (the right to access, rectify, block etc.).

The European institutions are committed to protecting and respecting your privacy. As this service/application collects and further processes personal data, Regulation (EC) N°45/2001¹, of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, is applicable.

This statement concerns the JRC Central Databases for EUROCAT (European network for the surveillance of Congenital Anomalies) undertaken by the Unit JRC.F.1 (Health in Society) of the Directorate F (Health, Consumers and Reference Materials), European Commissions' Joint Research Centre.

According to the Administrative Arrangement with DG SANTE, JRC is developing the EU Platform for Rare Diseases Registration. The JRC Central Database for EUROCAT is part of this EU Platform.

¹ [Regulation \(EC\) N° 45/2001](#) (OJ L8 of 12/01/2001).

2. Why do we process your data?

The Head of the JRC.F.1 Unit (referred to hereafter as Data Controller) collects and uses your personal information for statistical and research purposes.

The relevance of the EUROCAT network is to support recommendations, policies and decision-making in public health, and to contribute to the research on reducing mortality, anomalies, impairment and disabilities, improving quality of life, and promoting best practices for prevention and care for European citizens.

The processing operations on personal data in the context of the JRC Central Databases for EUROCAT are necessary and lawful under:

- 1) Communication from the Commission on Rare Diseases: Europe's Challenges. [Com(2008) 679 final];
- 2) Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02);
- 3) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare;
- 4) Administrative Arrangement between DG SANCO and DG JRC on the EU Platform for Rare Diseases Registration.
- 5) Treaty on the Functioning of the European Union, Title XIV (Public Health) Article 168.

The processing of personal data is lawful following Art. 5a. Art.20 (2) is applicable.

The processing of personal data falls under article 27 of the Regulation and has been "Prior-Checked" by the EDPS.

3. Which data do we collect and process?

The main role of the JRC EUROCAT Central Database is to host historical data and new prospective data on citizens with congenital anomalies, as well as information on stillbirths and terminations of pregnancy. The registry members of the EUROCAT network collect personal data on European citizens with rare conditions. Annually the registries submit data to JRC EUROCAT Central Database on all cases born on a specific year in the geographical region covered by the registry.

For the purposes of communication with local Registries the cases are identified by a unique identifier assigned by each Register with its own rules (a maximum of 11 characters long, consisting of numbers, letters or both). These codes are used for transmission of individual data to the JRC EUROCAT Central Registry and they are for sufficiently large groups so that individual cases cannot be identified at JRC EUROCAT Central Registry.

The personal data collected and further processed are:

- birth date
- sex
- multiple birth
- birth weight
- gestational age
- death date
- date of birth of the mother
- geographic area: place of birth (e.g. hospital), areas of residence (e.g. municipality), mother's residence code

The JRC EUROCAT Central Databases includes data concerning health, a special category of data that falls under Article 10 (Paragraph 3). The health data include medical descriptions, medical diagnosis and tests results, medical classifications, and socio-demographic data (maternal education, socioeconomic status of mother and father, migrant status).

4. How long do we keep your data?

The Data Controller only keeps the data for the time necessary to fulfil the purpose of collection or further processing. Keeping past data together with data received annually is a requirement for identifying changes in occurrence of events of interest over time and place.

The main purpose of the databases is to be used for epidemiologic surveillance which includes statistical monitoring of clusters and trends over time. The continuous accrual of cases in the databases allows estimating and comparing annual occurrence probabilities.

Once included, all data are kept in the JRC Central Databases for EUROCAT and SCPE for 25 years. After that period all variables containing personal data are cancelled.

5. How do we protect your data?

All data in electronic format (e-mails, documents, uploaded batches of data etc.) are stored on the servers of the European Commission; the operations of which abide by the European Commission's security decision of 16 August 2006 [C(2006) 3602] concerning the security of information systems used by the European Commission.

6. Who has access to your data and to whom is it disclosed?

Access to your data is provided to authorised staff according to the "need to know" principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

The recipients of the data are the staff working under the authority of the controller at JRC and the processors working on behalf of the controller.

All the results of the data analysis performed on individual data are published in aggregated form and do not refer to personal data. The recipients of the results of the data analysis are DG SANTE (scientific reports), academic and lay publications, and publicly available websites (public reports).

All members of the EUROCAT network have access to anonymised data (not containing variables with personal data) for research purposes. Access to these data is granted after a formal request procedure, which includes objectives and a brief study description, as well as a detailed study protocol. The request must be approved by the EUROCAT Management Committee who assesses the relevance of the study and the reliability of the scientific protocol.

Upon study approval by the Management Committee, according the Collaboration Agreement the JRC Central Registry asks from all the registries which participate in the study in subject a formal

approval to release the data. After approval the JRC Central Registry releases the agreed datasets and keeps a copy of all data and related documentation for 10 years on a secure server.

7. What are your rights and how can you exercise them?

According to Regulation (EC) n°45/2001, you are entitled to access your personal data and rectify and/or block it. You can exercise your rights directly with your local Registry that gathered your personal data, as the JRC Central Database receives all personal data from the local Registries. In case of conflict, you can contact the data protection authority in the country of the local Registry that gathered your personal data and also the Data Protection Officer and if necessary the European Data Protection Supervisor using the contact information given at point 8 below.

8. Contact information

If you have comments or questions, any concerns or a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller using the following contact information:

The Data Controller:

- Head of Unit JRC-F.1 (Health in Society)
- +39 0332 78 9861
- JRC-F1-SECRETARIAT@ec.europa.eu

The JRC Data Protection Coordinator: JRC-DATA-PROTECTION-COORDINATOR@ec.europa.eu

The Data Protection Officer (DPO) of the Commission: DATA-PROTECTION-OFFICER@ec.europa.eu

The European Data Protection Supervisor (EDPS): edps@edps.europa.eu.

9. Where to find more detailed information?

The Commission Data Protection Officer publishes the register of all operations processing personal data. You can access the register on the following link: <http://ec.europa.eu/dpo-register>

This specific processing has been notified to the DPO with the following reference: DPO-3768.
