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REGISTER NUMBER: 1341

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NOTIFICATION FOR PRIOR CHECKING

DATE OF SUBMISSION: 09-11-2015

CASE NUMBER: 2015-0982

INSTITUTION: THE EUROPEAN COMMISSION DG JRC

LEGAL BASIS: ARTICLE 27-5 OF THE REGULATION CE N° 45/2001⁽¹⁾

INFORMATION TO BE GIVEN²

1/ NAME AND ADDRESS OF THE CONTROLLER

CONTROLLER : NICHOLL CIARAN
E-MAIL: Ciaran.NICHOLL@ec.europa.eu

DELEGATE : DE LA CRUZ JAVIER

E-MAIL:

2/ ORGANISATIONAL PARTS OF THE INSTITUTION OR BODY ENTRUSTED WITH THE PROCESSING OF PERSONAL DATA

THE EUROPEAN COMMISSION
DG JRC - DIRECTORATE I.2

3/ NAME AND DESCRIPTION OF THE PROCESSING

NAME: JRC Central Databases for EUROCAT and SCPE

EUROCAT (European network for the surveillance of Congenital Anomalies) and SCPE (Surveillance of Cerebral Palsy in Europe) are two European networks of population-based registries which have been active since 1979 and 1998, respectively. According to the Administrative Arrangement with DG SANTE, JRC is developing the EU Platform for Rare Diseases Registration

¹ OJ L 8, 12.01.2001.

(see attachment at point 18). JRC Central Databases for EUROCAT and SCPE are part of the EU Platform for Rare Diseases Registration as an objective and deliverable of the Administrative Arrangement. Registry members of EUROCAT and SCPE networks sign a collaboration agreement with JRC that covers the transfer of historical data and the transmission of prospective data to the JRC Central Registry. The data in the JRC Central Databases for EUROCAT and SCPE include identifiable data (see attachment at point 18). Article 27 applies.

4/ PURPOSE OR PURPOSES OF THE PROCESSING, AND PROCESSORS

The data are collected for statistical and research purposes. The purpose of the notification is to cover the possibility of identifying data subjects by combining data in the databases. The databases include identifiable data (among others, date of birth of the subject and of the mother, residence codes) and detailed health data on very rare conditions of the data subject and the mother.

PROCESSORS:

JRC-IHCP IT Support and the contact person of the Data working groups of EUROCAT and SCPE will contribute to data processing on behalf of the controller. JRC is responsible for all processing operations done on the Databases.

5/ DESCRIPTION OF THE CATEGORY OR CATEGORIES OF DATA SUBJECTS

Citizens with congenital anomalies or cerebral palsies. Stillbirths and terminations of pregnancy data.

6/ DESCRIPTION OF THE DATA OR CATEGORIES OF DATA (*including, if applicable, special categories of data (Article 10) and/or origin of data*).

- Identification data: the cases are identified for the purposes of communication between JRC and local registries by a unique identifier. Other identification data: birth date, sex, multiple birth, birth weight, gestational age, death date, date of birth of the mother (see attachment at point 18).
- Geographic area: place of birth (e.g. hospital), areas of residence (e.g. municipality), mother's residence code.
- The JRC Central Databases for EUROCAT and SCPE include data concerning health, a special category of data that falls under Article 10. 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). These data combined can correspond to a unique individual. If matched to other sets of data, an individual can be identified.

7/ INFORMATION TO BE GIVEN TO DATA SUBJECTS

Art. 11 is not applicable. Art. 12(1) does not apply because of Art. 12(2): the provision of such information would involve a disproportionate effort for processing statistical data.

8/ PROCEDURES TO GRANT RIGHTS OF DATA SUBJECTS

Articles 13-16 are not applicable on the grounds of Art.20 (2): no disclosure of the data to third parties and no decisions producing legal effects concerning the data subjects.

9/ AUTOMATED / MANUAL PROCESSING OPERATION

Automated and manual database management processes are described in the networks procedural manuals (see attachments at point 18). Automated operations such as data import, data check and data analysis routines are performed with ad-hoc programming software products. Manual operations such as inspection, assessment, coding and classification are performed as preparation or result of data analysis.

10/ STORAGE MEDIA OF DATA

CD ROM/USB key and electronic storage media.

11/ LEGAL BASIS AND LAWFULNESS OF THE PROCESSING OPERATION

The processing operations on personal data in the context of the "JRC Central Databases for EUROCAT and SCPE" 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 (see attachment at point 19).

5) Regulation (EC) no 45/2001 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.

The processing of personal data is lawful following Art. 5a.

Art.20 (2) is applicable.

Art.27 is applicable.

12/ THE RECIPIENTS OR CATEGORIES OF RECIPIENT TO WHOM THE DATA MIGHT BE DISCLOSED

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. The recipients of the results of the data analysis (aggregated) are:

- DG SANTE (scientific reports)
- Academic and lay publications, publicly available websites (public reports).

13/ RETENTION POLICY OF (CATEGORIES OF) PERSONAL DATA

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.

13 A/ TIME LIMIT TO BLOCK/ERASE ON JUSTIFIED LEGITIMATE REQUEST FROM THE DATA SUBJECTS

Not applicable due to Art.20 (2).

14/ HISTORICAL, STATISTICAL OR SCIENTIFIC PURPOSES

If you store data for longer periods than mentioned above, please specify, if applicable, why the data must be kept under a form which permits identification.

Data used for research purposes are archived for 10 years and will then be destroyed.

15/ PROPOSED TRANSFERS OF DATA TO THIRD COUNTRIES OR INTERNATIONAL ORGANISATIONS

n/a.

16/ THE PROCESSING OPERATION PRESENTS SPECIFIC RISK WHICH JUSTIFIES PRIOR CHECKING

Article 27.2.(a) Processing of data relating to health and to suspected offenses, offenses, criminal convictions or security measures.

Article 27.2.(b) Processing operations intended to evaluate personal aspects relating to the data, including his or her ability, efficiency and conduct.

17/ COMMENTS

The registry members of the networks collect personal data on European citizens with rare conditions. At the local registry level data subjects can be fully identified. Annually the registries submit data to the Central Databases for EUROCAT and SCPE on all cases born on a specific year in the geographical region covered by the registry. The records submitted to the JRC do not include the name of data subjects but they include identifiable data. Based on the Administrative Arrangement between DG SANTE and JRC to develop and maintain the EU Platform on Rare Diseases Registration, the Central Registries for both networks are located at JRC-Ispira. The main role of the JRC Central Registries is to host the Central Databases of the networks. Historical data and new prospective data submitted annually are part of JRC Central Databases for EUROCAT and SCPE. The data will be processed and used in the same way and with the same purpose as it has been done for decades by central registries of EUROCAT and SCPE which are now transferred to the JRC. The relevance of EUROCAT and SCPE networks 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.

18/ MEASURES TO ENSURE SECURITY OF PROCESSING³ :

PLACE AND DATE: BRUXELLES, 09.11.2015

DATA PROTECTION OFFICER: RENAUDIÈRE PHILIPPE

INSTITUTION OR BODY: THE EUROPEAN COMMISSION

³ Not to be published in the EDPS' Register (Art. 27(5) of Regulation (EC) N°: 45/2001)

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EDPS OPINION

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FOLLOW UP *(in case of acting measures to be taken)*