Data protection

1 Overview

The collection, storage and use of the data in the European Cystic Fibrosis Registry (ECFR) must comply with EU Data Protection legislation as well as local and national data legislation. The compliance to this must be governed and controlled by the data controller (Hanne Vebert Olesen on behalf of ECFS), the data processor (Istituto di Statistica Medica e Biometria "G.A. Maccacaro", Università degli Studi di Milano), and the ECFR steering committee. In order to achieve this, the following procedures have been set up

1.1 Authorisation for ECFR

The ECFR is registered at the Danish Data Protection Agency, Borgergade 28, 5 1300 Copenhagen, Denmark, file number 2007-41-0909 (appendix 1), and is subject to the standard terms of the Danish Data Protection agency (appendix 2)

- Data controller is Hanne Vebert Olesen, Pediatric Department, Aarhus University Hospital, Skejby, 8200 Aarhus N, Denmark – co-chairman of the ECFS steering committee, on behalf to the ECFS.
- Data processor is Istituto di Statistica Medica e Biometria "G.A. Maccacaro", Università degli Studi di Milano, Cascina Rosa, Via Venezian 1, 20133 Milano,Italy, Director Adriano Decarli.
- Trusted Third Party is Patrizia Iansa, ECFR help-desk, UO Centro Fibrosi Cistica, Azienda Ospedaliera di Verona, P.le A. Stefani, 1, 37126 Verona, Italy

The registry has permission to collect data until 01-09-2015, and extension can be granted on application.

1.2 Data collection by contributors

Data submitted to ECFR must be collected after application to local/national data protection agencies or ethic committees, and the collection must be in accordance with the national data protection legislation as well as the EU data protection legislation (EU Directive 95/46/EC). The authorisation from the data protection authorities must include data collection from patients as well as data transfer to the ECFR. Authorisation for storage and processing of data locally (center-based or nationally) is outside the scope of the ECFR and is the responsibility of the local/national data controller.

Application to local/national data protection authorities can be done on a center and/or a national level as appropriate. A copy of the authorisation along with an English translation must be emailed and/or sent to the data controller for verification and approval before any data can be received by the ECFR. Furthermore, the data controller should receive a signed sheet confirming that the data collection is in accordance with the data protection legislation (appendix 3). A paper copy of these documents will be stored at the ECFS office (Kastanieparken 7, 7470 Karup, Denmark). For single centers or countries without existing national registry no username and password for the ECFR on-line entry software will be granted until the above authorisations have been approved. Invitational letter describing these procedures will be sent to all center contact persons (appendix 3).

For the purpose of acquiring written informed consent from the patients, the ECFR has supplied a template in English that can be translated and modified in order to meet the local/national legislation (appendix 4a-b).

1.3 Data protection verification

The data controller will collect the above mentioned authorisations and signed confirmations (appendix 5). The data controller will review these, and if they comply with the required data protection legislation, the data controller will inform the trusted third party (Patrizia Iansa at the ECFR help-desk), that the center/country is eligible to supply data for the ECFR and can be granted a center number and a username and password for the registry on-line software (appendix 5)

For countries with existing national registries the same information will be required, typically by copy of the authorization of the national registry to export anonymous data to the ECFR.

If there is any doubt about the legality of the authorisations, the data controller will take steps to gather further information before eligibility is granted. If the authorisations do still not meet the requirements, the applicant will be informed that we cannot accept their data into the ECFR until these matters are corrected.

1.4 Anonymisation of data:

1.4.1 Countries with existing national registries

Data from existing national registries will be imported in the form of an excel spread-sheet. This spreadsheet will contain country name, center number* (optional), gender and date of birth as identifiers.

*This number is provided by the national registry and is not an EU center number

1.4.2 Countries and/or centers without existing registry

Data will be submitted directly via an online database program supplied by the ECFR. The center will be granted an EU center number, which will be the sole identifier along with gender and date of birth. (appendix 5)

1.5 EU center number administration

The trusted third party (atm Patrizia Iansa) will appoint the EU center numbers. The trusted third party will keep a list of center names and contacts and the appointed center numbers. A copy of this list will be sent to the ECFS office at regular interval, and these two copies will be the only connection between center names and EU center number (appendix 5)

For the production of the annual report and for data analysis purposes, the epidemiologist will be informed of the center numbers connected to each country (but not the center names) on a need-to-know basis (appendix 5).

For contact with patients identified from registry data as eligible for clinical trials or other research, the trusted third party will receive the center numbers of the patients and will thereafter contact the center contact persons for information about the research project (by mail, email or phone as appropriate)(appendix 5). The patients will never be contacted directly from the ECFR staff.

1.6 National administrator

The individual centers reporting data via the online database system have the opportunity to appoint a national administrator, who will be granted access to the total data reported from that country. The center contact person of each center will have to sign a paper appointing this person in order for the ECFS to grant him access to the data (appendix 3). The national administrator will be able to view and extract data from his country only, but will not have access to change or delete data. The national data processor will be granted a special username and password. If any centers within a country will not grant the national data processor access to their data, this centers' data will be omitted from the accessible data.

1.7 Data security at data processor

It is the responsibility of the data controller to supervise the data storage and data processing, in order to assure that the data protection legislation concerning data security is met.

This is met by the following procedures:

1.7.1 Information about data security

The data processor will inform the data controller about the data protection measures taken, and the data controller will ascertain that these measures fulfil the EU, Italian and Danish Data Protection legislation.

1.7.2 Surveillance of data security

The data controller will visit the localities of the data processor to assure the presence of the described security measures.

1.8 Data security at the ECFS office

A hard copy of the registry data in a comma separated file will be forwarded to the ECFS office, Kastanieparken 7, 7470 Karup, Denmark after the finalization of each year's report. This copy will be stored in a locked safe in a separate lockable room. Furthermore, a regularly updated list of the center names and EU center numbers will be transferred electronically to the ECFS office and stored as hard copy.

1.9 Confirmation of compliance with data protection

After the recieval of the proper data protection papers from the country/center, the data controller will fill out the "Confirmation Data Protection" paper (app 6) and send this to the helpdesk for confirmation that the center/country has fulfilled the necessary obligations. The helpdesk cannot issue username/password to any center/country without this confirmation.