

ECFS Patient Registry (ECFSPR) – Code of Conduct

Confidentiality

- All participating centres/national registries are required to obtain written approval from the local data protection authorities for the recording of confidential patient data.
- Furthermore, patients are to be notified accurately of all plans for collecting and processing their data.
- Informed consent forms must be stored at the individual centres.
- The individual centres are responsible for informing the national registry or the ECFSPR if a patient has withdrawn his/her consent. Data concerning this patient should be immediately removed from the registry.
- The ECFS as data controller is responsible for storing and handling the data according to the Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 as well as Danish and Italian data protection legislation.

Compliance

- Centres agree to fully comply with the guidelines according to Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Centres agree to fully comply with other applicable legal requirements stipulated in ECFSPR guidelines and national data protection legislation for the individual country.
- It is the responsibility of the reporting centres/countries/registries to have the acquired permissions to export/report data to the ECFSPR.
- Each participating reporting centre will sign a Confirmation of Legal Ethical Compliance to use the ECFSPR software.
- The ECFS as data controller is responsible for obtaining proof that the centres/national registries have obtained the above permission (copy and translation of relevant permissions)

Financial Agreements

- Core content of financial agreements for the ECFSPR is ideally centrally negotiated between the ECFSPR Executive Committee and the sponsors providing a framework for:
 - a. Human resources (time) required for reviewing applications for data extracts.
 - b. Material resources.
 - c. maintenance of database
 - d. Purchase, maintenance and development of ECFSPR Software
 - e. coordination of ECFSPR activities
 - f. statistical assistance for annual report, data analysis, and data extraction for applications
 - g. travel imbursement for non-conference related meetings
- Resources for collection of data in individual countries should be funded locally

Data extraction

- Data extraction of data of patients referred by each centre/country can be done by written inquiry to the Executive Coordinator and will be performed within one week depending on format requested.
- The above extraction can be required by either the centre director or the appointed national coordinator. In case a country wants all national data but has not appointed a country coordinator, the single centres must apply and any merging of data must be done outside of the ECFSPR authority.
- Any other application for data extraction must be done in writing to the ECFSPR Scientific committee (directly or via the CTN).
- Any request that has been approved by either the ECFSPR Scientific Committee or the CTN AND the ECFSPR Scientific committee will be sent to the national coordinators/centre directors with the recommendations of the scientific committee
 - In case of applications from principal investigator led projects without commercial purpose, the applications will be forwarded to the national registries with a turn around deadline of 10 days . No answer from the National registries by the deadline will be considered as approval of the request..
 - In case of applications from pharmaceutical companies, the applications will be forwarded to the national coordinators/centre directors with a turn around deadline of 10 days. For applications where country specific data are requested, the country coordinators/center directors will be asked if they want their data included, and if so if they want to extract the data via their own registry, or want the ECFSPR to supply the data.
- All approved data extract applications will be reported to the national coordinators/center directors on a quarterly basis, in an overview format not conflicting with the applicants' need of confidence.

Conflict of Interest

- For applications requesting data extract information, conflict of interest has to be declared.
- Conflict of Interest includes, but is not limited to:
 - a. Direct financial involvement
 - b. Indirect financial involvement (e.g. shareholding)
 - c. Peer conflict of interest (e.g. colleagues)
 - d. Personal relationship.
- Failure to declare conflict of interest leads to exclusion from applications to the ECFSPR project for one year.
- The above is not applicable to data extraction for single centres or on a national level via the appointed national coordinator (= extraction of own data)

Relationship to Sponsors

- Overall liaison with the sponsor should be done by the ECFS.

Publication Policy

- The annual report on data must be available for review and comments from the national coordinators/center directors¹ before publication.
- All approved projects should be published preferably as an abstract at the ECFS conference. If this is not possible, the key results must be reported on the web page of the ECFSPR.
- A copy of any publication must be forwarded to the ECFSPR Executive Coordinator
- The ECFSPR should be acknowledged in any publication, as well as a link to the list of the national coordinators/centre directors of the presented data available on the ECFS webpage.
- In case of publication of data originating directly from the ECFSPR other than the annual report, the national coordinators/centre directors should be informed of the publication by the ECFSPR Executive coordinator, and co-authorship (including the responsibilities of such) should be offered

Communication

- General information about the ECFSPR will be done by the Executive Committee, or people appointed by the Executive committee to represent the ECFSPR under certain circumstances

Responsibilities of membership

Participating centres are committed to:

- Timely submission of registry data.
- Swift communication with the Executive Coordinator according to generally agreed timelines.

Failing to Comply

- ...with these stipulations will be handled by the Registry Steering Group

¹ If a national coordinator has been appointed, this person will be the contact person to ECFSPR. Center directors will be involved only in case such a coordinator has not been appointed