European Cystic Fibrosis Society Patient Registry
Code of Conduct

1. Confidentiality

- All participating centres/national registries are required to obtain written approval from the local data protection authorities for the recording of confidential data about people with Cystic Fibrosis (pwCF), CFTR-related disorder, designated CFSPID (CF Screening Positive, Inconclusive Diagnosis).
- All participating persons or their legal guardian/s must be notified of all plans for the collection and processing of their data and consent to such.
- Valid, signed (by the participating person or their legal guardian/s) and dated informed consent forms must be stored at the individual centres.
- The individual centres are responsible for informing the national registry or the ECFSPR if consent is withdrawn by the participating person or their legal guardian/s.
- Data concerning an individual for whom consent is withdrawn will be removed from the ECFSPR database (most recent database of unpublished data) in a timely manner.
- The ECFS, as Data Controller, is responsible for the storage and handling of the data in accordance with the General Data Protection Regulation (EU) 2016/79 of the European Parliament and of the Council of 27 April 2016 as well as Danish and Italian data protection legislation.

2. Compliance

- Centres agree to fully comply with the guidelines outlined in the General Data Protection Regulation (EU) 2016/79 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals regarding 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 must sign a Confirmation of Legal & Ethical Compliance declaration to use the secure, online ECFSPR data-collection platform.
- The ECFS as data controller is responsible for obtaining proof that the centres/national registries have obtained the above permissions (copy and translation of relevant permissions).

3. Financial Agreements

- Core content of financial agreements for the ECFSPR is centrally negotiated between the ECFSPR Executive Committee and the sponsors, providing a framework for:
  i. Human resources (time) required for the review of research project applications;
  ii. Material resources;
  iii. Maintenance of the ECFSPR database;
  iv. Purchase / creation, maintenance and development of the ECFSPR data-collection platform;
  v. Coordination of ECFSPR activities;
  vi. Statistical assistance for the creation of the annual data report, data analyses, data extraction for successful research project applicants;
  vii. Travel expenses for non-conference related meetings.
- Resources for collection of data in individual countries should be funded locally.

4. Data Extraction / Analyses

- A written request to the ECFSPR Operations Manager (coordination@ecfregistry.eu) for extraction of data for participating people stored stored in the ECFSPR database can be presented by participating centres / countries / national registries. Processing time for this request will be minimum one week, depending on the format requested.
- The above extraction can be requested by the Director of the participating centre or the appointed national registry coordinator. Where a country requests all national data, but for that country there is no appointed national representative, a request must be presented by all centres in the country and any merging of the ECFSPR data must be done outside of the ECFSPR authority.
- All other applications for data must follow the procedures for ECFSPR Research Project Applications; they will be reviewed by the ECFSPR Scientific Committee and, in the case of applications from Industry, the ECFS Clinical Trials Network.
- Any Research Project Application that has been passed by the ECFSPR Scientific Committee and, where relevant, the ECFS CTN, will be sent, with the recommendations of the former, for further review and approval to the centre Directors and the national registry coordinators:
  a) In the case of applications from Principal Investigator-led projects without commercial purpose, these will be forwarded to the national registry coordinators who must respond within 10 working days. If no answer is received within this time period the application will be considered approved by the national registry.
  b) In the case of applications from Industry, these will be forwarded to the national representatives of participating countries / centre Directors who must respond within 10 working days. For applications where country-specific data are requested, the national representatives / centre Directors will be asked to consent to inclusion of data from their centre, and if they prefer to extract the data via their own registry / centre or want the

ECFSPR to supply the data. Where no answer is received within this time period the application will be considered approved by that country / centre.

c) All Research Project Applications and other types of data extraction requests that are approved will be reported to the national representatives / centre Director on a quarterly basis; the overview of the reporting format will not be in conflict with need for confidence of the applicant.

5. Conflict of Interest

- For any request for data, in any format, from the ECFSPR, applicants must declare any conflict of interest.
- 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 will lead to a one-year ban on making Research Project Applications to the ECFSPR, or other requests for ECFSPR data.
- The above is not applicable to data extraction for individual centres or at national level via the appointed national representative (=extraction of own data).

6. Relationship to sponsors

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

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7. Publication Policy

- The ECFSPR Annual Data Report must be available for review and comments from the national representatives / centre Directors[1] before publication.
- All approved Research Project Applications should be published preferably as an abstract at the ECFS Conference. If this is not possible the key results must be reported on the ECFSPR website.
- A copy of all publications must be sent to the ECFSPR Epidemiological Research Liaison Manager and the ECFSPR Operations Manager at: coordination@ecfregistry.eu
- The ECFSPR must be acknowledged in any publications and a link should be included to the list of national representatives / centre Directors of the data presented. For an updated link contact the ECFSPR Epidemiological Research Liaison Manager at: coordination@ecfregistry.eu
- Where data originating directly from the ECFSPR is not from the ECFSPR Annual Data Report, the national representatives / centre Directors will be informed by the ECFSPR Operations Manager and co-authorship (including the responsibilities of such) will be offered.

8. Communication

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

9. Responsibilities of Participation in the ECFSPR

- Participating centres and national registries must commit to:
  - Submit annual data for consenting people with CF within pre-established deadlines;
  - Respond to data-related queries in a timely fashion and within deadlines;
  - Respond to all other data-cycle-related communications from the ECFSPR Operations Manager and other ECFSPR staff members in a timely fashion and within deadlines.

10. Failure to Comply

- .....with the above stipulations will be handled by the ECFSPR Steering Committee (comprised of national representatives of all participating countries).

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[1] If a national representative has been appointed for a participating country, he/she will be the main contact person with the ECFSPR. In the absence of a national representative, individual centre Directors will be the main contact person.