

Data and Sample Access Charter

FACE/BioFACE/PSY-COH

and Publication Rules

Documents available on the Fondation FondaMental website:

- *Data and Sample Access Charter for FACE/BioFACE/PSY-COH and Publication Rules.*
 - *Initial Request Form for Access to Data and Samples.*
- *Summaries of the FACE-Asp, FACE-BD, FACE-DR, and FACE-SZ databases, as well as biological data.*

1. The FACE and PSY-COH Cohorts

1.1. The FACE Cohort: FACE Database and BioFACE Biocollection

The FACE Cohort (FondaMental Advanced Center of Expertise: FACE-BP, FACE-SZ, FACE-DR, FACE-ASP) is a national cohort of patients with psychiatric disorders (Bipolar Disorders, Schizophrenia, Asperger Syndrome, Treatment-Resistant Depression) treated within the Fondation FondaMental Expert Centers (CE or CEF). Patients undergo a comprehensive, systematic assessment over two days in a day hospital setting outside of crisis periods. This assessment is conducted by various mental health professionals (psychologists, psychiatrists, neuropsychologists, nurses).

A wide range of data is collected during these assessments: sociodemographic information, mood state and disease severity, functioning, sleep patterns, cognitive assessments, somatic comorbidities, cardiovascular risk factors, family history, treatments, and standard biological tests. These data form the **FACE database**, derived from the digital medical records of the CEFs.

If patients consent appropriately, a collection of biological samples (DNA, RNA, serum, plasma, PBMCs, feces, urine) is also created. Biological data (e.g., exome data, SNPs, protein concentrations, immune cell phenotypic and functional descriptions) may be derived from these samples. The biological data are enriched as samples are analyzed.

The **BioFACE biocollection** consists of these biological samples and the associated data.

1.2. The PSY-COH Cohort (PSY-COH-BP and PSY-COH-SZ): PSY-COH Database and Biocollection

The PSY-COH Cohort is one of ten projects selected under the “Cohorts” call for projects funded through the “Investments for the Future” Program in June 2010.

PSY-COH is an observational cohort of 800 bipolar disorder patients and 400 schizophrenia patients followed for five years under the sponsorship of the Fondation FondaMental. Evaluations occur during routine care visits at one of the FondaMental Expert Centers for Bipolar Disorders or Schizophrenia. It represents a subset of the FACE cohort, with an extended follow-up period, additional clinical data collection (forming the **PSY-COH database**), and systematic biological sample collection (DNA, RNA, serum, plasma, PBMCs). Together, these samples and data constitute the **PSY-COH biocollection**.

Objectives of These Cohorts:

- Identify factors associated with and/or predictive of progression stages in bipolar disorder and schizophrenia, including clinical, therapeutic, biological, neuropsychological, environmental, and lifestyle factors.
- Establish a biobank to facilitate research into diagnostic and prognostic biomarkers for these disorders.

Secondary Objective: Create a research platform and provide access to clinical and biological databases for external public and private projects to enable new studies.

2. Access Modalities for Data and/or Samples

The access modalities described in this charter:

- Apply to research projects requiring clinical and biological data or samples already collected and stored in the FACE and PSY-COH databases and/or the BioFACE and PSY-COH biocollections.
- Apply to research projects intending to use these data to enrich other external databases.
- Apply to ancillary projects. Ancillary projects are those based on existing data collections (FACE, PSY-COH, or BioFACE) and involve gathering new types of data and/or including new subject groups to address objectives different from those defined in the initial project.

Members of the FondaMental Alliance (hospital services and research laboratories) and **Labex BioPsy**, as well as **non-member researchers** (academic or private), wishing to use clinical, biological, and/or biological samples from FACE, BioFACE, or PSY-COH must submit a request to the Fondation FondaMental (face@fondation-fondamental.org).

Additional information may be requested at any time.

2.1. Requesting Access to Clinical and Biological Data and Biological Samples

If the request is linked to a response to a call for projects (CFP) or other funding application, the access request procedure must be initiated before submitting the application. It is necessary to confirm access approval and the availability of the requested data.

A synthesis diagram of the data and sample access process, regardless of request type, is included in the appendix to this charter.

2.1.1. Data/Samples Requested by Hospital Services and Research Teams Within the FondaMental Network and/or Labex BioPsy

2.1.1.1. Initiating the Request and Composing the Request File

The Fondation FondaMental website (www.fondation-fondamental.org) provides access to the following documents:

The FACE/BioFACE/PSY-COH Data and Sample Access Charter and Publication Rules.

The Initial Access Request Form for Data and Samples.

Summaries of the FACE-ASP, FACE-BD, FACE-DR, and FACE-SZ databases, as well as biological data summaries.

These summaries provide a non-exhaustive overview of the data available, grouped by major themes.

Initially, **the requester (project manager) must complete and send the initial data access request form and the data/sample access charter to face@fondation-fondamental.org.**

Subsequently, a complete request file is sent to the requester, including: **The data access request form, The letter of commitment, The thesauri, Ancillary project submission files, if required.**

Important Information

Any request for updated data following an already approved and executed extraction is treated as a new request and follows the usual process.

Any request for additional data following an approved extraction will be processed after pending requests and must undergo new validation if added variables do not align with the original hypotheses.

Feasibility checks and variable completion rates can be requested before submitting a data extraction request.

2.1.1.2. Processing the Data Access Request File

Once all documents are completed and submitted to face@fondation-fondamental.org, the following steps are undertaken:

- **Eligibility Check:** Verifies the completeness of the file. Any incomplete or improperly filled file will be returned to the requester.
- **Review by Service Heads:** Heads of the CEFs from which the requested data originate assess the scientific validity of the project.
- **Evaluation by Fondation FondaMental:** Includes alignment with the cohort's general objectives, relevance of the subject, scientific nature, feasibility, statistical adequacy (sample size and analysis objectives), data relevance, project redundancy, monitoring, and financial viability. If necessary, reviews are conducted by the initial project's Steering Committee (PSY-COH/BioFACE) and the Biobank and Biological Analysis Committee.
- Decisions, along with any additional requirements, are communicated via email to the requester.
- In the event of approval of the request, the decision will be communicated to the bioinformatics team leader of the Foundation for the extraction of computerized data and, if appropriate, to the PSY-COH and BioFACE project manager for the transfer of biological samples.

Important: Projects involving the processing of biological samples require specific evaluation. The applicant must commit to securing dedicated funding to cover the cost of transporting the samples and analyzing the provided biological samples. They must also specify the timeline for completing these analyses (see the data access request form).

2.1.1.3. Provision of Data/Samples After Request Approval

Only the requester, as the project manager, is authorized to receive the data and/or samples. If their use or analysis is delegated to a third party other than the requester, the details and roles of the third party must be explicitly indicated in the data access request form.

The bioinformatics team at Fondation FondaMental prepares the selected data and provides them in the format requested by the project manager. The team also supplies the necessary documentation for data usage, such as catalogs and dictionaries including variable labels and descriptions.

For biological samples, regardless of their nature, the validated request is forwarded by the PSY-COH or BioFACE project manager to the storage facility manager (Biological Resources Platform in Mondor at Créteil or the DNA and Cell Bank of the ICM at Pitié-Salpêtrière Hospital in Paris). The storage manager then transfers the requested biological samples to the project manager or the identified third party.

For ancillary projects, data/samples are provided after the requester submits proof of obtained funding, mandatory regulatory authorizations, and identification details of the patients involved in the request.

The project manager is strictly prohibited from transferring or sharing the data/samples entrusted to them with anyone other than those designated in the access request form. For any data or sample transfer outside the FondaMental Alliance, the procedure outlined in paragraph 2.1.2 must be followed.

Only the analyses specified in the access request may be performed on the received materials. Any new analysis requires a separate access request (form completion) even if no new data extraction or sample transfer is needed.

Clinical, biological data and/or biological samples are made available for the duration specified in the letter of commitment or until publication. After the period specified in the letter of commitment, an additional one-year extension may be granted by the FondaMental Foundation, subject to justification. This will require an amendment to the letter of commitment. The project leader commits to providing a copy of the data produced and the results obtained after analyzing the biological samples (genotyping, concentration, etc.) to the bioinformatics team of the FondaMental Foundation as soon as they are available, to ensure accessibility.

The project manager undertakes to provide, as soon as they are obtained, a copy of the data produced and the results obtained after the analysis of biological samples (genotyping, concentration, etc.) to the bioinformatics team of the FondaMental Foundation to facilitate access to them.

2.1.2. Data/Samples Requested by Non-Member Academic Research Teams

Requests from hospital services and academic research teams not part of the FondaMental Network or Labex BioPsy follow the same access modalities as those described in section 2.1.1. However, they must also include the following:

- A signed Confidential Disclosure Agreement (CDA) before submitting the access request file.
- A signed Material Transfer Agreement (MTA) after request approval and before the transfer of clinical and/or biological data or samples.

The Fondation FondaMental will contact the requester upon receiving the initial request form.

2.1.3. Data/Samples Requested by Private Sector Actors

Requests from private sector actors or public-private partnerships follow the same procedures as those for non-member academic research teams (see section 2.1.2). Additionally, these must include **a specific partnership agreement** outlining the commitments of all parties.

3. Publication Rules

3.1. Scope of Application

These rules apply to all scientific articles describing results derived from **FACE data and/or PSY-COH** and BioFACE data/samples obtained under the conditions and criteria of this charter.

These rules must be followed by all applicants, whether academic or private, who access clinical/biological data as per the modalities defined in this charter.

These rules are subject to the publication guidelines imposed by the journal in which the article is submitted.

3.2. Exclusions

These rules do not apply when FACE, BioFACE, or PSY-COH data are used to enrich external databases. Such cases will be reviewed individually, taking into account the rules governing the external databases, and require validation by Fondation FondaMental and the CEF service heads.

3.2. Definition of Authors for Intra-Network Publications from FondaMental Expert Centers

- Named Authors

Each Expert Center contributing data may nominate a maximum of two signatories per publication. These signatories are proposed by the project lead and validated by the heads of the relevant Expert Centers.

Additional contributors (e.g., statisticians, geneticists) may be included if they played a significant role in data production, analysis, or article drafting.

- FACE-XX Group

Members of Expert Centers who are not individually cited are included under the "FACE-XX Group." The designation of members in the FACE-XX Group for each Expert Center is managed by the service head. Network leaders ensure that the FACE-XX Group composition is up to date.

For publications involving biological data generated by collaborators (e.g., immunological assays, genetic markers, metabolomics data), project leads must propose two authors from the collaborator's team. This proposal must be approved by the service heads and validated by the network leaders.

3.3. Definition of Authors for Inter-Network Publications

- Named Authors

Each Expert Center contributing data may nominate a maximum of one signatory per publication. These signatories are proposed by the network leaders of each Expert Center and approved by the service head of the hospital department hosting the Expert Center.

Additional contributors (e.g., statisticians, geneticists) may be included for significant contributions to data production, analysis, or drafting.

- Networks of Fondation FondaMental Group

A maximum of two members from Expert Centers in the four networks who are not individually cited are included under the "Networks of Fondation FondaMental Group."

Designation of members for this group is managed by the service head of each Expert Center.

For publications involving biological data generated by collaborators, project leads must propose two authors from the collaborator's team. This proposal must be approved by the service heads and validated by the network leaders.

3.5. Order of Authors

- Key Positions (1st, 2nd, 3rd, Penultimate, Last Authors)

These positions are determined by the contribution of each author (writing, analysis, initiation) as assessed by the article's submitting authors in consultation with the Expert Center network.

- **Intermediate Positions**

For non-critical positions, the order of authors is alphabetical.

- **FACE-XX or Networks of Fondation FondaMental Group**

The "FACE-XX" or "Networks of Fondation FondaMental" designation must appear at the end of the list of authors. Ideally, this mention should appear at the beginning of the article or otherwise at its conclusion.

The corresponding author must be able to specify and justify each author's contribution.

In the event of disputes, the author list and order will be reviewed by the service heads of the involved Expert Centers.

As a last resort, the Research Director of Fondation FondaMental will make the final determination.

3.6. Affiliations

The first or last author must include the following affiliation: **Fondation FondaMental, Créteil, France.**

3.7. Acknowledgments

3.7.1. General Case

In the acknowledgments of all articles, the following mention must be included:

"This work was supported (in part) by the Fondation FondaMental, Créteil, France, and by the Investissements d'Avenir programs managed by the ANR under references ANR-11-IDEX-0004-02 and ANR-10-COHO-10-01."

or

"This work was financed (in part) thanks to the Fondation FondaMental, Créteil, France, and the Investissements d'Avenir programs managed by the ANR under references ANR-11-IDEX-0004-02 and ANR-10-COHO-10-01."

Particular attention must be paid to the origin of the data/samples used to ensure that the corresponding funding sources are cited in the acknowledgments.

3.7.2. Specific Case for Data from CE-SZ

Articles using immunological or genetic data from Schizophrenia Expert Centers (beyond standard assessments) must also acknowledge the *Fondation if*.

3.8. Data Availability

When submitting an article, journals may request information on whether the analyzed data are publicly accessible. In such cases, the following declaration should be used:

Due to ethical and legal restrictions, data involving clinical participants cannot be made publicly available. All relevant data are available upon request to the Fondation FondaMental for researchers who meet the criteria for access to confidential data.

3.9. Submission of Scientific Articles to Fondation FondaMental

Accepted articles must be sent to Ophélia Godin (ophelia.godin@fondation-fondamental.org) and Constance Baudry (constance.baudry@agence-constance.fr) to catalog publications and consider external communication actions for result dissemination. A lay summary for the general public will also be requested.

4. Roles and Composition of Committees

Biobank and Biological Analysis Committee

Under this charter, the role of this committee is to evaluate requests for access to biological samples from the biocollections. In cases of limited resources, the committee prioritizes resource allocation.

PSY-COH Steering Committee (CoPil PSY-COH)

The committee includes:

- The Project Director and ANR program lead.
- The Coordinating Investigator for PSY-COH-SZ.
- The Coordinating Investigator for PSY-COH-BP.
- A representative from the Mondor Institute for Biomedical Research (UPEC).
- A representative from the Pierre Louis Institute of Epidemiology and Public Health (UPMC).
- A representative from the Clinical Epidemiology and Economic Evaluation Unit for Vulnerable Populations (Inserm).
- A representative from the Fondation FondaMental.
- The project manager.

BioFACE Steering Committee (CoPil BioFACE)

The committee includes:

- The Project Director.
- The Director of Fondation FondaMental.
- The Director of Care Services at Fondation FondaMental.
- The Research Director at Fondation FondaMental.
- The Coordinator for the Fondation FondaMental Expert Centers.
- A representative of the PRB partner (sample storage).
- The project support advisor.
- The project manager.

Commitment Declaration

I, the undersigned,, hereby declare that I have read and understood the FACE/BioFACE/PSY-COH Data Access Charter and Publication Rules. I commit to adhering to and enforcing the terms and conditions outlined therein.

Date:

Signature:

Annexe : Schéma d'accès aux données et aux échantillons de FACE/BioFACE/PSY-COH

