



# **EUROBIOBANK**

**European Network of DNA, Cell and Tissue Banks for Rare Diseases**

## **EuroBioBank Network Charter**

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## **0 - DEFINITIONS**

**“EuroBioBank Network”** means the network established in 2001 as recalled in section 1.1 of the Charter

**“Partners”** means the participants (taken individually or collectively) to the EuroBioBank Network according to section 5 here under.

**“Charter”** means the present document which sets out the principles agreed upon by the Partners of the EuroBioBank Network

## **1 – PREAMBLE / ABOUT THE EUROBIOBANK NETWORK**

### **1.1 PRESENTATION OF THE EUROBIOBANK NETWORK:**

EuroBioBank is a European network of biological banks established in 2001. The EuroBioBank Network is fully dedicated to supporting research into rare diseases by facilitating access to quality human biological resources (DNA, cells and tissues) and their associated data from patients with rare diseases.

The 16 EuroBioBank Network founding partners in 2001 represented 8 European countries. Over the following years new Partners joined the Network. So far, there are 24 Active partners in EuroBioBank from: France, Germany, Hungary, Italy, Malta, Slovenia, Spain, United Kingdom, Israel, and Canada.

EuroBioBank partners are listed in Annex 1 Table.

### 1.2 Management and Support

From 2003 to 2006, the EuroBioBank Network has received grants from the European Commission, under the European Union’s Fifth Framework Programme “Quality of Life and Management of Living Resources”. Its purpose was to expand by associating new biobanking Partners across Europe.

In 2006, the EuroBioBank network received support from the French Association against Myopathies (AFM-Telethon), the German Association for Patients with Muscle Disorders (DGM), as well as from corporate sponsors. In addition, the EuroBioBank partners each contributed a partnership fee.

From January 2007 to December 2011, EuroBioBank received support through the FP6 European Network of Excellence TREAT-NMD, “Translational Research in Europe - Assessment and Treatment of Neuromuscular Diseases”, under the leadership of EURORDIS, Partner 11, leader of WP04.1:“Develop and Manage Supranational BioBanks”.

As of January 2012, the Fondazione Telethon provides the administrative support for coordinating the EuroBioBank network and hosting the website at its expenses.

### **1.3 ACHIEVEMENTS OF THE EUROBIOBANK NETWORK BETWEEN 2003-2012:**

Between 2003 and 2005, while financed by the European Commission under FP5, major milestones were achieved by the EuroBioBank Network.

Common quality criteria were defined; Standard Operating Procedures and ethical guidelines were developed; standards for material transfer and biobanking were adopted; a new dedicated website ([www.eurobiobank.org](http://www.eurobiobank.org)) was developed to offer services to the scientific community. A web-based catalogue of samples available throughout the EuroBioBank Network was launched. It was specifically designed to provide easy access to referenced samples and to allow for the presentation of the collections. This is a key service which brings high added-value to the EuroBioBank Network as it enables researchers to quickly access the available collections and immediately send their specific request. Researchers may also receive technical support for sample use, by e-mail and phone.

The EuroBioBank Network has been instrumental in promoting standardised and quality banking practices among biobankers in accordance with the OECD's recommendations<sup>1</sup> on Biological Resources Centers (BRCs), through use of the documents generated by the EuroBioBank Network and published on its dedicated website (Standard Operating Procedures-SOPs, Material Transfer Agreement -MTA and the Informed Consent form).

At the end of the EC FP5 funding period 2003-2005, the EuroBioBank Network represented approximately 155,000 documented human biological samples, available via 12 biobanks. During the FP6 project period, five new biobanks joined the network. The inclusion of new biobanks and the constant biobanking activity of the partners has contributed to increasing the choice and number of samples to reach a total of almost 100,000 samples collected across the network at the end of 2012.

As a result of the 7,000 samples distributed a year on average, more than 150 scientific articles acknowledging EuroBioBank were published contributing to further progress in the treatment of rare and neuromuscular diseases. Work on quality control has especially been conducted to assess the activity parameters, the use of Standard Operating Procedures (SOPs) and customer satisfaction of the samples. Other achievements include the collaboration with the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) and the BIO-NMD projects.

The EuroBioBank Network continues to support the long-term promotion of BRCs networking on rare diseases through its dedicated website, the organisation of regular meetings between stakeholders and specialised training sessions on various biobanking techniques.

The EuroBioBank partners intend to consolidate the Network in the long-term and establish EuroBioBank as a permanent and integrated European service Network for research on rare diseases.

The EuroBioBank partners are fully dedicated to:

- operating the EuroBioBank Network as a non-profit trans-national platform managed by Fondazione Telethon;

- opening the EuroBioBank Network to new Partners across Europe;
- increasing the distribution of quality material for research into rare diseases;
- further improving services and biobanking standards;
- ensuring the sustainability of the EuroBioBank Network.

## **2 - PURPOSE OF THE CHARTER**

This Charter is the constituting instrument of the EuroBioBank Network from January 2006. It sets out the principles agreed upon by the Partners of the EuroBioBank Network.

In particular, the Charter recalls the ethical guidelines endorsed by the EuroBioBank Network and its Partners, defines the organisation and governance of the EuroBioBank Network, establishes the benefits and duties attached to partnership, as well as the conditions of access to and withdrawal of partnership.

## **3 - ETHICAL GUIDELINES ENDORSED BY THE EUROBIOBANK NETWORK**

The EuroBioBank Network and its Partners fully endorse the recommendations issued by the Oviedo Agreement <sup>2</sup> and the OECD Task Force on BRCs, in accordance with the applicable national and European laws and regulations.

The Partners further undertake to comply with the following good practices:

1. Sample collection: respect of non-patrimoniality;
2. Respect of the patient's autonomy through the Informed Consent (approved by each local Ethics Committee), for collection and use of the biological material for research;
3. Access to samples: no distribution of samples for cloning projects, respect of the Oviedo Convention on Human Rights and Biomedicine and Additional Protocols, 4<sup>th</sup> April 1997; and International declaration on human genetic information, UNESCO general conference, 32<sup>nd</sup> session, Paris October 8<sup>th</sup> 2003.
4. Confidentiality of the data;
5. Information to the patients on the use of collections and the outcomes of the research project(s).

## **4 –ORGANISATION AND GOVERNANCE OF THE EUROBIOBANK NETWORK**

### **4.1 MAIN BODIES**

The initial governance structure of the EuroBioBank Network shall comprise the following bodies:

A General Assembly as the decision-making and arbitration body of the EuroBioBank Network, co-chaired by both Coordinators.

Two Coordinators in charge of the management, who shall report and be accountable to the General Assembly and who shall make decisions in the day-to-day running of the EuroBioBank Network.

### **4.2 THE GENERAL ASSEMBLY**

- **Composition:**

The General Assembly is composed of one authorized representative of each Partner institution. All partners of the General Assembly are voting Partners.

When appropriate, any expert or qualified person may be invited to attend meetings of the General Assembly with a role of advisor, after due approval of both coordinators.

- **Role:**

The General Assembly is the decision-making and arbitration body of the EuroBioBank Network and shall decide on:

- strategic orientations of the EuroBioBank Network;
- establishment of an annual work plan;
- setting up of working groups according to the work plan; any such working group set by the General Assembly shall report to the Coordinators.
- modifications and amendments to the EuroBioBank Network organisation and the EuroBioBank Network charter;
- the EuroBioBank Network's budget (partnership fees, investments, etc.) in collaboration with the Finance Manager responsible for the EuroBioBank account;
- terms of use of the EuroBioBank name and logo;
- appointment of the scientific coordinator;
- inclusion of a new partner;
- exclusion of a partner;
- approval of each single sample request from private for-profit organizations.

- **Meetings:**

The General Assembly shall meet once a year (possibly around the same time) in a location agreed upon by both coordinators. The date of the next meeting shall be set at each General Assembly. Both coordinators shall co-chair the General Assembly.

The General Assembly may validly meet if 50% of its voting Partners are present or represented. Decisions are made by a majority vote of the voting Partners present. To be valid, a vote shall represent at least 50% of all Partners.

Voting partners of the General Assembly may grant power of attorney to other partners to represent them as proxies, with a limit of 1 proxy per partner.

Any urgent matters may be decided upon by the Partners via a written procedure sent by both coordinators.

- **Agenda:**

Any decision requiring a vote at the General Assembly must be identified as such on the notice of meeting sent within 15 working days of the meeting.

- **Minutes:**

The coordinators of the network shall draft the minutes of each General Assembly, to formalize in writing all decisions taken and shall send them to all participants and Partners within 30 calendar days of the concerned meeting.

The minutes shall be considered as accepted by the Partners if no objection is received by the coordinators within 15 days following the distribution of the minutes.

#### **4.3 COORDINATORS:**

The EuroBioBank Network is co-managed by two coordinators, respectively,

- an administrative coordinator appointed by Fondazione Telethon (ONLUS) from January 2012 (previously EURORDIS).
- a scientific coordinator, elected by the General Assembly for 1 year, from the biobanking Partners of the EuroBioBank Network, with a renewable mandate.

- **Role:**

Both coordinators shall act jointly on all matters under their responsibility, such as:

- day-to-day management of the EuroBioBank Network ;
- convening the General Assembly meetings;
- implementing the decisions taken at the General Assembly;
- producing written minutes of the meetings;
- reporting to the General Assembly on their activities and the work of the working groups;
- processing applications of new partners interested in joining the EuroBioBank Network.

In case of disagreement, the opinion of the administrative coordinator shall prevail for administrative matters and the opinion of the scientific coordinator shall prevail for scientific matters.

#### **4.4 WORKING GROUPS:**



In order to address relevant fields of Biobanking, three specific working groups have been approved:

- 1) Quality Control
- 2) Cost Recovery
- 3) Education/training.

- **Role:**

To define policies to be submitted to the General Assembly.

## **5 - PARTNERSHIP OF THE EUROBIOBANK NETWORK**

### **5.1 BENEFITS ATTACHED TO PARTNERSHIP:**

Benefits of partnership to the EuroBioBank Network include :

- Being involved in a highly visible and reputed European Network of biobanks dedicated to Rare Diseases;
- Displaying collections in the general EuroBioBank Network catalogue published on the EuroBioBank Network website;
- Being listed on the EuroBioBank Network website;
- Using the EuroBioBank name and logo, in accordance with the rules established by the General Assembly
- Having a privileged access to know-how and services provided by other Partners.

### **5.2 DUTIES ATTACHED TO PARTNERSHIP:**

Partners of the EuroBioBank Network undertake :

- To comply with the principles defined in the Charter
- To have referenced BRC activities (collection, preparation, storage and distribution of biological material) and to comply with minimum quality standards as defined by the OECD;
- To follow the recommendations of the EuroBioBank Network on the Material Transfer Agreement (MTA), the Standard Operating Procedures (SOPs), the Informed Consent form and the biological material sample catalogues;
- To comply with all applicable national and European laws and regulations in the field of biological samples management and distribution, for research purposes;
- To ensure the accuracy of any information on the materials it supplies to the EuroBioBank Network and to promptly correct any error therein of which it is notified
- To pay an annual partnership fee as determined by the General Assembly
- To publish and regularly update (as determined by the General Assembly) the information on their biological material samples published in the EuroBioBank Network catalogue, according to the minimum data set requested by the EuroBioBank Network;

- To inform the EuroBioBank Network of publications resulting from the use of the biological samples provided through the EuroBioBank Network, and provide the administrative coordinator with electronic copies of these publications;
- To actively contribute to the EuroBioBank Network: regular attendance to annual meetings, promotion of the EuroBioBank Network, research of external financial support, contributions and feedback on different topics of common interest presented by the coordinators or other Partners;
- To act at all times in good faith and in a manner that reflects the good name, goodwill and reputation of the EuroBioBank Network and in accordance with good business ethics;
- To demonstrate samples distribution activity through the yearly reports.

### 5.3 Applying for partnership:

Candidates should apply for partnership to the coordinators. Appropriate candidates are private or institutional Entities. In case of Biological Resource Centres (BRCs), they need to meet all criteria defining a BRC.

Applications for partnership to the EuroBioBank Network shall be submitted by email to the administrative Coordinator, returning the completed Partnership Application Form available on the web site.

Applicants for partnership should describe their structure and activities, the reasons for joining the EuroBioBank Network and their potential added-value for the EuroBioBank Network

Once approved by the coordinators, a temporary partnership is conferred to the applicant, until a full partnership is confirmed by the General Assembly.

During the temporary partnership, the new Partner's name shall be published on the EBB website.

The General Assembly will be asked to evaluate EuroBioBank candidates by a remote procedure: new candidates can be instantly approved if 100% of the EBB members agree, otherwise the decision will be postponed to the General Assembly meeting. The General Assembly may reject any application to partnership, under its sole discretion, without having to duly justify the rejection. Any decision of the General Assembly shall be final.

If an application is accepted, the administrative Coordinator shall notify the applicant in writing and add the new Partner's name in the official list of EuroBioBank Partners. If, during a particular period, EuroBioBank Partners are requested to pay fees, then the new partner would also have to pay fees. New Partner's benefits and duties begin after positive confirmation of the partnership by the General Assembly. Signature of the Partnership Application Form by the new Partner implies full adherence to the Charter principles.

### **5.4 ENDING PARTNERSHIP:**

Any EBB partner can voluntary withdraw from partnership:

through a written declaration sent to the coordinators until September 30 which has effect from the end of the calendar year

Or can be excluded from the EuroBioBank Network, with immediate effect and without judicial intervention:

1. through a vote of the General Assembly if any action damaging the interests of the EuroBioBank Network has been committed by the Partner. The coordinators will notify the excluded Partner within 7 days of the General Assembly decision ;
2. through a resolution of the coordinators, if a partner is in arrears with the payment of his annual fees and has not, in spite of two written warnings, cured its breach ;
3. through a resolution of the coordinators, if a partner seriously violates the one or several major principles of the Charter and has not, in spite of two written warnings, made any action to cure its breach

## **6- LIABILITY**

The present Charter cannot be interpreted as creating any liability between the Partners of the EuroBioBank Network. In particular,

- (1) With respect to information or materials supplied by one Partner to another through the EuroBioBank Network, the supplying Partner shall be under no obligation or liability other than as stated in this Charter, and no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials. The recipient Partner shall therefore in any event, be entirely responsible for any use whatsoever of such information and materials.
- (2) No Partner shall be responsible to another Partner for indirect or consequential loss or damages such as, but not limited to, loss of profit, loss of revenue or loss of Contracts.

## **7 - DECLARATION**

Nothing contained in this Charter shall constitute or be deemed to constitute either a partnership or any formal business organisation or legal entity between the Partners. Each Partner shall act as an independent entity and not as the agent of any of the other Partner. Nothing contained in this Charter shall be construed as constituting or organizing the sharing of profits or losses arising out of the efforts of any other Partner hereunder.

## **8- REFERENCES**

- (1) *OCDE report on the definition of Biological Resources Centres (Japan 1999): <http://www.oecd.org/dataoecd/55/48/2487422.pdf>*
- (2) *Oviedo-Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*