



# EUROBIOBANK

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

## Network Charter

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<b>0 - DEFINITIONS .....</b>	<b>3</b>
<b>1 – PREAMBLE / ABOUT THE EUROBIOBANK NETWORK.....</b>	<b>3</b>
1.1 Presentation of the EuroBioBank Network :.....	3
1.2 The founding partners of the EuroBioBank Network: .....	3
1.3 The achievements of the EuroBioBank Network between 2003-2005: .....	5
1.4 Objectives and future developments .....	5
<b>2 - PURPOSE OF THE CHARTER .....</b>	<b>6</b>
<b>3 - ETHICAL GUIDELINES ENDORSED BY THE EUROBIOBANK NETWORK</b>	<b>6</b>
<b>4 –ORGANISATION AND GOVERNANCE OF THE EUROBIOBANK NETWORK</b>	<b>7</b>
4.1 Main bodies .....	7
4.2 The General Assembly .....	7
4.3 Coordinators: .....	8
<b>5 - MEMBERSHIP TO THE EUROBIOBANK NETWORK .....</b>	<b>9</b>
5.1 Benefits attached to membership: .....	9
5.2 Duties attached to membership: .....	9
5.3 Applying for membership: .....	10
5.4 Ending membership:.....	10
<b>6- LIABILITY.....</b>	<b>11</b>
<b>7 - DECLARATION.....</b>	<b>11</b>
<b>8- REFERENCES .....</b>	<b>11</b>

## 0 - DEFINITIONS

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

“**Members**” 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 Members 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. From 2003 to 2005, the EuroBioBank Network received grants from the European Commission, under the European Union’s Fifth Framework Programme “Quality of Life and Management of Living Resources”. Its purpose is to expand by associating new biobanking members across Europe.

### **1.2 The founding partners of the EuroBioBank Network:**

The 16 EuroBioBank founding partners (as listed hereunder) represented 8 European countries (Belgium, France, Germany, Hungary, Italy, Malta, Slovenia, Spain) and formed a network composed of 12 academic or private biobanks: 2 IT services companies, 1 biotech company and 1 patient organisation, Eurordis (European Organisation for Rare Diseases), who initiated and coordinated the European project. This key network dedicated to research into rare diseases is supported by patient associations.

#### **1 - EURORDIS (European Organisation for Rare Diseases), Paris, France**

Fabrizia Bignami (PhD, Therapeutic Development Officer, Administrative Coordinator of EuroBioBank)

#### **2 - AFM (Association Française contre les Myopathies), Paris, France (banking partner)**

Cécile Jaeger (MD, Head of Tissue Bank, Scientific Coordinator of EuroBioBank until 03/2005)

#### **3 - INN CB (Istituto Nazionale Neurologico Carlo Besta), Milan, Italy (banking partner)**

Marina Mora (MD, Head of Laboratory)

#### **4 - Fundación CSAI Carlos III , Madrid, Spain (banking partner)**

Manuel Posada (MD, Head of Department), Maria-Concepción Martin-Arribas (PhD. in Public Health, Nurse Researcher, Head of the ISCIII biobank and Secretary to the Rare Diseases Ethical Committee)

**5 - GENETHON, Evry, France (banking partner)**

Jeanne-Hélène di Donato (PhD, Head of the Bank and Collection Department until 10/2004)

Safa Saker (PhD, Head of the DNA and Cell Bank)

**6 - UCL (Université Catholique de Louvain), Brussels, Belgium (banking partner)**

Christine Verellen-Dumoulin (Prof., MD, PhD, Head of the Center for Human Genetics and Medical Genetics Units)

**7 - UNIVERSITY OF LJUBLJANA, Ljubljana, Slovenia (banking partner)**

Marija Meznaric-Petrusa (Assistant Prof., MD, Head of Laboratory)

**8 - UOM (University of Malta), Malta (banking partner)**

Alexander Felice (Prof., MD, PhD, Head of Laboratory)

**9 - MTCC (Muscle Tissue Culture Collection) , Munich, Germany (banking partner)**

Hanns Lochmüller (Prof., MD, Head of MTCC, Scientific Coordinator of EuroBioBank since 04/2005)

**10 - SUN (Second University of Naples), Caserta, Italy (banking partner)**

Luisa Politano (Prof., MD, Head of the DNA bank)

**11 - NATIONAL CENTER FOR PUBLIC HEALTH -NCPH (Fodor József National Center for Public Health), Budapest, Hungary (banking partner)**

Veronika Karcagi (PhD, Head of Laboratory)

**12 - Ospedale Maggiore Milano IRCCS (University of Milan), Milan, Italy (banking partner)**

Maurizio Moggio (MD, Head of Bank)

**13 - NMTB (University of Padova), Padova, Italy (Banking partner)**

Corrado Angelini (Prof., MD, Head of the Neuromuscular Tissue Bank)

**14 - B.E.T. (Bio Expertise Technologies), Marseille, France (Partner until 2004)**

Jean-Claude Laurent (PhD, CEO of B.E.T.)

**15 - UJF (Université Joseph Fournier), Grenoble, France**

Olivier Cohen (Prof., MD, PhD)

**16 - TEAMLOG SA, Montbonnot, France**

Christophe Guitart-Arnau (Technical Manager), Sandrine Villaeys (Project Manager)

### **1.3 The achievements of the EuroBioBank Network between 2003-2005:**

Between 2003 and 2005, while financed by the European Commission, 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) ([www.eurobiobank.com](http://www.eurobiobank.com) /[www.eurobiobank.net](http://www.eurobiobank.net)) was developed to offer services to the scientific community. A web-based catalogue of samples available throughout the EuroBioBank Network was established. It was specifically designed to provide easy access to referenced samples and present the sample 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 the specific EuroBioBank request procedure.

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).

Today, the EuroBioBank Network represents approximately 400,000 documented human biological samples, available via the 12 biobanks of the EuroBioBank Network. Approximately 35,000 samples were distributed between 2003-2007, with a mean of 7,000 samples (DNA, tissue and cells) a year, indicating that the EuroBioBank Network effectively contributes to research on rare diseases.

Researchers may access the biological resources available within the EuroBioBank Network through its online catalogue of samples and can also receive technical support for sample use, by e-mail and phone.

### **1.4 Objectives and future developments**

The EuroBioBank Network is supportive of 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 Network founding partners intend to consolidate the Network as a self-sustained structure in the long-term and establish EuroBioBank as a permanent and integrated European service Network for research on rare diseases.

The founding partners are fully dedicated to :

- operate the EuroBioBank Network as a non-profit trans-national platform managed by Eurordis;
- open the EuroBioBank Network to new Members across Europe;
- increase the distribution of quality material for research into rare diseases;
- further improve services and biobanking standards;
- ensure the sustainability of the EuroBioBank Network.

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

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

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

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

The EuroBioBank Network and its Members 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 Members 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, for collection and use of the biological material for research;
3. Access to samples: ad-hoc board approval of the projects for which the biological samples are requested, 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:

- (1) A General Assembly as the decision-making and arbitration body of the EuroBioBank Network, co-chaired by both Coordinators.
- (2) 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 authorised representative of each Member institution. All members of the General Assembly are voting Members.

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 orientation 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 (membership fees, investments, etc.) in collaboration with the Eurordis 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 member;
- exclusion of a member.

- **Meetings:**

The General Assembly shall meet once a year possibly around the same time. 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 Members are present or represented. Decisions are made by a majority vote of the voting Members present. To be valid, a vote shall represent at least 50% of all Members.

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

Any urgent matters, may be decided upon by the Members 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 formalise in writing all decisions taken and shall send them to all participants and Members within 30 calendar days of the concerned meeting.

The minutes shall be considered as accepted by the Members 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 Eurordis.
- a scientific coordinator, elected by the General Assembly for 1 year, from the biobanking Members 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 members 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.

## **5 - MEMBERSHIP TO THE EUROBIOBANK NETWORK**

### **5.1 Benefits attached to membership:**

Benefits of membership 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
- Accessing the EuroBioBank Network Intranet;
- Having a privileged access to know-how and services provided by other Members.

### **5.2 Duties attached to membership:**

Members 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 membership 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 and hard copies of these publications;
- To actively contribute to the EuroBioBank Network: regular attendance to 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 Members;
- 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.

### **5.3 Applying for membership:**

Candidates should apply for membership to the coordinators. Appropriate candidates are private or institutional Biological Resources Centres (BRCs) meeting all criteria defining a BRC.

Applications for membership to the EuroBioBank Network shall be submitted in writing, by returning the Membership Application Form available from the EuroBioBank web site duly completed to one of the Coordinators.

Applicants for membership shall also provide a letter describing the applicant's 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 membership is conferred to the applicant, until a full membership is confirmed by the General Assembly.

During the temporary membership, the new Member's name shall be inscribed on the official list of “new applicants for EuroBioBank membership” published on the EuroBioBank website

The General Assembly may reject any application to membership, 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 Member's name in the official list of EuroBioBank Members upon full payment of the requested annual membership fee. New Member's benefits and duties begin after positive confirmation of the membership by the General Assembly. Signature of the Membership Application Form by the new Member implies full adherence to the Charter principles.

### **5.4 Ending membership:**

Any EuroBioBank member can voluntary withdraw from membership:

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 Member. The coordinators will notify the excluded Member within 7 days of the General Assembly decision ;
2. through a resolution of the coordinators, if a member 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 member 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 Members of the EuroBioBank Network. In particular,

- (1) With respect to information or materials supplied by one Member to another through the EuroBioBank Network, the supplying Member 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 Member shall therefore in any event, be entirely responsible for any use whatsoever of such information and materials.
- (2) No Member shall be responsible to another Member 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 Members. Each Member shall act as an independent entity and not as the agent of any of the other Member. Nothing contained in this Charter shall be construed as constituting or organising the sharing of profits or losses arising out of the efforts of any other Member 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*