

Document title	Agreement for the integration of a Secondary Biobank into the TGB Network
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Authors	<ul style="list-style-type: none"> • Marina Mora, Barbara Garavaglia (Involved Biobanks Directors) • Mirella Filocamo (Biobank Director and TGBN Coordinator) • Franca Dagna Bricarelli (TGBN Coordinator Emeritus) • Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Corrado Angelini, Maurizio Moggio, Giuseppe Merla (TGBN Biobank Directors) • Lorena Casareto (TGBN Secretary)

This document describes the management plan to achieve the integration of a secondary Biobank within the TGB Network.

PARTIES

1. **Primary Biobank: Cells, tissues and DNA from neuromuscular diseases (hereinafter referred to as NeuMD), Director Marina Mora**
2. **Secondary Biobank: Cell line and DNA bank of paediatric movement disorders (hereinafter referred to as PMD), Director Barbara Garavaglia**

NeuMD contains and stores biological samples (cell lines, muscle tissue and DNA) from patients affected by neuromuscular diseases. PMD is supported by one-year Telethon Foundation grant as a Secondary Biobank. The current financial support of Telethon Foundation is oriented to facilitate the merging of the PMD into the TGB Network. The full integration should be achieved within the end of 2010, upon the approval of the Telethon Scientific Committee.

This agreement underlines the procedures that will be adopted to get uniformity in terms of technical procedures such as sample collection and storage, submission and informed consent forms between PMD and TGB Network and, finally, the procedures for samples transfer.

Forms

PMD and NeuMD Biobanks, being both located at the Istituto Neurologico C. Besta (INCB) of Milan, have since 2001 a common informed consent which is shared by all the INCB laboratories collecting biological material and includes the authorizations to store the samples and to distribute them to external centres that have scientific collaboration with the INCB.

PMD has uniformed sample submission, sample request, confirmation of sample receipt and shipping forms (attached) starting 2010.

Sample transfer

All frozen samples are stored in a unique facility, managed by the SOL Company present inside our Institute, and handled with common procedures that include transfer to and retrieval from SOL as well as bar code assignment that will uniquely identify each sample. The SOL company ensures safe storage conditions by continuous presence of personnel during working hours and alert systems for security during non working hours, constant monitoring of liquid nitrogen tanks with alarm system in case of failure, access to the bank facility only by authorized personnel, constant monitoring of persons in and out of the facility, secure handling and movement of the samples from the bank to the laboratories and vice versa by SOL personnel. DNA samples are stored at least in double aliquots, one placed in a cold box common to both Biobanks and one in a freezer of each Biobank.

PMD ACTIVITIES

In accordance with Telethon, NeuMD shall support the PMD activities

Tasks

The PMD bank shall provide the services described below:

- Accessioning, processing and preserving biological specimens (DNA, cell lines) for genetic studies.
- Updating accurate data on quality, quantity and location of samples, for the computerized sample inventory.
- Organizing, aliquoting and distributing samples to the scientific community privileging Telethon investigators
- Maintaining appropriate quality assurance systems.

All of the above services will be conducted in accordance with Network Standard Operating Procedures (SOPs) using appropriate forms (request, submission, shipping forms and informed consent). All information about PMD collection, services and forms are available at the web site www.eurobiobank.org

Procedures for samples request

Users who want to access to the PMD services, should contact in advance the PMD Director.

For incoming samples, users must provide a detailed clinical documentation of the patient by filling in a specific form. A copy of signed appropriate informed consent will be also sent. The informed consent, which is the same of the NeuMD, includes all the procedures to protect donor's privacy, by getting identifiable with a code the samples and maintaining personal data confidential. Information, referring to personal and clinical data, diagnostic status, type of material and referring centre, will be managed with the common database shared by all Network partners. All data will be sent to the TGB Network server in order to be anonymized and published on the TGB Network web site <http://www.biobanknetwork.org/>. Samples processing will be performed according to Network SOPs and with the sample back-up rules stated in the TGBN Charter.

For out-coming samples, relevant information will be provided in an anonymous form to users upon a specific request. No materials will be sent in absence of signed ad hoc agreement form. All the PMD samples requests will be processed by PMD staff according to the access rules as stated in the TGB Charter. Also the samples retrieval, preparation and sending will be carried out by PMD upon authorization of the director.

Informatics

The informatics management of PMD activities will be adapted to TGB Network IT infrastructure through these stages:

- development of a specific plugin
- one time data conversion
- one time installation of a separate application instance on the Galliera Genetic Biobank Server.

The integration of GDB in the Telethon Genetic Biobank Network infrastructure will be carried out by Giovanni Premuda - SoftWerk sas, Genoa

Riva del Garda (TN), 08/03/2011

Mirella Filocamo
TGBN Coordinator

Marina Mora
NeuMD Director

Barbara Garavaglia
PMD Director