

Document title	Agreement for the integration of a Secondary Biobank into the TGB Network
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This document describes the management plan to achieve the integration of a secondary Biobank within the TGB Network.

PARTIES

1. **Primary Biobank: Galliera Genetic Bank (hereinafter referred to as GGB), Director Chiara Baldo**
2. **Secondary Biobank: Genomic Disorders Biobank (hereinafter referred to as GDB), Director Giuseppe Merla**

GDB contains and stores biological samples (DNA, RNA and tissue cell lines) from patients affected by Williams-Beuren Syndrome (WBS) and other genomic disorders including DiGeorge, Prader -Willi, Angelman, Beckwith Wiedemann, Idiopathic mental retardation and other cognitive disabilities.

GDB 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 GDB into the TGB Network. The full integration should be achieved within the end of 2009, 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 GDB and TGB Network and, finally the procedures for samples transfer.

Forms

Starting with 2009 the GDB and GGB biobanks have already uniformed the informed consent, sample submission, sample request, confirmation of sample receipt and shipping forms (attached).

In particular the new informed consent includes the authorization to store the samples at both GDB and GGB biobanks.

Samples transfer

As requested by Telethon Foundation, an aliquot of GDB DNA samples will be transferred to GGB within the end of 2009 and an aliquot of cultured cell lines will be transferred within the end of 2010.

All the samples will be transferred to GGB with the following data set: code, type and amount of specimen, maintenance and storage buffer and freezing medium.

To avoid the risk of losing/damaging valuable samples, the Parties propose that procedures of samples transfer from GDB to GGB will be developed as follows:

- DNA SAMPLES: only samples with total amount > 10 micrograms will be considered for shipment. For each sample an aliquot of 5 micrograms will be transferred.
- RNA SAMPLES: this material, being highly perishable and in a limited amount, **will not be transferred.**
- CELL LINES: only cryopreserved cell lines with a minimum of 4 cryotubes stored at GDB should be transferred in a number of 2 cryotubes for each cell line to GGB.

GDB ACTIVITIES

In accordance with Telethon, GGB shall support the GDB activities.

Tasks

The GDB bank shall provide the services described below:

- Accessioning, processing (including: establishment of cell lines EBV transformed lymphoblast cultures from human blood; establishment of cell lines of fibroblast, cryopreservation of primary or transformed cell lines and DNA/RNA extraction) and preserving biological specimens 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
- Transferring samples aliquots to Galliera Genetic Bank.
- Maintaining appropriate quality assurance systems.

All of the above services will be conducted in accordance with Network Standard Operating Procedures (SOP's) using appropriate forms (request, submission, shipping forms and informed consent). All information about GDB collection, services and forms are available at the GDB web site <http://www.operapadrepio.it/gdbbank/>

Procedures for samples request

Users whose want to access to the GDB services, should contact in advance the GDB 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 (including information about the storage at GGB of Genoa) will be also sent.

GDB will adopt all Network procedures, stated in the Charter, 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 manage 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 SOP's and with the sample back-up rules stated in the TGBN Charter.

For *outcoming 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



GDB samples requests will be processed by GDB staff according to the access rules as stated in the TGB Charter, while the samples retrieval, preparation and sending will be carried out by GGB upon request and authorization of GDB director.

Informatics

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

- development of a Williams Syndrome plug-in
 - 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

Following documents are an integral part of this agreement:

- GDB Submission form – Enclosure 1
- GDB Informed consent – Enclosure 2
- GDB Request form – Enclosure 3

Milan, 3rd December 2009

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