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1 - INTRODUCTION

1.1 Presentation of the Telethon Network of Genetic Biobanks

Genetic Biobanks (biospecimens and associated data) are an important resource for diagnostic and research purposes.

The objective of the Telethon Network of Genetic Biobanks (TNGB) is to interconnect and to coordinate Italian Genetic Biobanks. The Network has been designed to be the first national, standardized biospecimen resource related to genetic diseases. Its mission is to support research on genetic diseases, including rare ones, by facilitating access to quality human biological resources (i.e. cell lines, tissues, nucleic acids, sera/plasma, etc.) of interest to the scientific community, patients and families.

To achieve its objectives, the TNGB has adopted an Information Technology (IT) infrastructure which is currently supported by Fondazione Telethon grants. Fondazione Telethon is an Italian non-profit organisation supporting research on rare diseases (www.telethon.it).

We wish to mention here Franca Dagna Bricarelli, who passed away on December 2014. Franca is well remembered for her fundamental role in founding the Telethon Network of Genetic Biobanks, defining the governance structure and key organizational elements described in the Charter. She served TNGB as Coordinator Emeritus until 2014. Franca will remain as an inspiration to all of us.

1.2 Composition of the Telethon Network of Genetic Biobanks

The TNGB includes all Founding Partners and Joining Partners respectively listed in points 1.3 and 1.4. The Principal Investigator who applied to the TNGB proposal is identified as "Director" of the relevant Biobank.

1.3 Founding Partners of Telethon Network of Genetic Biobanks

- **Cell Line and DNA Biobank from patients affected by genetic diseases**
Laboratorio per lo Studio degli Errori Congeniti del Metabolismo – LABSIEM, U.O.C. Clinica Pediatrica, IRCCS Istituto G. Gaslini, Genova
Director: Marina Stroppiano
- **Biobank of the Laboratory of Human Genetics**
U.O.C.: Laboratorio di Genetica Umana, IRCCS Istituto Giannina Gaslini, Genova
Director: Domenico Coviello
- **Parkinson Institute Biobank**
Centro Specialistico Ortopedico Traumatologico G. Pini – CTO, Milano
Director: Roberto Cilia
- **Cell lines and DNA bank of Rett syndrome, X-linked mental retardation and other genetic diseases**
Medical Genetics, University of Siena; Genetica Medica, Azienda Ospedaliera Universitaria Senese, Siena
Director: Alessandra Renieri
- **Neuromuscular Bank of Tissues and DNA samples**
Università di Padova Azienda Ospedaliera Universitaria, Padova

Director: Elena Pegoraro

- **Bank of muscle tissue, peripheral nerve, DNA and cell culture (Acronym: biobankNMD-Milan)**
U.O.D. Malattie Neuromuscolari e Rare, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Centro Dino Ferrari, Università Studi Milano, Milano
Director: Monica Sciacco
- **Cell, tissues and DNA from patients with Neuromuscular Diseases**
Laboratorio di Biologia Cellulare, U.O. Malattie Neuromuscolari e Neuroimmunologia, Fondazione IRCCS Istituto Neurologico Carlo Besta, Milano
Director: Marina Mora

1.4 Joining Partners of Telethon Network of Genetic Biobanks (see point 9.3)

- **Genomic and Genetic Disorders Biobank**
Medical Genetics Unit, IRCCS Casa Sollievo della Sofferenza, S. Giovanni Rotondo (FG)
Director: Giuseppe Merla
- **Naples Human Mutation Gene Biobank**
Cardiomiologia e Genetica Medica, Dipartimento di Medicina Sperimentale, Università degli Studi della Campania "Luigi Vanvitelli", e Azienda Ospedaliera Universitaria "Luigi Vanvitelli", Napoli
Director: Luisa Politano
- **Cell line and DNA Bank of Genetic Movement Disorders and Mitochondrial Diseases**
U.O. Neurogenetica Molecolare, Fondazione IRCCS Istituto Neurologico Carlo Besta, Milano
Director: Barbara Garavaglia
- **BIOGEN - Biobank of Genetic Samples-**
S.S.D. Genetica Medica, Istituto Ortopedico Rizzoli, Bologna
Director: Luca Sangiorgi

Each Biobank (Founding and Joining Partners) stores biospecimens from patients and families affected by genetic diseases, including rare and "orphan" disorders. Telethon and Biobanks part of the Network have always maintained a close relationship with Rare Disease Patient Organisations.

1.5 Objectives

Genetic Biobanks are an important resource for diagnosis and research - both basic research and research applied to the treatment of genetic diseases. Several examples illustrate how access to relatively large numbers of biospecimens and associated data has played a pivotal role in the identification of genetic disease genes, susceptibility genes and the development of novel treatment.

The purpose of the Telethon Network of Genetic Biobanks is therefore to coordinate well-qualified Genetic Biobanks in order to improve access to human biological resources in the biomedical community. The Network creates harmonious environments which help to improve the protection of the privacy and confidentiality of individuals and their family members encouraging biobanks to harmonize the entire process of collection, storage, and use of biospecimens and linked data according to the more updated guidelines and best practice procedures.

The main Network's objectives can be summarised as follows:

- interconnecting and coordinating the Genetic Biobanks admitted to the Network (see 9.3);
- developing a centralized bioinformatics system designed to facilitate Network presentation and external access to the biospecimen collections;
- harmonizing ethical, legal and quality standards;
- helping Biobanks to increase collections and distribution of high quality biospecimens for

- research in the field of rare diseases;
- enhancing collaborations within the biomedical community, stimulating research projects;
- helping Biobanks to offer a service to researchers for the development of their studies;
- collaborating with Patient Organisations;
- promoting the Network services within patients and civil communities;
- opening the Network to new members;
- collaborating on common projects with European and international Biobanks.

2 - ORGANIZATION AND GOVERNANCE OF THE NETWORK

The governance structure of the Network comprises the following bodies:

2.1. Network Board (NB), the decision-making body of the Network is composed of the Scientific Coordinator (see point 2.2) and the Biobank Directors. The Network Board coincides with the Access Committee who evaluates the requests submitted to the TNGB (see point 6). The Network Board meets at least once a year. Whenever possible, it takes advantage of web-meeting tools, favouring open-source or free products, such as video conferencing, document sharing and collaborative writing.

Role of the Network Board:

- establishing an annual work plan;
- defining the strategic orientation of the Network;
- setting up working groups according to the work plan;
- making modifications and amendments to the Network organisation and the Charter;
- updating Network official documents, Standard Operating Procedures (SOPs) and forms;
- defining terms of use of the TNGB name and logo;
- establishing collaborative policies with Patient Organisations;
- promoting and disseminating the TNGB's activities within national and international congresses and events.

2.2. The TNGB Coordinator is elected by the Network Board for the whole duration of the project. The role of the Scientific Coordinator is to represent the TNGB and his/her tasks are:

- guaranteeing management of the Network;
- organizing the Network and Advisory Boards' meetings;
- coordinating working groups according to the Network work plan;
- ensuring implementation of the decisions taken during the assembly;
- providing a written summary of the meetings to the Network Board members;
- reporting to the Network Board on all activities;
- relating to Fondazione Telethon.

2.3 The TNGB Coordinator can rely on the **Coordination Office's** support taking care of the day-to-day management of all TNGB activities. The Coordination Office's staff shall include at least one **Operations Manager**, responsible for overseeing the operational activities, and one **IT and Data Manager**, responsible for the management and development of the TNGB IT platform and the interaction with the software provider.

The TNGB Coordinator and the Coordination Office staff shall continuously interact in order to achieve the goals defined in the TNGB work plan. The Coordination Office should also perform

regular monitoring of the TNGB sample workflow via the platform.

2.4 Fondazione Telethon is the **Funding Body** of the TNGB. Its role is to provide and maintain the IT infrastructure, the Coordination Office staff and the TNGB common resources. Fondazione Telethon should also perform regular monitoring the TNGB sample workflow via the platform and consider this in the general strategy over the years.

2.5 The role of the **working groups (WGs)** is to support the TNGB Scientific Coordinator in carrying out TNGB activities within specific areas. Every WG is composed of at least 3 NB members coordinated by a WG leader. The WG leader coordinates the activities of the WG according to the TNGB work plan and directly reports to the TNGB Coordinator. WGs thematic areas are identified by the Network Board and include, but are not limited to, sustainability, ethical-legal-social-implications, dissemination/training, sample catalogue and sample quality. WGs should carry out their activities by web-conferencing.

2.6. A **Coordinator Emeritus**, as support of the Coordinator and the Biobank Directors, could be nominated for the whole duration of the project by the Network Board. In case of election of the Coordinator Emeritus, his/her tasks will be defined by the Network Board.

2.7. An external **Advisory Board (AB)** is established to provide consultative support to the Network. The Network Board chooses a minimum of 3 AB members and nominates a chairperson chosen among AB members. This board, including legal, ethical and technical experts, advises the NB on the Network strategic plan. In particular, the Advisory Board supports the Network by providing expert advice on the following topics:

- TNGB governance strategies;
- strategies promoting for the sustainability of the network/biobanks, as well as, the Network involvement in European projects on biobanking and rare genetic diseases;
- specific advice on rare disease trends and needs;
- TNGB Charter, documents and policies and procedures;
- strategies promoting for the national and international development of Network;

Additionally, the AB will arbitrate the following issues:

- conflicts between Biobank Directors and users, concerning priority criteria in the use of materials from the Biobanks;
- conflicts among Biobank Directors concerning sample and data management;
- non-compliance or violation of the principles governing the Network as stated in the Charter.

The AB will meet at least once a year and will provide a report for Fondazione Telethon on the effectiveness and direction of Network.

2.8. In case of retirement/resignation of the Coordinator, the successor of the outgoing Coordinator will be nominated by the Network Board through the following procedures:

- the outgoing Coordinator must inform the Network Board, as well as the Fondazione Telethon, about the vacancy;
- the Coordinator will be replaced by a successor, elected by the Network Board among the Biobank Directors; an absolute majority is required to be elected;
- granting of Telethon funds to the successor Coordinator must be approved by Fondazione Telethon.

2.9. In case of retirement/resignation of a Biobank Director, the successor of the outgoing

Director will be nominated through the following procedures:

- the outgoing Biobank Director must inform the Network Coordinator and Partners, as well as the Fondazione Telethon, about the vacancy;
- the outgoing Biobank Director will nominate a successor;
- the nominated successor has to be a person approved by the Host Institution;
- the successor will take over daily operations related to Biobank administration before the departure of the outgoing Biobank Director;
- the new Director will be introduced at the first meeting of the NB, and will be obliged to adopt the principles and to adhere to the policies of the Network.

2.10. To leave the Network, a written official notice by the Director of the outgoing Biobank is required to announce the decision. The communication specifying the cause for leaving should be sent to the NB and all procedures should be formalized by the end of the financial year. Membership revocation is subjected, and contextual, to the renunciation to any ongoing Telethon grant by the Biobank Director.

The existing agreements related to the outgoing Biobank (see 10.1, 10.2) should be considered settled and new ones stipulated with another partner, if agreed by all parties.

3 - PURPOSE OF THE CHARTER

This Charter is the Constitution Document of the Telethon Network of Genetic Biobanks, which sets out the principles agreed upon by the Members of the Network.

In particular, the Charter recalls the ethical guidelines endorsed by Members of TNGB, defines the organisation and governance of the Network and establishes the duties attached to membership.

The NB may modify the Charter and the Network organisation. The AB must always be informed and consulted, but its approval is not necessary. Any modification has to be approved by the majority of the NB participants. The Coordinator and the Biobank Directors (or their deputies) must vote. Each biobank count for one vote. In the event of a tie, the Coordinator will decide on the issue.

4 - ETHICAL GUIDELINES

The Network adopts appropriate security measures at different levels:

- sample cryptification (identifiable samples);
- confidentiality and data protection;
- written informed consent for collection, storage and distribution;
- distribution to scientific community regulated through evaluation and approval of the project for which the samples are requested.

For all the ethical, legal and societal issues, the Network adopts the principles enunciated. Reference documents are:

- **Recommendations issued by the Oviedo Agreement, 1997** (Convention on Human Rights and Biomedicine, Oviedo, 4th April 1997)
<http://www.portaledibioetica.it/documenti/001316/001316.htm>
- **Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes (CETS n. 203), 2008** (Strasbourg, 27th November 2008)
<http://conventions.coe.int/Treaty/EN/Treaties/Html/203.htm>
- **Telethon - SIGU Guidelines for Genetic Biobanks, 2003**
<http://biobanknetwork.telethon.it/Pages/View/Documents>

- **International Declaration on Human Genetic Data, 2003** (16th October 2003, 32nd session, the General Conference of UNESCO - The International Declaration on Human Genetic Data)
http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

The Network operates abiding by the Italian Privacy and Data Protection Laws in force, including:

- **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016** on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR - General Data Protection Regulation)
- **Italian Data Protection Authority (*Garante Privacy*), National implementation of the Regulation (EU) 2016/679**, Legislative Decree no. 101, 10th August 2018, published in Official Gazette no. 205 of the Italian Republic, 4th September 2018, and possible subsequent amendments
- **Italian Data Protection Authority (*Garante Privacy*), Personal Data Protection Code**, Legislative Decree no. 196, 30th June 2003, published in *Official Gazette No. 174 of the Italian Republic*, 29th July 2003, and possible subsequent amendments

5 - INFORMATION TECHNOLOGY (IT) INFRASTRUCTURE

The partners have adopted a common IT infrastructure. The software has been developed by an external provider. The common software application suite is web-based and handles the core Biobank data and the full superset of patient and sample data currently collected by each Biobank, with optional modules used to handle sample/pathology subsets for which some partners collect specific data. Data are hosted and maintained by CINECA data center, a no-profit Italian Consortium guaranteeing reliable and secure environment for data storage and backup-archive. The system manages and monitors the complete workflow of sample submission and sample requests. Data aggregation and publishing are completely automated. Network governance and coordination is aided by the use of open-source or free collaboration products for project management, video conferencing, document sharing and collaborative writing.

The official TNGB website is <http://biobanknetwork.telethon.it/> where Users can find all information related to the Network.

6 - ACCESS TO NETWORK SERVICES

The main services provided by TNGB Partners, operating as single entities, are as follows:

- DNA/RNA extraction;
- Establishment of cell lines from appropriate tissue;
- Plasma and serum isolation from human blood;
- Preservation of biological specimens and recording of the related data for genetic studies;
- Distribution of samples to the scientific community for specific research projects;
- Repository services for patients and their families as well as external institutions, which do not have an independent biobank. This service is provided under condition that samples and related data will be made available to scientific community upon completion of the study.

Access to TNGB Services is provided both to for-profit and no-profit entities and patient organisations. Processing and storage services must be agreed with the Biobank Director/Staff of the individual biobank who will provide users with all necessary information for safely sending the biological material(s) and the appropriate forms to be enclosed in the package. All the samples and associated data stored in the TNGB Biobanks are made available to the scientific community provided that the participant gave the consent to use their samples for research purposes.

6.1. Access to samples

Sample request and submission are fully handled online by IT system and are shared through the Request Control Panel (RCP) by all Network partners as well as by the Telethon Program Manager. Users are requested to fill in an on-line request form and, once the request is received on the RCP, the Access Committee accepts or rejects it on the basis of the basic rules of access listed below (see 6.2). In case of a request for the use of samples managed under the Agreements with Patient Organisations (see point 10.1), the representative of the specific Patient Organisation will be made aware of the receipt of the request. The representative may express their opinion on the request evaluation, if deemed necessary. This opinion which should be adequately motivated is not binding but the Access Committee will take it into consideration. Assuming approval, Users are requested to send a signed hard-copy of the material transfer agreement form to the referring Biobank.

Samples will be made available to users for purposes of research only in the biomedical field, provided that an adequate portion of the samples derived from individuals affected by undiagnosed and rare diseases are safeguarded to the patient's advantage to allow retrospective analysis. Consequently, the Biobank will never send out the last vial related to a particular specimen for research purposes, because it has to be kept for diagnostic analysis.

6.2. Basic Rules of Access

Basic rules of access, applied to all researchers whether they work for for-profit or non-profit organisations, are as follows:

- adequate aliquot of sample to be saved for patient/family, aimed at retrospective analysis;
- sample distribution to qualified professionals working at research or medical institutions;
- appropriate justification for use (description of the research project, grant sponsor, expected results);
- use of signed material transfer agreement form;
- acceptance of Biobank rules that are:
 1. samples supplied cannot be used for commercial purposes (e.g., biospecimen resale);
 2. biospecimens cannot be distributed to other investigators without written permission of the Biobank Director;
 3. samples provided must be used only for the research project declared by the Principal Investigator (PI);
 4. if results obtained with Biobank specimens are included in a scientific report, PIs are expected to acknowledge the Biobank, and the TNGB, for having provided the biospecimens, and to send a paper reprint to the Biobank;
 5. feeding back the analytic results from each single sample to the Biobank Director, in order to support further research;
 6. paying for shipping and distribution services (see 6.3).

6.3. Charges

The TNGB provides its services on a basis of non-economic gain. However, Biobank distribution service might be subject to cost recovery. The costs of some consumables associated with the distribution operations are charged to the users through administrative mechanisms that may differ between Biobanks, this is depending on the administrative procedures of the host Institution. The official TNGB cost recovery list for researchers operating in public/non-profit organisations has been published on the Network website upon the NB approval. A different cost list, approved by NB, is applied to researchers operating in private companies and available upon request.

6.4. Particular Requests and Controversies

It is envisaged that particular requests or controversies will require a devoted approval

procedure by a third-party committee, hereafter referred to as the **Approval/Appeal Panel (AP)**. The panel will be composed by one of the members of the Advisory Board, one representative of Fondazione Telethon, and by a third external member selected among the international Scientific Community through the peer-review-based procedures.

In case of particular requests or controversies, the request of the convening of the AP, including an explanatory note illustrating the reasons for the controversy, will be sent to the TNGB Coordinator.

6.5. Biobank Director requests

The Biobank Directors do not have any advantage/special treatment in the access to samples for research purposes and their requests have to fulfil all the rules reported above. The Biobank Directors and their research group must request the samples using the same online form as other researchers. In this way their requests will be accessible to all partners and to the Telethon program officer through the IT management system.

To ensure transparency of possible conflicts of interests, self-request number of each Biobank should be compared with the total number of the external requests received and detailed in the Annual Report.

7 - Sample Back-up

7.1. General Rules

In order to minimize the risk of losing important samples the Network Biobanks plan the sample back-up as follows:

- a **master stock** is produced, whenever possible, and is used to generate the distribution stock;
- the **biological material** is preserved, if possible, by at least two methods (whole blood/DNA, whole blood/cell line, RNA/cell line);
- **each biospecimen** (e.g. whole blood, DNA, RNA) is subdivided into several very small aliquots to avoid repeated freezing and thawing; in the case of cryopreserved cell lines, a minimum number of 3/4 cryotubes from the original biological material must be ensured, and out of these at least one cryotube is stored in another container and in another place; *In view of events such as power loss, fire, flooding, earthquakes, user errors etc. samples and aliquots should be divided and stored in separate buildings or, ideally, at separate sites.*
- the divided and aliquoted samples are stored in different containers and locations, under the responsibility of the Biobank Director.

Note: *When banking biological material, it is essential to always preserve a sample aliquot for the **patient/family**.*

7.2. Difficulties with Sample Back-up

There are, however, circumstances in which the biological material cannot be easily aliquoted due to sample scarcity/characteristics.

Exemplifications:

- **foetal samples** collected after abortion;
- **tissue samples**, for which planning the storage of aliquots would imply the collection of an amount of material that would be detrimental to the individual undergoing biopsy.

Another important point to be considered is that there are sample types requiring swift storage, to which a back-up relocation could therefore potentially cause damage rather than yield a benefit.

Sample back up in neuromuscular collections may be hampered due to the following issues:

- neuromuscular diseases are rare;

- samples are perishable;
- size of the muscle sample taken is small for ethical reasons*;
- muscle biopsies cannot be repeated for ethical reasons;
- it is not easy to divide the samples and place them in different tissue Biobanks*;

*The available sample may be even smaller for several practical reasons:

- *critical physical conditions of the patient;*
- *scarce availability of tissue due to disease severity;*
- *muscle involved in the disease not easily accessible for biopsy;*
- *patient age (i.e. babies and children).*

8 – QUALITY ASSURANCE (QA)

To minimize errors the Network Biobanks have developed a quality assurance (QA) system that guarantees that the biological samples and related data are of adequate quality.

The system will be a continuous process that aims at measuring, evaluating and continuously re-evaluating quality and, if necessary, changing and improving it. Therefore, the QA system involves all the Biobank operators and covers all management activities including planning, implementation, documentation, assessment, and improvement.

According to national/international laws and recommendations in force, each Biobank regularly updates the QA processes related to:

- data management (coding and registration);
- storage systems;
- safety plan;
- training schedules;
- adherence to Standard Operating Procedures (SOPs) (<http://biobanknetwork.telethon.it/Pages/View/Documents>);
- equipment maintenance and repair.

9 - MEMBERSHIP TO TNGB

Conditions of access to TNGB is subject to the participation to a devoted call for proposal issued by FT. New memberships are evaluated by FT in consultation with the NB according to specific assessment criteria implemented to ensure adherence to minimal entry conditions favouring the adoption of the standardisation and harmonisation measures needed for a successful inclusion to the TNGB.

The assessment criteria should take into consideration the following topics:

- disease(s) of interest;
- quality assurance system;
- ethical, legal and social implications (ELSI);
- informatics set-up.

9.1. Benefits of Membership

TNGB Partners will benefit by:

- being integrated into the IT platform (including implementation of the software application for data management);
- sharing a wide number of biospecimens related to rare genetic diseases;
- having a high visibility through TNGB website;
- being an acknowledged national infrastructure;

- belonging to the first national Network on rare genetic diseases;
- having the necessary requirements to access international projects/funding.

9.2. Undertaken Duties

TNGB Partners will undertake to:

- comply with the principles defined in the *TNGB Charter*;
- adopt TNGB SOPs and guidelines concerning informed consent, privacy, sample management, priority access criteria and quality control;
- regularly update the information on the biological samples in the central database according to the minimum dataset defined by TNGB;
- ensure the accuracy of any information on the samples;
- inform the Network of scientific publications resulting from the use of biological samples provided through the TNGB;
- actively contribute to the TNGB's development through regular participation to meetings and its promotion.

9.3. New Membership

- new memberships are subject to availability of Fondazione Telethon funds. However, if the applicant provides its own funding to cover minimal starting costs for the integration in the IT platform, new membership could be taken into account regardless availability of Fondazione Telethon funds;
- the criteria that have to be met to qualify as a TNGB member are defined by Fondazione Telethon and shared with the Network Board;
- new entries are requested to submit a letter of intent to Fondazione Telethon.

9.4. Penalties in the event of non-compliance with TNGB Charter

In the event of any non-compliance with the Charter and Network policies the Approval/Appeal Panel (see 6.4) should be convened.

9.5. Authorship/Collaboration

It is understood that the main objective of the Network is to facilitate Biobanks to provide the scientific community with biological samples and related data as a service. This service will be acknowledged as such in any ensuing scientific publication and will not necessarily entail co-authorship of the publications by the Network's members.

However, if the Biobank's staff actively participates in the scientific activities described in the publication, besides providing biological samples and associated data from the Biobank, co-authorship will be admissible.

Moreover, in case of request of extended clinical data related to the sample(s), the relationship between the user and the biobank should be configured as a scientific collaboration and the biobank Director, or a member of their staff, must be included among the authors of the scientific articles resulting from the research.

If Biobank members use biological samples from their Biobank and produce a scientific publication as first or last author, they should comply with the same rules followed by external researchers (see 6).

10 - AGREEMENTS

10.1. Agreements between TNGB and Patient Organisations

TNGB can facilitate agreements between Biobanks and national and international Patient Organisations. Each agreement should be regulated by a written document approved by the

Network Board who selects the Biobank/Biobanks providing the required service on the basis of some pre-defined criteria.

The selected Biobank and the Patient Organisation should completely accept their respective Charters. The document should describe all the requested and the provided services. It will be detailed the economic aspects and all the "sample in and out" procedures.

10.2. Agreements between TNGB Partners

The Network can benefit from Biobank services in order to fill possible technical gaps. In this regard written agreements can be made between Biobank Directors to provide services to each other.

Services should occur following the "sample in and out" rules.

If the sample information is maintained in the database of each involved Biobank, it should be published only once in the TNGB catalogue, the decision depending on the parties involved.

11 – ACKNOWLEDGMENTS OF PAST CONTRIBUTORS

This Charter, known as the TNGB Charter, was originally drafted in 2008 by the funding members of the Telethon Network of Genetic Biobanks, that were Franca Dagna Bricarelli and Mirella Filocamo (in charge as TNGB Coordinators), Stefano Goldwurm, Alessandra Renieri, Corrado Angelini, Maurizio Moggio, Marina Mora (Biobanks Directors) and Chiara Baldo (Biobank staff member). It was adapted from a draft version by TNGB, 6 October 2008 and it was revised over the years by the members of the TNGB.

| REVISION HISTORY | | |
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| Revision no. | Date of approval | Authors |
| Rev. 1 | September 2009 | Mirella Filocamo (TNGB Coordinator), Franca Dagna Bricarelli (TNGB Coordinator Emeritus), Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Marina Mora, Maurizio Moggio, Corrado Angelini and Lorena Casareto (TNGB Administrative Assistant) |
| Rev. 2 | September 2010 | Mirella Filocamo (TNGB Coordinator), Franca Dagna Bricarelli (TNGB Coordinator Emeritus), Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Marina Mora, Maurizio Moggio, Corrado Angelini, Giuseppe Merla and Lorena Casareto (TNGB Administrative Assistant) |
| Rev. 3 | October 2011 | Mirella Filocamo (TNGB Coordinator), Franca Dagna Bricarelli (TNGB Coordinator Emeritus), Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Marina Mora, Maurizio Moggio, Corrado Angelini, Giuseppe Merla, Luisa Politano, Barbara Garavaglia and Lorena Casareto (TNGB Administrative Assistant) |
| Rev. 4 | July 2012 | Mirella Filocamo (TNGB Coordinator), Franca Dagna Bricarelli (TNGB Coordinator Emeritus), Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Marina Mora, Maurizio Moggio, Corrado Angelini, Giuseppe Merla, Luisa Politano, Barbara Garavaglia and Lorena Casareto (TNGB Administrative Assistant) |
| Rev. 5 | September 2012 | Mirella Filocamo (TNGB Coordinator), Franca Dagna Bricarelli (TNGB Coordinator Emeritus), Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Marina Mora, Maurizio Moggio, Corrado Angelini, Giuseppe Merla, Luisa Politano, Barbara Garavaglia and Lorena Casareto (TNGB Administrative Assistant) |
| Rev. 6 | November 2014 | Mirella Filocamo (TNGB Coordinator), Franca Dagna Bricarelli (TNGB Coordinator Emeritus), Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Elena Pegoraro, Maurizio Moggio, Marina Mora, Giuseppe Merla, Luisa Politano, Barbara Garavaglia and Lorena Casareto (TNGB Administrative Assistant) |

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| Rev. 8 Preliminary draft | September 2018 | Working Group on TNGB Charter: Mirella Filocamo, Serena Maria Giovanna Grossi, Chiara Baldo, Luisa Politano and Lorena Casareto (TNGB Operations Manager) |

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