INSTITUTION / BIOBANK LOGO

TELETHON NETWORK OF GENETIC BIOBANKS
[NAME OF THE BIOBANK]

INFORMATION LEAFLET AND CONSENT FORMFOR THE STORAGE OF BIOLOGICAL MATERIAL

Dear Sir/Madam,

Before expressing your consent to store biological material in the Biobank, we would like to inform you about the aims, services and policies of the Genetic Biobanks which are partners of the "Telethon Network of Genetic Biobanks" (TNGB, http://biobanknetwork.telethon.it/). In particular we would like to bring to your attention how TNGB manages the biological material and protects the rights of the person concerned (hereinafter referred to as "participant").

A. WHAT ARE THE GENETIC BIOBANKS?

The Genetic Biobanks are service units which operate according to the high-quality standards with the aim to collect, process, store, distribute human biological material (hereinafter referred to as "sample") from individuals affected by genetic diseases. The primary goal of the biobanks is to facilitate the diagnosis and research for patients and their family members as well as for the scientific community.

A requirement of a Genetic Biobank is that the stored samples are linked to the personal, genealogical, and clinical data (hereinafter referred to as "linked data") of the participant(s) and are traceable by the biobank's director and authorised staff. This link is essential to return potentially vital results to the participant(s) and necessary to gain maximum research value. In order to guarantee the security and confidentiality of the participants' personal data, the Genetic Biobanks operate according to high ethical and legal standards and in compliance with Italian laws and international recommendations.[1,2,3,4,5]

B. WHAT IS THE "TELETHON NETWORK OF GENETIC BIOBANKS" (TNGB)?

TNGB is a project funded by the Telethon Foundation started in 2008 with the aim to coordinate well established non-profit Genetic Biobanks supported since '90s, as single core facilities, on the basis of specific research projects.

The main aim of TNGB is to facilitate biomedical research on genetic diseases through:

- sharing of operating procedures adopted by each Biobank;
- granting access to a unique online sample catalogue (http://biobanknetwork.telethon.it/Pages/View/Catalogue);
- monitoring of usage of the samples provided to the scientific community.

The Network, currently consisting of 11 Biobanks, works closely with Rare Disease Patients' Organisations, in particular with UNIAMO F.I.M.R. onlus, the Italian Federation of Rare Diseases (www.uniamo.org). TNGB also participates in other networks/projects[6], having similar purposes to TNGB's ones, including sharing the sample catalogue on their relevant platforms.

C. WHAT PROCEDURES ARE ADOPTED FOR PROCESSING THE PERSONAL DATA?

The Genetic Biobank guarantees personal data confidentiality enforcing the current regulations[3,4] as follows:

1. alphanumeric code assignment to each sample to protect participant's identity;
2. protected storage of code keys by the Biobank Director (or authorised Biobank's personnel), the only ones entitled to decode the participant's identity and to track back the linked data (clinical, genetic, genealogical, etc.);
3. access to databases: all registered data are controlled by security measures adequate to prevent data circulation or data usage from unauthorised parties. In particular, access is controlled by double personalised passwords assigned to the authorised personnel by the Biobank Director in order to reduce the risk of illegal or not authorised accesses;
4. use of samples for research: the biobank staff must ensure that possible research results, published in scientific journals or reported at scientific conferences, do not contain information revealing participant's identity.

Finally, the Biobank Director recognises to the participants the right to access to their own samples.

Concerning the option to withdraw the consent, please refer to "K" point.

The person in charge for personal data processing (hereinafter referred to as "Data Processor") is [Name of the Biobank Director].

D. HOW CAN THE BIOBANKED SAMPLES BE USED?

Samples and linked data can be used for both diagnosis and research purposes in the field of the pathology for which they have been biobanked. Generally, portions of samples (hereinafter technically defined as "aliquot(s)") are coded and transferred to researchers who work in national and international research institutes and solely after the project evaluation and approval by the Network Board, as stated in the *TNGB Charter* (http://biobanknetwork.telethon.it/Pages/View/TheCharter). If a sample is requested beyond the purposes specified above, the Biobank will recontact the participant. During the distribution service, the Biobanks of the Network undertake with the participant(s) to safeguard an adequate aliquot of the samples for future analyses with diagnostic purpose.

If the participant declares in the "expression of consent" (point 7) to have deposited their data in a patient registry or clinical database, managed by a third party, the presence of their biological material in the Biobank could be notified to the third party in accordance with the regulation in force.

It could happen that results from scientific research conducted on samples distributed by the Biobank are patented (e.g. diagnostic kit validations). It should be noted that potential economic gain, deriving from these activities, are solely owned by

the Institution/Company responsible for the research, therefore there are no economic returns for both the participant(s) or the Biobank.
It might happen that TNGB samples, such as blood, skin or other tissue samples, might be used to generate primary cells in order to obtain "Induced Pluripotent Stem (iPS) cells". The iPS cells are suitable to be used for "in vitro" research studies to regenerate and substitute damaged cells as well as to develop potential therapeutic products.

E. WHAT ARE THE POSSIBLE BENEFITS FOR THE INDIVIDUAL AND THE COMMUNITY?

Results obtained from research projects bring benefits to both the participant and the community, and include identification of genes responsible for diseases, studies of molecular mechanisms, development of therapeutic strategies, etc. The scientific community has extensively used the TNGB services with different purposes as shown by the huge amount of the scientific results published on international journals (the complete list of articles acknowledging the Biobanks is available on the TNGB website at http://biobanknetwork.telethon.it/Pages/View/Documents).

F. HOW CAN I KNOW THE RESULTS OF THE RESEARCH CONDUCTED ON MY SAMPLE(S)?

The results of the research conducted on the samples deposited into the Biobank are given, with the consent of the interested participant, only when such results represent an advantage for the health in terms of prevention, diagnosis, therapy or reproductive choice. In addition, it can happen that, even if the participant did not give the consent or cannot be contacted, samples and/or related genetic data may be provided to third party belonging to the same biological family if these are essential for both their health or reproductive choices (aforesaid Authorisation 8/2016, section 3.1b).

G. PARTICIPANTS WHO ARE MINORS

In the case of minors, as they grow toward maturity, they should be informed by their parents/legal guardian that their biological material and the linked genetic data are stored in the Biobank. This is essential to give them the opportunity to renew or withdraw their consent. If the sample is taken when the minors can be considered sufficiently mature enough to understand the TNGB activities, they should be informed and involved in the choice. Their opinion will be taken into consideration, whenever possible. Adequate strategies will be adopted to aptly involve the minors and to inform them, in respect of their level of maturity and growth, and their comprehension ability. Each choice will be made considering the preeminent interest of the minor.

H. WHO FINANCIALLY SUPPORTS THE BIOBANK?

Presently, the Biobank activity is supported by the host Institution and by the Telethon Foundation funding (proj. GTB12001, yrs. 2012-2017). Even though the Biobank activities are free of charge, the sample distribution services might be subject to cost-recovery in order to partially contribute to the Biobank sustainability. Users might be asked to partially contribute for sample processing, transfer and shipping costs. The official TNGB cost-recovery list is available on the Network website (http://biobanknetwork.telethon.it/Pages/View/pricelist).

I. WHAT HAPPENS TO THE STORED SAMPLES IF THE BIOBANK CEASES ITS ACTIVITY?

If the Biobank ceases its activity for any reason, the stored samples and the linked data will be transferred to another Biobank, preferably partner of the TNGB. The participant shall be readily informed about this relocation through a written communication which includes the address of the receiving Biobank and the indication to avail themselves of the option specified in "K" point.

J. HOW LONG ARE SAMPLES AND DATA STORED?

Samples and data will be stored as long as is strictly necessary and shall be used exclusively for the purposes specified above, and in any case as long as the intrinsic properties of the sample will be suitable.
To be noted that an aliquot will be stored into the Biobank for the purposes specified in "D" point.

K. CAN I WITHDRAW MY CONSENT OR CHANCE MY CHOICES?

Storing samples into a Biobank is a completely voluntary act and free of charge. However, any option you have chosen can be changed and the consent withdrawn at any time. In this case, you should notify the Biobank's Director in writing of your decision and afterwards the sample and linked data will be destroyed. This action cannot have a retroactive effect as there is no way to delete potential data generated and/or published before the consent withdrawal. The Biobank's Director also undertakes to notify any third party, to whom such sample aliquots may have been supplied, of the consent withdrawal and the obligation to destroy such samples.

L. WHAT EFFECTS IF I DENY OR WITHDRAW CONSENT?

If the consent to store the sample into the Biobank is denied or withdrawn as described in "K" point this decision shall not have any effect on access to medical care and/or diagnostic tests.

We would greatly appreciate it if you inform us about any change of address, telephone number(s) or e-mail address to allow us to easily contact you.

For further information or explanation please contact: [Name and contacts of the Biobank Director]

[1] Genetic Biobank Guidelines, Telethon - SIGU, Analysis 4/5, 2003, www.biobanknetwork.org
[2] Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs), OECD 2009
[3] Italian Data Protection Authority (Garante Privacy), Personal Data Protection Code, Legislative Decree no. 196, 30th June 2003
[4] Italian Data Protection Authority (Garante Privacy), General Authorisation for the processing of genetic data no. 8/2016
[5] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, Strasbourg 2008
[6] EuroBioBank (www.eurobiobank.org); B.B.M.R.I. (www.bbmri-eric.eu); BBMRI.it (http://www.bbmri.it/); RD-Connect (http://rd-connect.eu/)

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NETWORK OF GENETIC BIOBANKS Telethon

EXPRESSION OF CONSENT

I, the undersigned _____

born in _____ on _____

residing at _____ Prov./State _____ ZIP code _____

address _____ Phone _____

E-mail address (if available): _____

after having received, read and fully understood the "Information leaflet for the storage of biological material", and after having had the opportunity to ask questions about it and received satisfactory answers,

DECLARE:

1) ☐ to want ☐ not to want
the storage into the forenamed Biobank of the biological material and any possible derivatives as described in this information leaflet:
☐ Blood ☐ Tissue ☐ Other *(specify)* _____
taken on _____ at _____
The biological sample belongs to:
☐ me ☐ _____ born on _____ of whom I am _____

2) ☐ to authorise ☐ not to authorise
the possible use and transfer of such biological material for the following purposes:
a) diagnosis ☐ Yes ☐ No ›) scientific research ☐ Yes ☐ No
in the field of the pathology of interest to the participant and/or to some biological family members.

3) ☐ to want ☐ not to want
to be contacted and informed about possible results, derived from studies/research on such biological material, including incidental findings, if they have direct impact on health. In case of a positive answer, please specify if you wish to be:
☐ directly contacted ☐ informed through third party *(specify)* _____

4) ☐ to consent ☐ not to consent
my coded data, including genetic ones, are processed for the following purposes:
a) diagnosis ☐ Yes ☐ No ›) scientific research ☐ Yes ☐ No

5) ☐ to consent ☐ not to consent
members of my biological family (i.e. siblings, children and grandchildren) can be informed on the results on my sample, if these have an impact on their health. I am also aware that, under the law, if such results represent an advantage for their health in terms of prevention, diagnosis, therapy or reproductive choice and prevent damage, they can be communicated upon request to the biological family members ("F" point of the information leaflet).

6) ☐ to consent ☐ not to consent
the biological material and the linked data could be transferred to private biomedical companies for research purposes (e.g. therapies or diagnostic kit validations).

7) ☐ to have ☐ not to have ☐ not to be aware of having
deposited related data to said biological material in a patient registry or clinical database.
(please specify the Registry details) _____

8) To be aware that potential economic gain or rights, deriving from activities conducted by third parties on samples supplied by the Biobank, will not return to me and that such results could be subject to patent protection ("D" point of the information leaflet).

9) To receive a copy of this expression of consent and the enclosed information leaflet.

Date *(dd/mm/yy)* _____ Signature _____

Name _____ 2nd Signature (in case of minors) _____

Consent for sensitive data processing (according to section 81 of Legislative Decree no. 196 of 30 June 2003). Having been provided with the information by the Data Processor, according to section 13 of the aforesaid Decree, and being aware that data processing refers to "sensitive data", pursuant to section 4.1d as well as section 26 of the aforesaid Decree, viz. personal data and those disclosing health, I the undersigned give consent to processing the data needed to conduct the activities described in the information leaflet.

Date *(dd/mm/yy)* _____ Signature _____

Health personnel who has collected the consent:

Surname and Name _____ Dept./Institute _____

Phone _____ Fax _____ E-mail _____

Date *(dd/mm/yy)* _____ Signature _____

The undersigned, [NAME OF THE BIOBANK DIRECTOR], person in charge of the Biobank, guarantees respect for the above declarations.

Signature _____

The original copy of the "Expression of consent" (no information leaflet) must be sent to the biobank together with the sample.
Copies of the "Expression of consent" and of the "Information leaflet" must be given to the signatory.