INSTITUTION / BIOBANK LOGO

FONDAZIONE Telethon NETWORK OF GENETIC BIOBANKS

FONDAZIONE TELETHON NETWORK OF GENETIC BIOBANKS [NAME OF THE BIOBANK]

INFORMATION LEAFLET AND CONSENT FORM FOR THE STORAGE OF BIOLOGICAL MATERIAL FOR DIAGNOSIS AND RESEARCH PURPOSES

Dear Sir/Madam,

Before expressing your consent to store biological material in the Biobank [NAME OF THE BIOBANK] (hereinafter referred to as “Biobank”), we would like to inform you about the aims, services and policies of the Genetic Biobanks which are partners of the “Fondazione 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 with the aim to collect, process, store, distribute human biological material (hereinafter referred to as “sample”) from individuals affected by genetic diseases. They operate according to the high-quality standards within national healthcare facilities and their primary goal 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.[i,ii,iii,iv]

B. WHAT IS THE “ FONDAZIONE TELETHON NETWORK OF GENETIC BIOBANKS” (TNGB)?

TNGB is a project funded by Fondazione Telethon (https://www.fondazionetelethon.it/) started in 2007 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[v], having similar purposes to TNGB’s ones, including sharing the sample catalogue on their relevant platforms. The Biobank is a partner of the Fondazione Telethon Network of Genetic Biobanks and as such adheres to the network regulation and procedures.

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

The Genetic Biobank guarantees personal data confidentiality enforcing the current regulations[1] 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 Data Controller is [NAME AND ADDRESS OF THE CONTROLLER]. The Data Protection Officer (DPO) is [NAME, ADDRESS AND CONTACTS OF THE DPO].
The person in charge for personal data processing 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 [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGIES] 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).

Sample transfer is protected by the *Material Transfer Agreement* (http://biobanknetwork.telethon.it/Documents), a contract between the organization of the supplier and of the recipient that regulates sample transfer and defines the rights of the parties, respecting the biological material, its derivatives and the choices of the participant. However, it should be noted that some rights, in the event of the transfer outside the European Union, may not be guaranteed.

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[1].

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.

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 directly to the participant, with their consent, when such results represent an advantage for the health in terms of prevention, diagnosis, therapy or reproductive choice. In addition, aggregated results of the research conducted on the samples can be consulted on the TNGB website as well as the list of scientific publications in international journals resulting from the use of samples.

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?

The Biobank activity is supported by the host Institution and by the funding from Fondazione Telethon devoted to the maintenance of the Information Technology infrastructure (project no. GTB18001, yrs. 2018-2021). Even though the Biobank activities are free of charges, 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 could be transferred with the consent of the participant to another Biobank, preferably partner of the TNGB. The participant shall be informed through a communication about the cessation of the activity and the explicit 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.

Data and samples will be stored for the time necessary to achieve the TNGB purposes, indicated in the present information leaflet, and in any case until the biological characteristics of the sample can be considered suitable for producing scientific information using the most advanced technologies.

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 OR TRANSFER MY SAMPLE?

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.

The participant can also at any time decide to transfer their sample to another structure upon written communication to the Biobank.

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]

PARTE 2/2 EXPRESSION OF CONSENT

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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 to third parties, even if they are located outside the European Union, for the following purposes:
a) diagnosis ☐ Yes ☐ No) scientific research ☐ Yes ☐ No
in the field of the [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGIES] of interest to the participant and/or to some biological family members (“D” point of the information leaflet).

3) ☐ to want ☐ not to want
to be contacted and informed about possible incidental findings, derived from studies/research on such biological material, if they are useful on health. In case of a positive answer, please specify if you wish to be:
☐ irectly 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 b) scientific research ☐ Yes ☐ No

5) ☐ to consent ☐ not to consent
the possible use and transfer of the coded biological material and the linked data to private biomedical companies for research purposes

6) ☐ 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) ________________________________

7) ☐ to consent ☐ not to consent
to any patenting, or inventions developed by third parties, operating in the biomedical field, starting from biological material.

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 GDPR (EU) 2016/679). Having been provided with the information by the Data Processor, according to section 13 of GDPR (EU) 2016/679, and being aware that data processing refers to personal data, pursuant to section 4.1, viz. personal data and those disclosing health, I the undersigned

☐ give ☐ not give
consent to processing the data needed to conduct the activities described in the information leaflet.

Date *(dd/mm/yy)* __________________ Signature ______________________________
Name ____________________ 2nd Signature (in case of minors)______________________________

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.

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[i] Regulation (EU) 2016/679 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; Italian Data Protection Authority (Garante Privacy), Personal Data Protection Code, Legislative Decree no. 196, 30th June 2003

[ii] Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs), OECD 2009

[iii] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, Strasbourg 2008

[iv] Genetic Biobank Guidelines, Fondazione Telethon - SIGU (Italian Society of Human Genetics), Analysis 4/5, 2003

[v] 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/)