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TELETHON NETWORK OF GENETIC BIOBANKS

GALLIERA GENETIC BANK

INFORMATION LEAFLET AND CONSENT FORM FOR 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). 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 called “donor”).

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 called “linked data”) of the donor(s) and are traceable by the biobank’s director and authorised staff. This link is essential to return potentially vital results to the donor(s) and necessary to gain maximum research value. In order to guarantee the security and confidentiality of the donors’ 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 Telethon Foundation project started in 2008 with the aim to coordinate well established no-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’ Associations, in particular with UNIAMO F.I.M.R. onlus, the Italian Federation of Rare Diseases (www.uniampo.org).

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 donor’s identity;
2. protected storage of code keys by the Biobank Director (or authorised Biobank’s personnel), the only ones entitled to decode the donor’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 donor’s identity.

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

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

The person who is responsible for personal data processing is Dr. Domenico Coviello (Director of S.C. Laboratorio di Genetica Umana).

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 donor. During the distribution service, the Biobanks of the Network undertake with the donor(s) to safeguard an adequate aliquot of the samples for future analyses with diagnostic purpose.

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 benefits, deriving from these activities, are solely owned by the Institution/Company responsible for the research, therefore there are no economic returns for both the donor(s) or the Biobank.

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

Results obtained from research projects bring benefits to both the donor 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 donor, 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 donor 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 (Italian Data Protection Authority (Garante Privacy), Aut. 8/2014, art. 3.1b).

G. DONORS 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 Italian 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 recovery-cost 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 donor 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 CHANGE MY CHOICES?

Storing sample 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 parties, 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 or e-mail address to allow us to easily contact you.

For further information or explanation please contact:

Dr. Chiara Baldo responsible for the "Galliera Gentic Bank"

S.C. Laboratorio di Genetica Umana

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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, 30 June 2003

4 Italian Data Protection Authority (Garante Privacy), General Authorisation for the processing of genetic data no. 8/2014

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



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 Certificazioni ISO 9001/2008 e SIGUCERT
 Direttore: Dott. Domenico Coviello
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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 being informed of the content of this information leaflet, and having had the opportunity to ask questions about it and having received satisfactory answers,

DECLARE:

- 1) to want not to want
 the storage in 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 _____ of whom I am _____
- 2) to authorise not to authorise
 the possible use and transfer of said biological material for the following purposes:
 a) diagnosis Yes No b) scientific research Yes No
 in the field of the pathology of interest to the donor and/or to some family members.
- 3) to want not to want
 to be contacted and informed about possible results, derived from said studies/researches on the 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 b) 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.
- 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
 deposited linked data to said biological material in a Patient Registry.
 (*please specify the Registry details*)
- 8) To accept that no economic benefits deriving from activities conducted by third parties on samples supplied by the Biobank will return to me (see "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 _____ 2° Signature (in case of minor donor) _____

Consent for sensitive data processing (according to section 81 of Legislative Decree no. 196 of 30 June 2003)

Having been informed by the person who is responsible for personal data processing according to section 13 of Legislative Decree no. 196 of 30 June 2003 and being aware that data processing is related to "sensitive data" as described in section 4, point 1d as well as section 26 of Legislative Decree no. 196 of 30 June 2003, 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 address _____
 Date (dd/mm/yy) _____ Signature _____

The undersigned, Dr. Chiara Baldo, person in charge of the Biobank, guarantees respect for the above declarations. Signature

A COPY OF THIS "INFORMATION LEAFLET HAS BEEN PROVIDED TO THE SIGNER(S)

Chiara Baldo