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

INFORMED CONSENT FOR THE STORAGE OF HUMAN BIOLOGICAL MATERIAL FOR RESEARCH AND DIAGNOSTIC PURPOSES AND FOR THE PROCESSING OF PERSONAL DATA INFORMATION SHEET

The Informed Consent for the storage and use of human biological material and associated data for research and diagnostic purposes consists of two parts: the *Information Sheet* and the *Expression of Consent Form*. The *Information Sheet* provides information and guidance to understand what it means to collect and use biological samples and data for research and diagnostic purposes. Each topic addressed in the *Information Sheet* corresponds to a specific consent request in the *Expression of Consent Form*, allowing you to clearly express your preferences.

Dear Madam/Sir,

Before expressing your consent to store biological material (your own / your child's / the person under your guardianship) in the [NAME OF THE BIOBANK] at the [NAME OF THE HOST INSTITUTION] (hereinafter referred to as the "Biobank"), it is your right to receive information about the purpose of this process.

Storing biological material of human origin (hereinafter "samples") in a biobank means depositing it, and therefore entrusting it, to a service facility which guarantees and manages the collection, preservation and distribution of the samples and associated data according to established quality standards (activities collectively referred to as "biobanking"), with the purpose of facilitating research activities and possible diagnosis. The Biobank serves a public function and guarantees the rights of all individuals involved. The person who decides to deposit samples and data in the Biobank (hereinafter referred to as the "depositor") is involved not only as receiver of the research process, but also as an active subject by making a crucial contribution to the patients' community, especially in rare diseases.
We therefore ask for your cooperation and consent to store the sample and associated data (your own / your child's / the person under your guardianship) in the Biobank, and to allow their processing and distribution within the limits set in this *Information Sheet*.
This *Information Sheet* aims to provide you with the information necessary to understand what it means to store your sample and data in the Biobank, the activities carried out and the services provided and the contents of the regulations of the TNGB - Fondazione Telethon Network of Genetic Biobanks (http://biobanknetwork.telethon.it/), of which the [NAME OF THE BIOBANK] is a member.
Your participation is entirely voluntary. If you decide to change your choices at any time, this will not affect the possibility to access medical care and/or diagnostic testing.
The healthcare professional collecting your consent is available to answer any questions you may have regarding this document. If you are interested in finding out more about the topics addressed by this *Information Sheet*, the Biobank staff are at your disposal and can be contacted using the details provided at the end of the document.
Further information on the TNGB Network and the terminology used in these notes can be found at biobanknetwork.telethon.it.

A. WHAT IS A "SAMPLE"?

"Samples" are defined as human cells, tissues, and biological fluids, including all molecular fractions (proteins, RNA, DNA, etc.) that can be derived from them, originating from either healthy or affected individuals. Samples can provide access to the information contained in the human genome, meaning that a 'genetic profile' of an individual can be obtained from them.

B. WHAT ARE GENETIC BIOBANKS?

Genetic biobanks are non-profit service units systematically managing the collection, processing, storage, and distribution of samples, ensuring the protection of the rights of the individuals involved. Biobanks must be institutionally recognized and operate according to quality standards to support diagnostic and research services. Genetic biobanks store samples alongside the depositor's personal, genealogical, clinical and genetic data which are essential for research, diagnostic and prognostic purposes. In particular, the connection to personal data is essential when relevant results need to be returned to the depositor. To ensure the privacy and rights of data subjects, genetic biobanks operate in accordance with rigorous ethical and legal standards, complying with Italian and European regulations (see section H for further details).

C. WHAT IS THE " TNGB - FONDAZIONE TELETHON NETWORK OF GENETIC BIOBANKS"?

The TNGB - Fondazione Telethon Network of Genetic Biobanks (hereinafter "TNGB") is a project funded by Fondazione Telethon (https://www.fondazionetelethon.it/), started in 2007 to coordinate existing well established non-profit Italian

genetic biobanks, selected on the basis of competitive calls for proposals and supported since '90s as single core facilities within specific research projects.
The main aim of TNGB is to facilitate biomedical research on genetic diseases through:

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

The TNGB is currently composed of 11 Italian Biobanks and works closely with Rare Disease Patients' Organisations. TNGB also participates in other networks, national and international projects as well as research infrastructures[1], with similar purposes, including sharing the sample catalogue on their respective platforms. The [NAME OF THE BIOBANK] is a TNGB partner and, as such, adheres to the network regulations and procedures.

D. HOW LONG ARE SAMPLES AND RELATED DATA STORED?

Samples and data will be stored as long as the quality of the samples remains suitable for the purposes for which they are used, to ensure reliable results. Currently, it is not possible to specify the retention time. In any case, your sample will be stored in the Biobank until it is exhausted (except as specified in section E) or until you decide to withdraw your consent.

E. HOW CAN THE SAMPLES STORED IN THE BIOBANK BE USED?

Genetic material (DNA/RNA) can be extracted from the samples deposited in the Biobank (cell lines, blood, saliva, other tissues and biological fluids) and stored alongside the original sample. Additionally, cell lines for in vitro studies may be obtained from blood, skin or other tissue samples. Some of these cells could be transformed within specific research projects into Induced Pluripotent Stem Cells (also known as iPS cells), and/or cell derivatives relevant to the disease (e.g. neurons, cardiomyocytes, etc.), useful for research aimed at understanding the pathogenetic mechanisms and developing potential therapeutic products.

What purposes can the samples be used for?

The samples and linked data may be used to conduct diagnostic and scientific research activities in the field of your disease and/or group of diseases of interest (this field will be specified in Option 2 of the *Expression of Consent Form*). Furthermore, we would also like to inform you that the material stored in the TNGB biobanks may also be used for diagnostic purposes, in accordance with the choices you have expressed in the *Expression of Consent Form*. For this reason, a portion of the sample (technically referred to as 'aliquot'), preferably DNA, will remain available to you and your family members for future analysis or diagnostic investigations. If your sample is requested for other purposes, the Biobank will contact you again, if you have consented to this in Option 8 of the *Expression of Consent Form.*

Can samples be transferred to third parties?

Biological samples stored in TNGB biobanks can be transferred to organisations and companies, including for-profit organizations, that operate in the field of biomedical research.
This is subject to a formal request from the researcher and its evaluation by the TNGB Access Committee, as set out in the TNGB Charter (http://biobanknetwork.telethon.it/Pages/View/TheCharter).
If the request is approved and you have consented to sample distribution in the *Expression of Consent Form*, the aliquots of your sample will be transferred to researchers working at national and international institutions, including those outside the European Union (provided you have positively consented to Option 3 in the *Expression of Consent Form*).

How are the samples transferred?

To protect the privacy of the depositor, samples and associated data are transferred in pseudonymised form. Sample transfer is governed by the *Material Transfer Agreement* (http://biobanknetwork.telethon.it/Documents), a contract between the organisation hosting the biobank and the recipient organisation. This agreement regulates the sample transfer and defines the rights of the parties involved, safeguarding the sample, its derivatives and the choices of the depositor. This procedure is guaranteed for all EU Member States, which are subject to the European Regulation 2016/679 (GDPR)[2,3], as well as for all other countries that guarantee the same standards (as per the assessment performed by the European Commission), which are listed on the website of the Italian Data Protection Authority[4]. If you have explicitly consented (Option 3 of the Expression of Consent Form), aliquots of your sample may be

[1] European Network of Biobanks *EuroBioBank* (www.eurobiobank.org); European Research Infrastructure for biobanking and biomolecular resources *BBMRI-ERIC* (www.bbmri-eric.eu) and its Italian node, *BBMRI.it* (https://www.bbmri.it/biobanche); European Project *RD-Connect* (http://rd-connect.eu/)
[2] Regulation (UE) 2016/679 (GDPR) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing (https://eur-lex.europa.eu/eli/reg/2016/679/oj)
[3] Italian Degree no. 101/2018 -) on harmonization of the national privacy legislation to the General Data Protection Regulation (UE) 2016/679 https://www.gazzettaufficiale.it/eli/id/2018/09/04/18G00129/sg
[4] Personal Data Transfer adroad. https://www.garanteprivacy.it/temi/trasferimento-di-dati-all-estero

Template

transferred, under the Standard Contractual Clauses specified in the Material Transfer Agreement, even to countries that are not part of the EU or do not guarantee the rights established by the GDPR.

Can profits be derived from the use of the samples?
It could happen that results from scientific research conducted on the samples distributed by the biobank may lead to patent applications, with possible commercial use (e.g., diagnostic kit validations). It should be noted that any potential profit, deriving from these activities are solely owned by the Institution/Company responsible for the research, therefore there are no economic returns for both participant(s) and biobank.

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

Results from research projects obtained using the samples could contribute to the identification of genes responsible for or associated with diseases, the study of molecular mechanisms and the development of therapeutic strategies, thereby leading to advancing scientific knowledge. The scientific community has extensively used the Network's services for various diagnostic and research purposes, whose results have led over the years to a large number of scientific publications in international journals and determined the discovery of new disease genes allowing diagnoses for patients and families who were previously undiagnosed or undiagnosable (the publication list is available on the TNGB website: http://biobanknetwork.telethon.it/Pages/View/Documents). Furthermore, stored samples can be crucial for identifying potential participants in clinical trials, thus facilitating the development of new therapeutic approaches.

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

The results of research conducted on samples deposited into the Biobank are communicated directly to the interested parties, with their prior consent (Option 8 of the *Expression of Consent Form*), when such results, including unexpected findings, represent useful information in terms of prevention, diagnosis, therapy or informed reproductive and personal choices. "Unexpected results" refers to information relevant to the depositor's health that may emerge during a research study and were not included among the study's original objectives.
Scientific publications and related aggregated results obtained using your samples are available upon request to the [NAME OF THE BIOBANK] at the [NAME OF THE HOST INSTITUTION]. The list of publications is also available on the TNGB website (http://biobanknetwork.telethon.it/Pages/View/Documents).

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

The Biobank guarantees personal data confidentiality enforcing the current regulations as follows:

1. alphanumeric code assignment to each sample so that the name of the person from whom it comes cannot be directly associated with the samples and data, making it extremely difficult for third parties to trace the identity of the depositor;
2. connection between the code and the depositor's identity and related information (clinical, genetic, genealogical, etc.) can only be made by the biobank director, or by the Biobank's personnel explicitly authorised in writing (pseudonymisation);
3. access to the information systems, where all data are recorded, is controlled by appropriate security measures to prevent their circulation or use from unauthorized parties. Specifically, access is controlled by personalized double passwords assigned by the Biobank Director to the authorized personnel, minimising the risk of illegal or unauthorized access.
4. your data, recorded in information systems, are stored and used within the "virtual" datacentre of the Fondazione Telethon, hosted at the CINECA computing centre, a non-profit Italian interuniversity consortium (https://www.cineca.it/en). CINECA guarantees a secure and reliable environment for data storage and backup. Neither Telethon Foundation nor CINECA staff have access to your data.
5. any research results published in journals and/or communicated at scientific conferences, disclosed anonymously and/or in aggregate form, will not contain any information that it would allow to trace the identity of the depositor.

The Biobank recognises the right of the data subject to access their data by contacting the Biobank Director. See Section L below for information on withdrawing consent. You may, at any time, exercise your legal rights under Articles 15 et seq. of the GDPR (for example, the right to rectification of your data or restriction of their processing) by contacting the Data Controller or Data Protection Officer (see contacts below). To protect your rights, if you believe they have been violated, you may always file a complaint with the Italian Data Protection Authority. The Data Controller for the data linked to the samples stored in the Biobank is [DATA CONTROLLER NAME] with registered office in [DATA CONTROLLER ADDRESS], represented by the Delegate [DELEGATE NAME] (hereinafter "Data Controller"). The Data Protection Officer (hereinafter referred to as "DPO") is [DPO NAME] who can be contacted at the following contact details: [DPO CONTACTS, ADDRESS, PHONE, EMAIL]. The data processor is [BIOBANK DIRECTOR NAME].

I. SAMPLES BELONGING TO MINORS OR INCAPACITATED PERSONS

Template

If the depositor is a minor or incapacitated person, consent will be provided by the parents or legal representative. In accordance with provisions no. 146/2019 of the Italian Data Protection Authority (Garante Privacy), regarding the processing of genetic data and biological samples for research purposes, the opinion of the minor or incapacitated person is taken into account where possible, particularly in the event of dissent. Each decision will be made in consideration of the best interests of these vulnerable individuals. Specifically, if the sample is taken when the minor is deemed "sufficiently mature" to understand the purposes of storage and possible use of the sample and associated data, the minor depositor will be informed and involved in the decision-making process whenever appropriate and possible. Their opinion will be taken into consideration, especially in the event of dissent, according to their level of understanding and maturity. The continuation of biobanking activities, with reference to samples and data from subjects who have reached adulthood, is subject to obtaining new consent from the newly adult.

J. WHO FINANCIALLY SUPPORTS THE BIOBANK?

The Biobank's activity is supported by the host institution and by the funding from Fondazione Telethon devoted to coordination and management activities and maintenance of the Information Technology infrastructure. Furthermore, the Biobank is co-financed by [SPECIFY FUNDING BODY OR DELETE THE SENTENCE]. However, please note that, although the Biobank's activities are provided free of charge, a cost-recovery system may be applied to the sample distribution service to partially contribute to the Biobank sustainability. Researchers may be asked to partially contribute to the sample preparation process for transfer and shipping costs. The official TNGB cost-recovery list is available on the TNGB website (http://biobanknetwork.telethon.it/Pages/View/pricelist).

K. WHAT HAPPENS TO THE STORED SAMPLE IF THE BIOBANK CEASES ITS ACTIVITY?

If, for any reason, the Biobank ceases operations, the stored samples and the linked data may be transferred, with prior consent, to another biobank (preferably part of TNGB), destroyed or anonymized. The depositor will be notified through communication about the cessation of the operations.

L. CAN I WITHDRAW MY CONSENT OR CHANGE MY CHOICES OR TRANSFER THE SAMPLE?

Storing samples in a genetic biobank is completely voluntary and free of charge. Consent may be withdrawn at any time without providing a reason. Likewise, changes to what it was declared and choices expressed may be made at any time. In case you withdraw your consent to storage, to be done in writing to the Biobank's Director, the Biobank will destroy or anonymise the sample and linked data in accordance with your expressed choices. This action, however, cannot have retroactive effect, so any data generated and/or disclosed prior to the consent withdrawal cannot be deleted. The Biobank undertakes to notify any third party holding any sample aliquots of the depositor's consent withdrawal and the obligation to destroy such samples.
The depositor may also decide at any time to transfer their sample to another facility upon written communication to the Biobank.

M. EFFECTS OF NON-PARTICIPATION OR WITHDRAWAL OF CONSENT ON TREATMENT

Denial to store the sample or the exercise of the right to withdraw consent as described in Section "L" will have no effect on access to healthcare or on its quality.

We would greatly appreciate it if you would inform the Biobank about any change in your address and/or telephone number(s) and/or e-mail address to allow us to always contact you.

For further information and clarifications, please contact:

[NAME AND CONTACT DETAILS OF THE BIOBANK DIRECTOR]

Template

FONDAZIONE Telethon | NETWORK OF GENETIC BIOBANKS

EXPRESSION OF CONSENT

I, the undersigned _____

born in _____ on _____

residing at _____ Prov./State _____ ZIP code _____

address _____ Phone _____

E-mail address (if available): _____

After having read and fully understood the contents of the *Information Sheet*, o**f which I receive a copy**, and after having had the opportunity to ask questions about it and received satisfactory answers,

DECLARE:

Storage and Purpose

1) ☐ to want ☐ not to want
the storage into the [NAME OF THE BIOBANK] at the [NAME OF THE HOST INSTITUTION] the sample and any possible derivatives:
☐ Blood ☐ Tissue ☐ Other *(specify)* _____
taken on _____ by _____

Transfer

2) ☐ to authorise ☐ not to authorise
the possible use and transfer of such sample **to third parties located in countries that comply** with the standards imposed by the European General Data Protection Regulation (GDPR), for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No
in the field of [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGY]: (*Information Sheet* - Section E).

3) ☐ to authorise ☐ not to authorise
the possible use and transfer of such sample, under the agreed clauses specified in the *Material Transfer Agreement*, also **to third parties located in countries that do not comply with** the standards imposed by the European General Data Protection Regulation (GDPR), having been informed of the possible risks of such transfers, for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No
in the field of [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGY]: (*Information Sheet* - Section E).

4) ☐ to consent ☐ not to consent
to the possible use and transfer for research purposes of the sample and linked data in pseudonymised form (*Information Sheet* - Section H) **to entities and companies, including for-profit ones,** operating in the biomedical field.

Personal data processing

5) ☐ to consent ☐ not to consent
to the processing of personal data, including genetic ones, for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No

Patenting and commercial use

6) ☐ to consent ☐ not to consent
to any patenting, i.e., inventions developed from the biological material, by third parties, operating in the biomedical field and to any commercial use knowing that, in relation to these, no remuneration or rights shall be recognised to me (*Information Sheet* - Section E).

Return of results

7) ☐ to want ☐ not to want
to be contacted and informed about any possible results, including incidental findings, derived from the aforementioned studies/research conducted on my sample, if they may be useful for my health. (*Information Sheet* - Section G).
In case of positive answer, please specify whether you wish to be:
☐ directly contacted ☐ informed through third party *(specify)* _____

Recontact

8) ☐ to consent ☐ not to consent
To be contacted by the Biobank to renew or modify the choices made and/or to express a new specific consent, should new or different possible research purposes arise.

Termination of biobank operations:

9) In the event of biobank's operations termination, (*choose the desired option*):
☐ authorise the destruction of my sample
☐ wish to be contacted, even if I did not consent to point 8, in order to express my preferences

Template

10) Receive a copy of this form and the *Information Sheet.*

Date _____ **Signature** _____

Consent for the processing of sensitive data (pursuant to GDPR 2016/679). The undersigned, having been provided with the information by the data controller, pursuant to section 13 of GDPR 2016/679, and being aware, in particular, that data processing refers to personal data, pursuant to section 4 paragraph 1, namely personal data and those disclosing health, declares

☐ consent ☐ not to consent
to processing of data needed to conduct the operations described in the *Information Sheet*

Date _____ **Signature** _____

Health personnel who has collected the consent:

Surname and Name _____ Dept./Institute ___
Phone _____ Fax _____ E-mail ___

Date _____ Signature _____

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

Signature _____

NOTE TO THE HEALTH PERSONNEL WHO HAS COLLECTED THE CONSENT:
THE ORIGINAL COPY OF THE "EXPRESSION OF CONSENT" (NO INFORMATION SHEET) MUST BE SENT TO THE BIOBANK TOGETHER WITH THE SAMPLE.
COPIES OF THE "EXPRESSION OF CONSENT" AND OF THE "INFORMATION SHEET" MUST BE GIVEN TO THE SIGNATORY.

Template

EXPRESSION OF CONSENT FOR MINOR

I/We, the undersigned

PERSONAL DATA

Name _____ Surname _____

Born in _____ on _____

Residing at _____ Prov./State _____

address _____ ZIP code _____

E-mail address (if available): _____ Phone _____

PERSONAL DATA

Name _____ Surname _____

Born in _____ on _____

Residing at _____ Prov./State _____

Address _____ ZIP code _____

E-mail address (if available): _____ Phone _____

☐ declares that the other parent is unable to sign this consent due to remoteness or another impediment (Art. no. 317 of the Italian Civil Code).

As parent(s) of the MINOR:

Name _____ Surname _____

Born in _____ on _____

Residing at _____ Prov./State _____

Address _____ ZIP code _____

After having read and fully understood the contents of the *Information Sheet*, **of which I/we receive a copy**, and after having had the opportunity to ask questions about it and received satisfactory answers,

DECLARE:

Storage and Purpose

1) ☐ to want ☐ not to want
the storage into the [NAME OF THE BIOBANK] at the [NAME OF THE HOST INSTITUTION] the sample and any possible derivatives:
☐ Blood ☐ Tissue ☐ Other *(specify)* _____
taken on _____ by _____

Transfer

2) ☐ to authorise ☐ not to authorise
the possible use and transfer of such sample **to third parties located in countries that comply** with the standards imposed by the European General Data Protection Regulation (GDPR), for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No
in the field of [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGY]: (*Information Sheet* - Section E).

3) ☐ to authorise ☐ not to authorise
the possible use and transfer of such sample, under the agreed clauses specified in the *Material Transfer Agreement*, also **to third parties located in countries that do not comply** with the standards imposed by the European General Data Protection Regulation (GDPR), having been informed of the possible risks of such transfers, for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No
in the field of [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGY]: (*Information Sheet* - Section E).

4) ☐ to consent ☐ not to consent
to the possible use and transfer for research purposes of the sample and linked data in pseudonymised form (*Information Sheet* - Section H) **to entities and companies, including for-profit ones,** operating in the biomedical field.

Personal data processing

5) ☐ to consent ☐ not to consent
to the processing of personal data, including genetic ones, for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No

Template

Patenting and commercial use

6) ☐ to consent ☐ not to consent
to any patenting, i.e., inventions developed from the biological material, by third parties, operating in the biomedical field and to any commercial use knowing that, in relation to these, no remuneration or rights shall be recognised to me/us (*Information Sheet* - Section E).

Return of results

7) ☐ to want ☐ not to want
to be contacted and informed about any possible results, including incidental findings, derived from the aforementioned studies/research conducted on my sample, if they may be useful for my health. (*Information Sheet* - Section G).
In case of positive answer, please specify whether you wish to be:
☐ directly contacted ☐ informed through third party *(specify)* _____

Recontact

8) ☐ to consent ☐ not to consent
to be contacted by the Biobank to renew or modify the choices made and/or to express a new specific consent, should new or different possible research purposes arise.

Termination of biobank operations:

9) In the event of biobank's operations termination, (*choose the desired option*):
☐ authorise the destruction of my sample
☐ wish to be contacted, even if I/we did not consent to point 8, in order to express my/our preferences

10) Receive a copy of this form and the *Information Sheet*.

Date _____ **Signature** _____

Date _____ **Signature** _____

Consent for the processing of sensitive data (pursuant to GDPR 2016/679). The undersigned, having been provided with the information by the data controller, pursuant to section 13 of GDPR 2016/679, and being aware, in particular, that data processing refers to personal data, pursuant to section 4 paragraph 1, namely personal data and those disclosing health, declares

☐ consent ☐ not to consent
to processing of data needed to conduct the operations described in the *Information Sheet*

Date _____ **Signature** _____

Date _____ **Signature** _____

POSSIBLE ASSENT OF THE MINOR

Thanks to the explanations I received, I now understand what it means to store samples and data in a biobank for research and diagnostic purposes.

☐ I want my samples and data to be collected in the Biobank and I agree with the preferences expressed in this document
☐ I do not want my samples and data to be collected in the Biobank and I agree with the preferences expressed in this document

Surname and Name _____

Date _____

Health personnel who has collected the consent:

Surname and Name _____ Dept./Institute ___
Phone _____ Fax _____ E-mail ___

Date _____ **Signature** _____

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

Signature _____

Template

NOTE TO THE HEALTH PERSONNEL WHO HAS COLLECTED THE CONSENT:
THE ORIGINAL COPY OF THE "EXPRESSION OF CONSENT" (NO INFORMATION SHEET) MUST BE SENT TO THE BIOBANK TOGETHER WITH THE SAMPLE.
COPIES OF THE "EXPRESSION OF CONSENT" AND OF THE "INFORMATION SHEET" MUST BE GIVEN TO THE SIGNATORY.

Template

EXPRESSION OF CONSENT FOR SUBJECT UNDER GUARDIANSHIP

I, the undersigned

Name _____ Surname _____

born in _____ on _____

residing at _____ Prov./State _____

address _____ ZIP code _____

E-mail (if available): _____ Phone _____

As a guardian of the depositor:

PERSONAL DATA_OF THE SUBJECT UNDER GUARDIANSHIP

Name _____ Surname _____

born in _____ on _____

residing at _____ Prov./State _____

address _____ ZIP code _____

After having read and fully understood the contents of the *Information Sheet*, o**f which I receive a copy**, and after having had the opportunity to ask questions about it and received satisfactory answers,

DECLARE:

Storage and Purpose

1) ☐ to want ☐ not to want
the storage into the [NAME OF THE BIOBANK] at the [NAME OF THE HOST INSTITUTION] the sample and any possible derivatives:
☐ Blood ☐ Tissue ☐ Other *(specify)* _____
taken on _____ by _____

Transfer

2) ☐ to authorise ☐ not to authorise
the possible use and transfer of such sample **to third parties located in countries that comply** with the standards imposed by the European General Data Protection Regulation (GDPR), for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No
in the field of [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGY]: (*Information Sheet* - Section E).

3) ☐ to authorise ☐ not to authorise
the possible use and transfer of such sample, under the agreed clauses specified in the *Material Transfer Agreement*, also **to third parties located in countries that do not comply with** the standards imposed by the European General Data Protection Regulation (GDPR), having been informed of the possible risks of such transfers, for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No
in the field of [SPECIFY THE PATHOLOGY OR GROUP OF PATHOLOGY]: (*Information Sheet* - Section E).

4) ☐ to consent ☐ not to consent
to the possible use and transfer for research purposes of the sample and linked data in pseudonymised form (*Information Sheet* - Section H) **to entities and companies, including for-profit ones,** operating in the biomedical field.

Personal data processing

5) ☐ to consent ☐ not to consent
to the processing of personal data, including genetic ones, for the following purposes:
a) diagnosis ☐ Yes ☐ No b) scientific research ☐ Yes ☐ No

Patenting and commercial use

6) ☐ to consent ☐ not to consent
to any patenting, i.e., inventions developed from the biological material, by third parties, operating in the biomedical field and to any commercial use knowing that, in relation to these, no remuneration or rights shall be recognised to me (*Information Sheet* - Section E).

Return of results

7) ☐ to want ☐ not to want
to be contacted and informed about any possible results, including incidental findings, derived from the aforementioned studies/research conducted on my sample, if they may be useful for my health. (*Information Sheet* - Section G).
In case of positive answer, please specify whether you wish to be:

☐ directly contacted ☐ informed through third party *(specify)* _____

Recontact

8) ☐ to consent ☐ not to consent
To be contacted by the Biobank to renew or modify the choices made and/or to express a new specific consent, should new or different possible research purposes arise.

Termination of biobank operations:

9) In the event of biobank's operations termination, (*choose the desired option*):
☐ authorise the destruction of my sample
☐ wish to be contacted, even if I did not consent to point 8, in order to express my preferences

10) Receive a copy of this form and the *Information Sheet*.

Date _____ **Signature** _____

Consent for the processing of sensitive data (pursuant to GDPR 2016/679). The undersigned, having been provided with the information by the data controller, pursuant to section 13 of GDPR 2016/679, and being aware, in particular, that data processing refers to personal data, pursuant to section 4 paragraph 1, namely personal data and those disclosing health, declares

☐ consent ☐ not to consent
to processing of data needed to conduct the operations described in the *Information Sheet*

Date _____ **Signature** _____

Health personnel who has collected the consent:

Surname and Name _____ Dept./Institute ___
Phone _____ Fax _____ E-mail ___

Date _____ Signature _____

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

Signature _____

NOTE TO THE HEALTH PERSONNEL WHO HAS COLLECTED THE CONSENT:
THE ORIGINAL COPY OF THE "EXPRESSION OF CONSENT" (NO INFORMATION SHEET) MUST BE SENT TO THE BIOBANK TOGETHER WITH THE SAMPLE.
COPIES OF THE "EXPRESSION OF CONSENT" AND OF THE "INFORMATION SHEET" MUST BE GIVEN TO THE SIGNATORY.

Template