SACRO CUORE DON CALABRIA
IRCCS
Istituto di Ricovero e Cura a Carattere Scientifico
Sacro Cuore - Don Calabria
Ospedale Classificato e Presidio Ospedaliero Accreditato - Regione Veneto

Dipartimento di Malattie Infettive - Tropicali e Microbiologia (DITM)
Direttore: Prof. Federico Giovanni Gobbi

DISCLOSURE AND CONSENT FOR STORAGE OF BIOLOGICAL SAMPLES FOR RESEARCH PURPOSES
and
INFORMATION AND CONSENT FOR PROCESSING OF PERSONAL DATA

Dear Sir/Madam,

By accessing this facility, you, or the person for whom you exercise parental responsibility or legal representation, will undergo the collection of biological samples for diagnosis and treatment and/or for possible experimental research. We hereby propose that you give your consent to the storage in the biobank of the Department of Infectious, Tropical Diseases and Microbiology, called "Tropica Biobank", of the biological material that will remain at the end of the investigations on you or the person for whom you exercise parental or legal responsibility (hereafter referred to as the "donor" for ease of reference). Preservation could be very useful for any subsequent investigations and follow-up. Biological samples involving the donor could also prove to be of great value for **experimental research purposes**, which may include **genetic studies**, and therefore in this case without any specific direct benefit. In any case, the material deposited in the said biobank will never be used for the purpose of direct profit. The donor's contribution may therefore be of benefit to the community in future biomedical developments.

DISCLOSURE

This information is in addition to what you may have already received when accessing the hospital's health care services, and relates only to the storage and processing of biological samples and of personal data for biomedical research purposes. It includes specific information for giving the necessary consent for each individual topic, as specified in the attached "Consent" form. In particular, we provide the following information, both from a scientific and ethical point of view and in relation to the protection of personal data.

1) WHAT IS A BIOBANK?

A biobank is a non-profit service for the collection, storage, processing and distribution of human biological material, organised and structured according to common and internationally agreed rules. It is an important tool for biomedical research as the stored biological material is made available to the scientific community on the basis of standardised procedures and rules aimed at protecting both the rights, dignity and confidentiality of the individual and the community.

As an assurance to the donor, we inform you that the protocol for the establishment of the Biobank in question has been drawn up in accordance with the European Union's Standards of Good Clinical Practice, in compliance with the Declaration of Helsinki and the current regulations on the storage and use of biological samples, and has been approved by the Ethics Committee of reference for our institution.

Scientific publications resulting from the use of samples for research purposes will be made available on the biobank's institutional website by framing the QRcode.

Should the donor or the person having parental or legal responsibility for the donor require further clarification, they may contact the Scientific Secretariat of the IRCCS Ospedale Sacro Cuore Don Calabria, via A. Sempreboni, 5 - 37024 Negrar di Valpolicella (VR), e-mail: segreteriascientificairccs@sacrocuore.it.

2) DATA CONTROLLER AND DATA PROTECTION OFFICER.

The data controller of your personal data is Istituto Don Calabria - IRCCS Ospedale Sacro Cuore, in its capacity as data controller of your personal data (hereinafter also referred to as "the Hospital" or "the Data Controller"), Via Don A. Sempreboni, 5 - 37024 Negrar di Valpolicella. For any further clarification, please

contact the Hospital's Scientific Secretariat at the following e-mail address: segreteriascientificairccs@sacrocuore.it.
The Hospital has appointed a Data Protection Officer (DPO) who can be contacted at privacy@sacrocuore.it.

3) PURPOSE OF PROCESSING BIOLOGICAL SAMPLES AND DATA

In addition to the processing carried out on biological samples for diagnostic and therapeutic purposes and/or for possible experimental research, it is possible that the same samples may be used, subject to your consent requested below, for other research purposes useful for the advancement of knowledge in the biomedical field of infectious diseases, tropical medicine and microbiology. In particular:

(a) Known objectives

- To define the molecular and cellular reasons for the onset and development of the disease;
- To identify and validate new diagnostic methods;
- Identify new molecular markers for early diagnosis, prediction of natural history of disease and development of new therapies.

The results could contribute to the advancement of diagnostic and therapeutic research.

(b) Unknown objectives

Biomedical and biotechnological progress may have such positive spin-offs that further investigations of the samples may be appropriate for purposes that are not yet defined in the current state of knowledge and may be independent of the reasons for which their use is hereby consented. The studies may also concern the genetic field (DNA), i.e. the human genome, and may result in the genetic profile of the donor. Artificial intelligence (AI) based tools may also be used to conduct the research. We emphasise that all information will be treated with full respect for privacy, as explained in the next paragraph. Finally, it is possible that the results of the research or the development of the studies carried out on the site or in collaboration with third parties may generate indirect economic benefits for the health institution hosting the biobank, for other entities, research institutes, associations, public and private bodies with research objectives, as well as for the industrial sectors related to the field of biomedicine that may be involved, without any expectations of economic benefits for the donor.

4) LEGAL BASIS OF THE PROCESSING.

The legal basis that legitimises the processing is the consent given in accordance with Art. 6 par. 1(a) and 9 par. 2(a) of the EU Regulation 2016/679. In the case of a donor who is a minor, the consent must be given by the person exercising parental responsibility (both parents) or the person acting as their representative. In the case of a donor who is a minor, the right to properly express or revoke consent is guaranteed when the donor reaches the age of majority and on the occasion of the first access/contact with the biobank. It should also be noted that if the sample is collected when the minor can be considered "mature" in terms of understanding the purposes of the storage and possible use of the biological sample, he or she will be informed and involved, as far as possible and appropriate, in the decisions to be taken. His or her opinion will be taken into account, especially in cases of disagreement. Any decision will therefore be made in the best interests of the child. We remind you that you have the right to revoke consent at any time, without affecting the lawfulness of the processing based on the same consent given before the revocation.

5) TYPES OF INFORMATION PROCESSED AND METHODS OF PROCESSING

The research carried out may involve the use of general information (biographical, etc.), health status and genetic information related to the donor, i.e. information related to **personal data**[1], **special categories of personal data**[2] and **genetic data**[3]. The examination of the biological samples and the subsequent processing of the related information will be carried out in a **de-identified mode**, i.e. the samples and the related information will be protected by an encryption system that ensures anonymity and only allows authorised personnel to indirectly trace you, if necessary.

The processing of biological samples and related information will be carried out with the adoption of appropriate security measures and with full confidentiality and protection of personal and sensitive data (Legislative Decree no. 196/03 as amended; EU Regulation 2016/679). Disclosure of information resulting from research studies may not in any way disseminate donor data, except in a completely anonymous form (e.g. through statistical processing of aggregated data, in publications, in the context of scientific conferences, etc.). Scientific

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publications resulting from the use of samples for research purposes will be made available on the Biobank's institutional website by framing the QRcode.
We also inform you that other statistical or research studies for the protection of public health may be carried out, which, as provided for by law, do not require your specific consent.

6) CHARACTERISTICS OF THE REQUIRED CONSENTS

All the required consents are optional, and a decision not to donate the sample for research purposes will have no effect on the therapeutic-diagnostic process carried out or to be carried out on the donor. Your decision will be considered valid for samples collected at the same time or at different times during diagnostic investigations or hospitalisation/treatment. We also inform you that the consent, if given by signing this document, is only valid for what is stated herein and may be withdrawn at any time and without giving any reason. In this case, any biological samples that can be traced back to the donor and that have not yet been used will be destroyed. Furthermore, no further data on the donor will be collected, without prejudice to the use of the data already collected to determine the results of the ongoing research without altering them.

7) NATURE OF THE SAMPLES AND DATA PROVISION AND CONSEQUENCES IN CASE OF REFUSAL

Failure to provide samples and data prevents the department from storing them at the biobank. Please note that such refusal will in no way affect the treatment or health services to which the donor is entitled.

8) POSSIBLE TRANSFER OF BIOLOGICAL SAMPLES

Genetic and non-genetic information and biological samples collected for scientific research purposes may be disclosed or transferred to third parties (research organizations and institutes, associations and other public and private bodies with research purposes) in de-identified form even without your consent only:

• Whether third parties participate in joint projects;

• if, while not participating in joint projects, the third parties will use the data, in a completely anonymous form that will prevent the identity of the donor from being traced, in pursuit of research objectives directly related to those for which they were originally collected, and clearly determined in writing in the request for the data and/or samples. In such a case, third party requesters may not use the information and/or samples for purposes other than those stated in the request, and may not communicate or transfer them further to third parties.

Each request for disclosure or transfer of genetic and nongenetic information and biological samples will be subject to evaluation and approval by an internal biobank committee that will assess the requirements of the studies for which the request is made.

9) COMMUNICATION AND UNEXPECTED RESULTS (INCIDENTAL FINDINGS)

If the investigations carried out for scientific purposes would produce information, including unexpected information (incidental findings), capable of providing a concrete and direct benefit in terms of therapy or prevention or as a function of conscious reproductive choices, this information may be communicated to the donor only with her/his own authorization, except for exceptions provided for in the regulations in force.
At any time, the donor, or the person exercising parental responsibility or legal representation, may contact our Hospital's Data Protection Officer, who can be reached at privacy@sacrocuore.it, in order to know the data concerning you, or concerning the donor, to know how it was acquired, to verify whether it is accurate, complete, up-to-date and well kept, and to assert your rights in this regard.
Specifically, with reference to the specific use of genetic data, we inform you that you have the right to:

• To be informed by a health professional of the attainable results and possible unexpected information knowable as a result of the investigations performed;

• to refuse to disclosure the processing of genetic data and the use of genetic data for the benefit of the donor and his/her family members;

• to limit the scope of communication of the donor's genetic data and the transfer of your biological samples, as well as the possible use of them for purposes other than those defined;

• Know the retention times for genetic data and biological samples;

• Know the type of research projects for which genetic data and biological samples will be used.

It is specified that the right of access to information pertaining to the use of genetic data does not include the right of access to biological samples acquired, stored and used, for scientific research objectives.

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Generally, scientific research on biobank samples produces results on aggregated data from multiple subjects. General scientific results obtained from biobank samples are always available on the institutional website. For any information, you can contact the scientific secretariat at: segreteriascientificairccs@sacrocuore.it

10) SAMPLE STORAGE PERIOD

Donor specimens, will be stored at the biobank of the Department of Infectious, Tropical Diseases and Microbiology of this Hospital, for a number of years equal to 40, with guarantees of confidentiality and with technical requirements essential to ensure the good preservation of the material. Any extensions will be sent in advance for approval to the relevant Ethics Committee in the form of a substantial amendment. At the end of the approved storage time, the samples will be destroyed and no further data will be collected on said samples, without prejudice to the use of any data already collected to determine, without altering them, the results of research already in progress.

It should be noted that using the material for the authorized purpose(s) may result in its exhaustion, thus making the sample no longer available.

11) DATA SUBJECT'S RIGHTS

The donor, or the person exercising parental responsibility or legal representation, may exercise their rights provided for in Articles 15 et seq. of European Regulation 2016/679 (e.g., accessing personal data, supplementing them, updating them, rectifying them, opposing their processing for legitimate reasons, etc.) by contacting the biobank directly through the scientific secretariat of IRCCS Ospedale Sacro Cuore Don Calabria, via A. Sempreboni, 5 - 37024 Negrar di Valpolicella (VR), email segreteriascientificairccs@sacrocuore.it.

The donor, or who exercises parental responsibility or legal representation, has the right to file a complaint with the Italian Data Protection Authority. You may terminate your membership in the biobank at any time and without providing any justification: if you do so, your biological samples will be destroyed. In fact, the donor, or who exercises parental responsibility or legal representation, has the right to revoke the consent given at any time. In that case, the data will not be further processed, without prejudice to the use of any data already collected to determine, without altering them, the results of the research for which they were used, if it is no longer possible to exclude them due to the time that has elapsed.

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[1] By **personal data** we mean "any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is considered to be any natural person who can be identified, directly or indirectly, by reference, in particular, to an identifier such as a name, an identification number, location data, an online identifier, or to one or more characteristic elements of his or her physical, physiological, genetic, mental, economic, cultural or social identity" (Art. 4 para. 1 no. 1 of Regulation 2016/679 of the European Parliament and of the Council on the protection of personal data).

[2] **Special categories of personal data** are data "revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of genetic data, biometric data intended to uniquely identify a natural person, data concerning health, sex life or sexual orientation" [Art. 9(1) of Regulation 2016/679 of the European Parliament and of the Council on the protection of personal data].

[3] **Genetic data** are defined as "personal data relating to inherited or acquired genetic characteristics of a natural person which provide unambiguous information about the physiology or health of that natural person and which result, in particular, from the analysis of a biological sample of that natural person" [Art. 4(1)(13) of Regulation 2016/679 of the European Parliament and of the Council on the protection of personal data].

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INFORMED CONSENT FOR THE USE OF BIOLOGICAL MATERIALS AND TO THE PROCESSING OF PERSONAL DATA

The donor

First name_____ Last name_____

Date and place of birth _____Gender □ M □ F

Fiscal Code_____Phone Number _____e-mail: _____

in the case of a minor or donor with a legal representative give the following references:

□ Parent or □ Legal representative

First name _____ Last name _____

Place and date of birth_____

Phone number _____e-mail: _____

□ Parent or □ legal representative

First name _____ Last name _____

Place and date of birth_____

Phone number _____e-mail: _____

STATES OF:

- Having received and clearly understood all information pertaining to the use of biological samples and the processing of special and genetic data.
- Having understood that the decisions made will be considered valid for all biological samples that will be taken at one time or at different times during hospitalization/treatment/access to our Operating Unit, until revoked or rectified.

Considering the information received:

☐ I agree ☐I do not agree
- to the preservation of the biological material collected, for possible subsequent investigations, for purposes of diagnosis and treatment to protect my health, and for possible experimental research that may include genetic studies.
- That my data be made de-identified and protected by an encryption system.

☐ I agree ☐I do not agree
- to receive information, even unexpected, capable of providing a concrete and direct benefit in terms of therapy or prevention or as a function of conscious reproductive choices.

Date_ _/__ /____ Donor's signature: _____

In case of minor or donor with legal representative:
Date_ _/__ /____ Signature of parent or legal representative: _____
Date_ _/__ /____ Signature of parent or legal representative: _____

Signature requested also in the following page →

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☐ I agree ☐ I do not agree
- To the processing of personal data for the purpose of scientific research.

☐ I agree ☐ I do not agree
- To the processing of genetic data for the purpose of scientific research.

Date_ _/__ /____ Donor's signature:_____

In case of minor or donor with legal representative:
Date_ _/__ /____ Signature of parent or legal representative: _____
Date_ _/__ /____ Signature of parent or legal representative: _____

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