CHAIN BIOBANK Informed Consent

INFORMATION TO THE DONOR

Title of the Research Project
CHAIN Biobank of NOVA Medical School – Human biological samples Bank for biomedical research.

Aim of the study
The creation of a biobank of human biological samples will enable the development of research and diagnostic tools in different research areas of medicine with potential positive impact on science concomitant benefit in terms of better health and/or healthcare of the society. Nonetheless, this objective will only be achieved with the collaboration of the population, through the donation of biological samples of patients or healthy individuals that will be stored and preserved under appropriate conditions to be used for future studies. If a patient or healthy individual and/or her/his legal representative decides to participate, they will only have to go to a usual medical appointment.

Procedure
If you agree to participate in this project, a biological sample will be collected. The sample usually requested will be used from the collection of blood and/or urine and/or faeces that you will carry out. For individuals who are undergoing diagnostic tests or who are undergoing surgical treatments, an authorization may be requested to collect a small sample of the material removed during the procedure (such as saliva, cerebrospinal fluid, tissues removed for biopsies or removed during surgery). These collections will be carried out without changing the usual medical procedures and without interfering with the diagnostic procedure or with the success of the surgery. This sample will be preserved under appropriate conditions and the clinical information related to it will be entered into a database, with your personal identification becoming codified and not accessible to sample users.
The donation of the sample is voluntary and revocable, and the donor, or his/her legal representative, has the right to withdraw the sample and/or interrupt the collaboration as soon as he/she deems it convenient, without the need for justification, and cannot be discriminated against for doing so. The donor, or his/her legal representative, must express in writing the intention to withdraw the sample or interrupt the collaboration, and in these situations, the sample will be immediately destroyed.
The CHAIN Biobank proposes to store human biological samples and their possible derivatives such as serum, plasma, DNA, RNA, and cells.
CHAIN Biobank will not disclose results involving biological material.
However, the donor will be able to choose whether he wants to be informed of results with potential relevance to his/her health. The request for results must be made in writing to CHAIN Biobank by the donor or legal representative and must be expressed in the informed consent.
CHAIN Biobank works in compliance with all international ethical standards for the use of biological materials for research purposes.
All projects that make use of samples deposited in the CHAIN Biobank will be submitted to the competent Ethics Committee for their evaluation.

Sample identification and confidentiality
The existence of a Biobank presupposes the existence of a database containing clinical information regarding the patient or healthy individual. After collection, the samples will be identified by a code to preserve privacy.

During the development of a research project, the research team may need to collect information from the clinical process for the execution of the study. Anonymity will, however, be maintained, that is, the data contained in the clinical file will be provided to the researcher, but without any identification or any information that allows to know who they belong to.
The decoding can only be carried out by the doctor (who will be responsible for the database, according to the information provided to the National Data Protection Commission - CNPD), in case of absolute necessity, for reasons of the donor's health and at their request, and always in accordance with the legal requirements.
Data will be treated confidentially in accordance with the law, regulations, and ethical standards approved by the Ethics Committee of CHAIN Biobank and the CNPD.
The data resulting from the studies carried out will be published anonymously and aggregated, in terms of percentages or numerical data, never individually.

Time of storage

The samples will be kept for a period of 25 years in the CHAIN Biobank of the NOVA Medical School, under the responsibility of the Team linked to the project, while it is duly accredited by the competent authorities.

Sample collections will be evaluated periodically to assess their quality and dependent on their quality may be destroyed earlier or at the end of the conservation period an extension of conservation may be requested. Under these exceptional conditions, CHAIN Biobank may contact donors again.

Communication and data disclosure

Genetic data and biological samples collected for scientific research purposes may be transferred to other organizations or research centers for research purposes with the participant's consent expressed in the informed consent statement. The identity of the donor is always preserved as the share of samples/data is always in anonymity.

Possible benefits for the participants

This is an altruistic donation, therefore there is no compensation for the donor. There is no guarantee that this study will involve any indirect benefits for the participant. If any of the studies may be relevant to the donor's health, the donor will be informed, if this is their wish expressed in the informed consent declaration. However, the participation will provide the acquisition of knowledge that could benefit donor or others in the future.

Predictable physical risks

In most cases, the associated risks and discomfort will be minimal or non-existent. In collection associated with procedures for diagnostic or therapeutic purposes, the risks and discomfort will be those inherent to the procedure itself. In any case, the donor will always be informed in advance of the risks and degree of discomfort associated with the procedures.

Voluntary participation and right to withdraw

The presumed donor will be free to refuse to participate in the study or revert his consent and suspend participation at any time and consequently, the samples will be destroyed.

Participation is voluntary and your refusal to participate will not involve any penalty or loss of benefits and will not jeopardize the right to receive treatment or medical assistance, now or in the future.
The donor may withdraw his consent in the modalities without future contact (the samples can be used normally until they run out, but future contacts will not be established to obtain more samples) or without future use (future contacts will not be

established and the samples will be immediately destroyed, and records deleted).

In case of doubt on this study, at any moment, even after the sample collection, please contact the CHAIN Biobank executive commission:

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INFORM CONSENT

Biobank of human biological samples for Biomedical Research

Doctor: _____
Recruitment center: _____
Donor Name: _____
Study number of the Donor: _____
Diagnose _____
Sub-grup _____

I, _____, with identity card/citizen card no. [_____], declare that I have become aware of and agree to participate in this project, in order to contribute to the creation of a bank of human biological samples with associated clinical information, for the purposes of biomedical research.

I accept that my biological sample will be used in research projects into disease mechanisms, early diagnosis, prognostic factors and new therapeutic targets in multiple areas of medicine, namely oncological, cardiovascular, neurological, bone, immunological and infectious diseases. I may revoke authorization to use my biological sample and clinical information at any time. The purpose of the biological sample bank was clearly explained to me and I was given the opportunity to ask questions about its operation, as well as the procedures relating to the collection and use of my biological sample and associated data.

I declare that I voluntarily accept to participate in this study. Specifically, I agree with the following points:

1. I consent to the collection of biological material (blood / ..... /.....) and authorize the conservation of samples in the Biobank, so that can be used for new lines of research, including genetic studies and cell line culture by Portuguese and foreign researchers, on a non-profit basis;

   Yes ☐ No ☐

2. **This option is to be answered only by participants who have already donated biological samples collected as part of other projects.** In these circumstances, I authorize the transfer to Biobank of my biological samples, previously collected within the scope of other projects, so that they can be used in future research, including genetic studies and cell line culture by Portuguese and foreign researchers, but without profits;

   Yes ☐ No ☐

3. I am aware that my participation is voluntary and that I can at any time request the destruction of my biological samples, thus invalidating prior informed consent, without giving reasons, having received the guarantee that my request will not result in discrimination;

   Yes ☐ No ☐

4. I declare that I want to know results that may be relevant to my health.

Yes ☐ No ☐

5. I authorize being contacted again by CHAIN Biobank to request an update on my clinical situation;

Yes ☐ No ☐

6. I authorize CHAIN Biobank to contact my family members to request authorization to collect biological samples and/or clinical information;

Yes ☐ No ☐

Date	Donor Signature /Legal Representative

In case of legal representative, this is a:

- ☐ Owner of the parental authority if the donor is a minor.
- ☐ Tutor, if the donor is declared legally incompetent.
- ☐ Heir, if the donor deceases

I Discuss this research study with the participant and/or their legal representative, using comprehensive and relevant language. I informed the participant about the nature of this study and its possible benefits and risks, considering that the participant understood my explanation.

Date	Doctor Name	Doctor Signature

A duplicate of this document was delivered to the patient/legal representative.