

.....
1st SURNAME.....
2nd SURNAME.....
NAME

MEDICAL RECORD

INFORMED CONSENT

Patient's ID card No.:

Date: _/ _/ _

Clinician responsible for collecting the consent:

Professional license number:

INFORMATION AND INFORMED CONSENT FOR THE DONATION, STORAGE AND USE OF SAMPLES IN THE BIOBANK OF THE HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Given that you are being treated at a University Hospital, **we are inviting you to donate** your remnant biological material (samples or parts of your body) following its use for your diagnosis or after a therapeutic procedure (surgery, etc.), and which would otherwise be disposed of. If you agree, this material will be stored at this **hospital's Biobank** to be used for training and scientific purposes, in compliance with the legislation in force, with a view to attempt to contribute to improve our current knowledge of diseases and advance in their diagnosis and treatment.

A biobank is a place where samples, tissue, DNA and other specimens, which represent a valuable tool for the research of diseases and could enable the acquisition of knowledge in the interest of the development of new strategies and therapies applicable to patients, are stored in adequate conditions.

You are being asked to provide your consent for the **storage** of these samples for an indefinite period during which they will be available for the conduct of various research projects, whose ethical and scientific aspects will be assessed by the biobank's external committees, including the Clinical Research Ethics Committee. These projects may be carried out both at the **Hospital Universitario "12 de Octubre"** and in other Centers. Among other studies, *your samples will be used in research lines for which genetic analyses may be (occasionally generating animal models) used to develop and improve new therapies and treatments that might benefit you, your family members and society in general.*

Your cooperation is **voluntary and free**; therefore, you waive any economic, patrimonial or optional right that you may have on the potential benefits that could directly or indirectly result from the research studies performed with the samples that you are submitting for such research. The quality of your health care will continue being the same regardless of whether or not you grant this consent. The only expected benefits are the potential medical progress made for the benefit of society, in general, and the knowledge that you have participated in this process. Thus, the sample may not be the direct object of profit-oriented activities. The donation of our sample will not entail extra expenses for you (or your legal representative). Your participation will not entail **any additional risk** or discomfort for you either, as no further test or intervention will be carried out apart from that performed to collect the sample.

Your samples and clinical information will be coded to ensure that your identity will be protected. Each sample will be identified with a code and the scientific group in charge of performing the research study will not be able to link your identity with the assigned code at any time; although this association may be revealed, if necessary, using the code.

The results of the research studies will be analyzed by groups of researchers and experts, and may be reported in meetings, medical congresses or scientific publications, although always safeguarding your confidentiality.

If any additional sample or datum were needed, you will be contacted again, although you will **always** have the right to choose whether or not you wish to participate. Upon completion of the research study, your samples will be stored again in the biobank. If information concerning your health or that of your family members becomes available, you will have the right to be informed of the genetic data generated and you may decide whether or not to exercise such right. According to the Spanish Law, when the responsible doctor deems it necessary to notify such information to avoid serious damage to your health or that of your biological relatives, a close relative or a representative may be informed, previous consultation with a Welfare Committee, if available. In any case, this communication shall be limited exclusively to the information needed for such purpose.

You are free to request the withdrawal of your consent to the use of your samples at any moment, as well as their destruction or anonymization (destruction of the code linking the sample to your identity). However, the effects of this withdrawal will not apply to the data resulting from the previous research performed with these. You also have the right to include restrictions regarding the use of your samples.

Continued overleaf

04.625

Your personal data will be collected, processed and stored complying at all times with the duty of secrecy, according to the current legislation on the protection of personal data. In international projects, your data may be transferred to countries that do not provide a level of data protection comparable to that granted by the Spanish Law on the Protection of Personal Data. Your personal data will be included in a file registered in the Spanish Data Protection Agency, in accordance with the terms set out by the legislation in force. For greater ease in the exercise of your rights of access, opposition, rectification or cancellation of your data, in addition to withdrawing, destroying or anonymizing your samples or data by notifying the clinician responsible for informing you of the procedure or the service of this hospital who provided the consent form, you may also do so at the following email address:

biobanco.hdoc@salud.madrid.org

We guarantee that, in case of the eventual closure of the biobank or withdrawal of its authorization, the information on the destination of your samples will be available at the National Biobank Registry for Biomedical Research, and that you will be given the opportunity to discuss it.

In case of storage of samples from underage patients, the source subjects may access all information associated with the sample when they reach adulthood.

Please do not hesitate to ask your doctor if you need more information or clarifications.

DECLARATIONS AND SIGNATURES

I hereby declare:

- I have read, been informed and understand the content of this informed consent, which I certify by my signature as proof of my consent.
- I have asked questions and these have been clarified by Dr.....
- I understand that my participation is voluntary and free, and that I can request to have this consent withdrawn at any time, without having to give explanations and without this having an impact on my current and/or future medical care.
- I authorize the storage and use of this biological material in the Biobank of the University Hospital 12 de Octubre.
- I authorize the consultation of my medical records whenever this may be crucial for the conduct of the research project for which my samples were requested, with the prior authorization of the Research Ethics Committee.
- If the research studies performed with my samples yield biomedical results that may be of interest to myself or my relatives, according to the current legislation:
 - I wish to be informed. Yes ☐ No ☐
 - I do not wish to be informed, although I agree to my relatives being informed of the results that may affect them.
Yes ☐ No ☐
- I do not want my samples to be used in research projects concerning.....
- Three copies of this document will be issued, one for you, another for the records of the Biobank of the UNIVERSITY HOSPITAL 12 DE OCTUBRE, and a third for the site where the sample was collected.
- I consent the transfer of my data to other countries: Yes ☐ No ☐

I AGREE TO DONATE MY SAMPLES AND DATA TO THE BIOBANK OF THE HOSPITAL 12 DE OCTUBRE, AUTHORIZING THE STORAGE AND USE OF THE DONATION UNDER THE CONDITIONS DESCRIBED IN THIS DOCUMENT AND, IN WITNESS THEREOF, I SIGN THIS INFORMED CONSENT FORM.

Madrid, on

Patient's signature

Doctor's signature

Name of the legal representative in case of the patient's inability to consent, either due to being underage, or to a legal incapacity or incompetence, indicating the nature of their relationship (Father, Mother, Tutor, etc.).

Name:

Personal identification No.:

I authorize the conduct of the cited procedure.

Signature

REFUSAL OF CONSENT

After having been informed of the nature of the proposed procedure, I freely and consciously manifest my REFUSAL TO CONSENT its conduct.
Madrid, on

Patient's signature

Doctor's signature

Name of the legal representative in case of the patient's inability to consent, either due to being underage, or to a legal incapacity or incompetence, indicating the nature of their relationship (Father, Mother, Tutor, etc.).

Name: _____ Personal identification No. _____ :

I authorize the conduct of the cited procedure.

Signature

For any questions, withdrawal of consents, etc., please contact: the clinician who informed you of the procedure, the service of this hospital who provided the consent form, the Patient Care Unit of the HOSPITAL 12 DE OCTUBRE, or the following email address: biobanco.hdoc@salud.madrid.org