

INFORMED CONSENT FOR THE VOLUNTARY DONATION OF BIOLOGICAL SPECIMENS FOR RESEARCH TO LA FE BIOBANK OBTAINED IN THE COURSE OF SURGICAL, DIAGNOSTIC OR THERAPEUTIC PROCEDURES

1.- DESCRIPTION OF THE PROCEDURE

Biological specimens may be taken during the intervention or procedure to which you or person you represent is to be subjected.

The proposed procedure consists of **voluntarily donating** any biological specimen left over from the intervention or test to which you or person your represent is going to be subjected, to **La Fe Biobank**, as a **public biobank authorised to manage biological specimens for biomedical research and/or diagnostic purposes in accordance with current legislation**, without this entailing any additional risk to your health or compromising the correct diagnosis or treatment of your illness or dysfunction. These surplus biological specimens may be used in biomedical, clinical or translational research projects that have been previously approved by external ethics and scientific committees to which the biobank refers. The specimens will be managed by La Fe Biobank until they have all be used, if there is no revocation of this consent.

The health professional who has explained the procedure for voluntary donation of biological specimens to you is responsible for ensuring that you or the person you represent receives the information in an understandable form so that you can make a free and informed decision. Ask him/her any questions you may have about this process before, during or after the procedure.

2.- OBJECTIVE

The purpose of La Fe Biobank is to manage the collection, processing and conservation of human biological specimens for subsequent use in biomedical, clinical and/or translational research projects or to complete diagnostic tests. The results of these research projects may lead to the discovery of new methods for the better diagnosis, prognosis and/or treatment of diseases and/or dysfunctions.

The information obtained through such research projects cannot be obtained in any other way than through the study of biological specimens. Moreover, such information may vary depending on the stage of the disease at which the specimen is obtained. It must therefore be taken at this point in the diagnostic or treatment process in order to be useful.

Research projects using the biological specimens shall have the purpose of improving the knowledge, diagnosis and treatment of clinical conditions that you or your client may present, with this knowledge leading to a potential benefit for the population and, if applicable, for you or the person you represent.

3.- CONDITIONS OF THE DONATION

Neither you nor person you represent will receive **any financial compensation** or other material benefits for donating your specimens. However, successful research may in the future help patients who have the same disease or dysfunction as you or the person you represent or who suffer from other similar diseases or dysfunctions. Your specimens or those of the person you represent **will not be sold or distributed** to third parties for commercial purposes, but the costs of obtaining, storing and sending the material will be passed on, without any profit motive, to those who use them in accordance with current legislation.

The donation of specimens will not prevent you, the person you represent or your family **from using them**, provided that they are available, when required and if their final use is clinically, therapeutically or legally justified. You should be aware that the diagnostic use of the donated specimen will have priority and that La Fe Biobank will guarantee the availability of specimens for this purpose.

In the event of a possible closure of the biobank or revocation of the authorisation for its constitution and operation, **the information on the destination of the specimens** for biomedical research **will be available** in the National Biobank Register or in the register of the public authority that holds the competence at that time, so that it can **express its conformity or disagreement** in relation to the intended use of the specimens.

4.- FORESEEABLE CONSEQUENCES OF ITS IMPLEMENTATION

You may be **contacted again in order** to obtain new information about your situation or that of the person you represent, or to take a new specimen that may be of interest in the development of biomedical, clinical or translational research. In this case, **you will be informed again and will be free to accept or refuse** such participation. For this reason, it is important that you inform the Admissions Service of the Hospital Universitari i Politècnic La Fe or the doctor in charge of your treatment, care and/or follow-up, or that of the person you represent, of any future **changes of address and contact telephone numbers**, this being the only means of contact with you, the person you represent or your family.

It is possible that information relating to your health or that of the person you represent may be obtained as a result of the development of biomedical, clinical or translational research projects and, in particular, genetic data of clinical relevance. In this regard, **you may request information relating to your health or that of the person you represent arising from the study** of donated specimens. To exercise this right, you may contact the Scientific Directorate of La Fe Biobank by sending a written request to:

Biobanco del Hospital Universitari i Politècnic La Fe
Avda. Fernando Abril Martorell, 106. C.P.: 46026 (Valencia) - Torre A - Sótano

For this reason, it is important that future changes of address are **recorded in your medical records.**

The information obtained may also be **relevant for your relatives.** It is your decision and/or the decision of the person you represent to inform them so that, if they so wish, they can be studied, thus allowing for the assessment of their future health options. When this information is medically necessary to avoid serious harm to the health of your biological relatives, you will be informed after consultation with the Health Care Ethics Committee.

5.- RIGHT TO WITHDRAW CONSENT

The decision to donate your specimens is **entirely voluntary.** You or the person you represent may refuse to donate them, or once they have been donated, **you may revoke your consent at any time,** without having to give any explanation and without this having any repercussions on the medical care you receive at the centre.

If the consent now provided is revoked, we will ask you your preference as regards **whether to destroy the specimens or store them without identifying data.** This action will take effect only for the portion of the specimens donated to La Fe Biobank. Specimens or clinical information necessary for the treatment and resolution of your disease and/or dysfunction will not be destroyed.

6.- RISKS

The proposed procedure **does not pose any additional risk** to your health, nor does it compromise the correct diagnosis or treatment of your illness or dysfunction or that of the person you represent, as it involves a specimen left over from the surgery, diagnostic or therapeutic process that was to be carried out in any case.

7.- PROTECTION OF PERSONAL DATA AND CONFIDENTIALITY

In compliance with **Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights**, we inform you that:

The personal data are collected in the files "*Clinical-care information*", "*Organisation and management of healthcare activity*", "*Pharmaceutical prescription and dispensing*", "*Epidemiology*", "*Clinical health and pharmacological research*", which have been **published and registered with the Spanish Data Protection Agency**, with the Department of Universal Healthcare and Public Health being responsible for them. The processing, communication and transfer of your personal data will also comply with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (RGPD).

In accordance with the provisions of the aforementioned legislation, you may exercise your rights of access, modification, opposition, cancellation of data, limit the processing of data that is incorrect and request a copy of the data or that it be transferred to a third party (portability), to do which you may contact the Patient Care and Information Offices of this Hospital (SAIP), the entry registers of the Regional Ministry of Universal Healthcare and Public Health, as well as the territorial services of the same, or the Institution's Data Protection Officer, who may be contacted by e-mail at: dpd@gva.es.

In the event of transfer to third parties of specimens and/or information derived from the studies, any data that may reveal your personal identity and/or that of your family will be deleted. This Hospital treats your personal data in the **strictest confidence** and only for the purposes indicated and informs you that it implements the necessary security measures to guarantee the security and confidentiality of your data.

COPY FOR THE CENTRE

DECLARATION OF CONSENT - SIGNATURE SHEET

Mr / Ms years of age, with National ID Card No. and Health Card (SIP) no.

Mr / Ms years of age, with National ID Card No. and Health Card (SIP) no., as authorised representative (in case of incapacity)

DECLARE THAT:

- I have read the information provided to me.
- I have been informed by the undersigned health professional about the donation of specimens to La Fe Biobank.
- I understood the explanations provided and they were given in clear and simple language.
- I have been able to make observations and all my questions have been answered.
- I have understood that the donation of biological specimens for biomedical, clinical and/or translational research purposes is voluntary, and I may revoke my consent at any time, without having to give any explanation and without any repercussions.
- I freely and voluntarily agree to the voluntary donation of organs and/or specimens for biomedical, clinical or translational research purposes.
- I can include restrictions on the use of the same:
.....

I CONSENT THAT:

The hospital or other research centres, public or private, may use my data and the specimens donated under the conditions set out in the information sheet and in accordance with the legislation in force.

DONOR, FAMILY MEMBER OR LEGAL REPRESENTATIVE

HEALTH PROFESSIONAL

Mr/Ms
National ID Card:
Date:

Mr/Ms
National ID Card:
Medical Licence No. Date.....

I WISH:

To be informed of relevant findings that may have implications for me or my family.

YES NO Name..... National ID Card.....
Address: Phone:.....

COPY FOR LA FE BIOBANK

DECLARATION OF CONSENT - SIGNATURE SHEET

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DONOR, FAMILY MEMBER OR LEGAL REPRESENTATIVE

HEALTH PROFESSIONAL

Mr/Ms
National ID Card:
Date:

Mr/Ms
National ID Card:
Medical Licence No. Date.....

I WISH:

To be informed of relevant findings that may have implications for me or my family.

YES NO Name..... National ID Card.....
Address:Phone:.....

COPY FOR THE DONOR

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Mr / Ms years of age, with National ID Card No.
..... and Health Card (SIP) no.

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HEALTH PROFESSIONAL

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National ID Card:
Date:

Mr/Ms
National ID Card:
Medical Licence No. Date.....

I WISH:

To be informed of relevant findings that may have implications for me or my family.

YES NO Name National ID Card.....
Address:Phone:.....

REVOCAION OF CONSENT

I revoke the consent given onof..... 20..... and do not wish to continue the voluntary donation, which I hereby terminate.

DONOR, FAMILY MEMBER OR LEGAL REPRESENTATIVE

HEALTH PROFESSIONAL

Mr/Ms
National ID Card:
Date.....

Mr/Ms
National ID Card:
Medical Licence No.

In, on of 20.....