

COPY FOR THE DONOR

Informed Consent Document

FOR VOLUNTARY DONATION FOR RESEARCH OF BIOLOGICAL SAMPLES OBTAINED DURING SURGICAL, THERAPEUTIC OR DIAGNOSTIC PROCEDURES

1. IDENTIFICATION AND DESCRIPTION OF THE PROCEDURE

Samples of your tissues and/or blood will be taken during the surgical operation or diagnostic test to be carried out on you. The procedure being proposed consists in voluntarily donating any biological samples left over from the operation or test to which you are to be submitted to a biobank for biological samples. This will not entail any additional risk for your health, nor jeopardize the proper diagnosis and treatment of your illness. Any such surplus biological samples may be used in biomedical research projects.

If you authorize this, a relatively small volume of blood will also be taken for storage in the biobank and possible use in research. Any samples donated will be stored at the [CIBERER-Biobank](#), which forms part of the Valencian Biobanks Network, authorized by the regional authority and complying with the requirements laid down in current legislation.

Your samples may only be used in scientifically backed research projects which are previously approved by the external committees to which this biobank is attached, including the Research Ethics Committee and the Scientific Committee. Sometimes such studies will be performed outside the centre at which you have been treated.

The samples will continue to be stored at the [CIBERER-Biobank](#) until the stocks run out, unless this consent is revoked.

2. PURPOSE

The [CIBERER-Biobank](#), located at the Centro Superior de Investigación en Salud Pública (CSISP) in Valencia, is a biobank set up with the aim of collecting and storing human biological samples to perform biomedical research projects. The results of these research projects may lead to the discovery of methods and drugs for better diagnosis and treatment of these diseases. Both the samples and the data associated with these will be safeguarded and, where applicable, given to third parties for biomedical research purposes in the terms envisaged in Act 14/2007, of 3rd July, and in Royal Decree 1716/2011, of 18th November.

3. EXPECTED BENEFITS

No economic compensation or of any other kind will be received for the samples donated and these will have no commercial value. If any research which might be performed were to be successful, in the future they could nevertheless help patients suffering from the same or similar diseases.

The donation implies the donors' relinquishment of any economic or other kind of right over the results which might stem directly or indirectly from the research carried out with the biological samples.

No samples of tissues and/or blood will be sold or distributed to others for commercial purposes, although the costs of keeping and sending these will be covered on a non-profit-making basis.

The donation of samples will not prevent you or your family from using these whenever these are available, when they could be necessary for health purposes.

4. FORESEEABLE CONSEQUENCES OF THE DONATION

Only if you wish, there is a possibility of your being contacted in the future in order to complete or

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update the information which we now have and/or to take a further sample which could be of interest in the development of biomedical research. In this case you will be informed about the situation again and be free to participate or refuse such participation.

The studies performed on your samples may possibly provide relevant information for your health or that of your relatives. You are entitled to be informed or not to be informed of your genetic data and other personal data obtained in the research. For this purpose, you will be understood not to want to receive such information unless you declare otherwise, using the form for this purpose which is at your disposal at the health centre where you are being treated.

This data could affect certain members of your family, and you must therefore decide whether it is advisable or not to pass this information on to them.

In the event of storing samples taken from minors, the CIBERER Biobank guarantees access of the source subject to the information about this, as soon as he or she comes of age.

5. FORESEEABLE CONSEQUENCES OF NOT DONATING AND YOUR RIGHT TO WITHDRAW CONSENT

The decision to donate your samples is absolutely voluntary, and you can refuse to donate them and even withdraw your consent at any time, without having to give any explanation and without this having any effect on the medical care that you receive.

If you should decide to withdraw the consent now being given, the part of the samples that has not been used in the research will be destroyed or made anonymous. Such effects shall not extend to data stemming from any research that may have been carried out beforehand.

6. RISKS

The procedure being proposed does not entail any further risk for your health nor jeopardise the proper diagnosis and treatment of your disease.

The donation of blood hardly has any side effects; the one most commonly found is the appearance of small bruises at the puncture area which disappear after one or two days.

7. PROTECTION OF PERSONAL DATA AND CONFIDENTIALITY

Your personal and health data will be included in a data file for processing in accordance with what is laid down in Organic Act 15/1999 on Protection of Personal Data, of 13th December (LOPD), for which the CIBERER-BIOBANK is responsible.

Any assignment to other public or private research centres of your samples of tissue and/or blood or their derivatives, as well as the information contained in the databases connected with these and their state of health, will be done by means of a procedure of encoding and dissociation of data, that is, separating any information that identifies you.

The subject of the personal data may furthermore make use of their rights of access, rectification, cancellation and opposition to processing of personal data and withdrawal of consent (in this last case, by means of the form that you have available at the health centre at which you are being treated) in the terms envisaged in applicable regulations by means of a letter sent to the CIBER (Calle Monforte de Lemos 3-5. Pabellón 11. Planta Baja 28029 Madrid, SPAIN).

8. USE OF THE SAMPLES IN THE EVENT OF THE BIOBANK BEING CLOSED

In the event of any possible closure of the CIBERER-BIOBANK, the information about the destination of the samples will be at your disposal at the *Registro Nacional de Biobancos para Investigación Biomédica* in order for you to be able to state your agreement or disagreement with the intended use of these.

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9. DECLARATION OF CONSENT

Mr./Ms.....of..... years of age, whose address is
....., I.D. card nº.....
and health card nº.....

Mr./Ms.....of..... years of age, whose address is
....., I.D. card nº.....
as representative (in the case of being legally underage or incapable) of the
patient.....with I.D. card nº..... and health
card nº....., hereby

DECLARES

That I have read the datasheet that I have been given.

That I have been informed by the healthcare professional mentioned below about the donation of
samples to a biobank.

That I have understood the explanations that I have been given.

That I have been able to comment on this and any doubts that I have brought up have been cleared
up.

That I may withdraw my consent at any time without having to give any explanations and without this
having any effect on my medical care.

That I am freely and voluntarily making the donation of samples of ☐ Blood ☐ Tissue ☐ Others*

* Indicate:

That I may include restrictions on the use of these

I HEREBY CONSENT

To the Biobank or other public or private research centres using my data and the samples donated in
the conditions established in the datasheet.

To the CIBERER Biobank being able to access my data insofar as this is necessary and always
keeping this secret.

To the staff of the CIBERER Biobank contacting me in the future in the event of considering it
appropriate to add further data to the information already collected and/or to take new samples.

☐ Yes ☐ No

☐ I wish to include the following restriction to the use of my samples:

Signed: Mr./Ms.

In this..... of 20.....

Declaration of the healthcare professional:

I have properly informed the donor

Signed.: Dr. I.D. card nº
.....Professional Association member Nº

In..... this of 20.....

CIBERER CBK-F003_Informed Consent_v03

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appropriate to add further data to the information already collected and/or to take new samples.

☐ Yes ☐ No

☐ I wish to include the following restriction to the use of my samples:

Signed: Mr./Ms.

In this..... of 20.....

Declaration of the healthcare professional:

I have properly informed the donor

Signed.: Dr. I.D. card nº.....
.....Professional Association member Nº

In..... this of 20.....

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and health card nº.....

Mr./Ms.....of..... years of age, whose address is
....., I.D. card nº.....
as representative (in the case of being legally underage or incapable) of the
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☐ Yes ☐ No

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.....Professional Association member Nº

In..... this of 20.....

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WITHDRAWAL OF CONSENT

I, Mr./Ms. with I.D. card nº hereby withdraw the consent granted on of 20 and do not wish to go through with the voluntary donation, which I am considering over as of this date.

Signed.:

In..... this of 20.....

I, Mr./Ms., holder of I.D. card nº as legal representative of Mr./Ms., with I.D. card nº, hereby withdraw the consent granted on of 20and do not wish to go through with the voluntary donation, which I am considering over as of this date.

Signed:

In..... this of 20.....

COPY FOR THE BIOBANK

APPLICATION FOR INFORMATION ON GENETIC DATA STEMMING FROM THE RESEARCH

Mr./Ms.....of.....years of age, whose address is
....., I.D. card nº.....
and health card nº.....

Mr./Ms.....of.....years of age, whose address is
....., I.D. card nº.....,
as representative (in the case of being legally underage or incapable) of
patient....., with I.D. card nº..... and health card
nº

HEREBY REQUESTS

To be informed of the results of the research involved in the voluntary donation made on
..... 20.....if these affect my health or that of the person I am representing.

Signed.:

In..... this of 20.....

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COPY FOR THE BIOBANK

INFORMED CONSENT FOR THE IMMORTALIZATION OF CELL LINES

The immortalization of cell lines is a technique used in order to ensure an unlimited source of biological material (i.e., your cells) to perform different research work on these.

The CIBERER Biobank is going to establish this cell line with your sample so that the researchers can access an inexhaustible source of your DNA with no need to take more samples again.

This implies that this donation is being made for an unlimited time, as your cells will be immortalized and we will be able to obtain material from them indefinitely.

The CIBERER Biobank may make the cell lines obtained from these samples available to any researchers who request this.

This cell line will only be destroyed if you request this (by means of withdrawing this consent).

By signing this document I am hereby authorizing the CIBERER Biobank to carry out the immortalization process.

Mr./Ms.....of.....years of age, whose address isI.D. card nº..... and health card nº.....

Mr./Ms.....of.....years of age, whose address isI.D. card nº....., as representative (in the case of being legally underage or incapable) of patient....., with I.D. card nº and health card nº

Signed: Mr./Ms.

In..... this of 20.....

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Signed: Mr./Ms.

In..... this of 20.....

COPY FOR THE BIOBANK

INFORMED CONSENT FOR THE OBTAINING OF INDUCED PLURIPOTENT CELLS AND ORGANIDS

Induced pluripotent cells (iPSCs) come from differentiated adult cells that have been genetically manipulated to give rise to a cell type similar to that of embryonic stem cells. These cells can be kept in the laboratory indefinitely and can differentiate in a controlled way into any of the cell types present in the adult organism. In turn, from iPS cells, organoids can be generated, which are aggregates of cells cultured in specific three-dimensional (3D) matrices, giving rise to simplified miniature organs that retain some physiological functions. iPS cells derived from patients can allow the unlimited generation of cells where a particular disease manifests itself, thus enabling their study in the laboratory and the development of new drugs for the treatment of certain pathologies.

Only if you so indicate, part of the cells obtained will be used to obtain iPS cells and generate organoids. Both the iPS cells obtained and the organoids generated will be used in research for therapeutic purposes and/or the study of diseases and never in reproductive medicine. The samples will only be transferred to research projects that have the approval of the corresponding Scientific and Ethical Committees. The iPS cells will be deposited in a National Bank of Cell Lines in compliance with the current legislation of the country where they are generated so that they remain available to the scientific community.

At any time, if you so request (by revoking this consent) this cell line would be destroyed.

By signing this document, you authorize CIBERER Biobank to transfer the cells obtained to from skin biopsy to researchers who wish to obtain iPS cells from them.

Mr./Ms.....of.....years of age, whose address isI.D. card nº..... and health card nº.....

Mr./Ms.....of.....years of age, whose address isI.D. card nº....., as representative (in the case of being legally underage or incapable) of patient....., with I.D. card nº and health card nº

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