We are writing to you to request your authorization to incorporate into the CIBERER Biobank (CBK) the biological material left over from the tests or interventions that, as part of your current care process, have been performed - or will be performed - at this health center, so that these samples and their associated clinical or health data can be used in biomedical research.

This authorization refers solely and exclusively to biological samples left over from the care procedures that, indicated by the medical staff and for the treatment of your illness, will be carried out at this center and that, if not used in research, would be destroyed. In no case will samples be obtained exclusively for research purposes. If you authorize it, these surplus samples and the clinical and/or health data associated with them will be kept in the CBK until they are exhausted due to their use in research projects or until you withdraw your authorization. This donation is altruistic and completely voluntary. You can refuse without it affecting your health care or the relationship with the health care professionals who care for you in any way.

1. What does a donation to a biobank consist of?

Biomedical research is necessary to progress in the knowledge of diseases and in their prevention, diagnosis, prognosis and treatment. In many cases, research requires storing biological samples and clinical data that are generated during routine diagnostic and treatment processes. Many of the scientific advances obtained in recent years are the result of studies carried out with this biological material and the clinical data stored.

Biobanks are centers of public interest that store these biological samples and their associated data, preserving them in adequate and maximum security conditions so that they can be used in research. They incorporate human samples (blood, biological fluids, tissues and others) that represent a valuable instrument for the investigation of diseases and that can allow obtaining knowledge that can be used to develop new strategies and therapies applicable to patients.

2. Biological samples, clinical and health data

The CBK is a non-profit center of public interest, authorized under current regulations and registered in the National Registry of Biobanks under the Carlos III Health Institute (of the Ministry of Science and Innovation) with reference B.0000590. It houses organized collections of biological samples and their associated information under the conditions and guarantees of quality and safety required by current legislation on biomedical research, data protection and codes of conduct approved by the Ethics Committees. These samples and their associated information will be available for use by the scientific community that requests it from the biobank.

Any research, for which the use of these samples and their data is requested, must have the approval of a Research Ethics Committee (CEI), which will ensure that it is carried out following strict ethical and legal standards. The biobank's Scientific Committee guarantees that the projects are of scientific excellence.

For the proper development of the research studies, it is necessary to obtain clinical data related to the donor, for which you also authorize Biobank personnel or authorized health personnel to access your clinical history and collect the information to be kept with your samples. If any additional information or sample is necessary, and as long as you do not express otherwise, the health institution may contact you to request your collaboration again.

3. Data protection and confidentiality

Your personal data will be obtained, processed and stored by the Valencian Biobanking Network, an agency of the Conselleria de Sanitat Universal i Salut Pública, complying at all times with the duty of secrecy and current legislation on personal data protection.

If you consent to depositing your samples in the biobank, your data will be processed out of the public interest for scientific research, regulated by Law 14/2007 on Biomedical Research and by Royal Decree 1716/2011 on the authorization and operation of biobanks and the treatment of biological samples of human origin.

Biological samples and their data will be subjected to a pseudonymization process in the biobank. Each sample will be uniquely identified by a code, and only authorized biobank personnel will be able to associate your identity with that code. The research staff that uses your samples will not be able to know any data that allows you to be identified. Nor can you be identified in the results that are published in scientific journals, or in any other media.

It is possible that during the course of a research project, a large amount of genetic information will be generated from your samples. If the results obtained from the projects are relevant from a scientific point of view, the information obtained, detached from any data that may allow its identification by reasonable means, could be sent

to be included in scientific databases and other means of disseminating scientific content to which scientific researchers will have access, on a restricted basis.

Your samples and the clinical data associated with them will become part of the Treatment Activities Register of the entity that owns the CBK (Owner: Network Biomedical Research Center (CIBER)). You may exercise your rights of access, rectification, cancellation and opposition in accordance with the current legislation by contacting the biobank and identifying yourself sufficiently. You also have the right to obtain information about the use of your samples and data, by contacting info-biobank@ciberer.es. If you are not satisfied with the exercise of these rights, you can contact the Spanish Data Protection Agency (C/Jorge Juan, 6 Madrid 28001. www.aepd.es).

In the event of the closure of the biobank or revocation of its authorization, the information on the destination of the samples will be at your disposal in the National Registry of Biobanks for Biomedical Research, in order to declare the expected destination of the samples.

The CBK is part of the Valencian Biobanking Network (RVB), coordinated by the Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO). The RVB coordination office will have access to your personal data and associated clinical information for the sole purpose of being able to coordinate in the most efficient way possible from a scientific point of view the information obtained by the different biobanks of the Network, always in accordance with the applicable regulations.

4. Donation conditions

The donation is altruistic in nature. You will not obtain, now or in the future, any economic benefit from this donation, nor will you have rights to possible commercial benefits from the possible research discoveries in which they were used. However, you should know that the knowledge obtained through studies carried out from the donated samples contributes tremendously to medical advances and to the benefit of many patients.

The donation will not entail any additional risk or inconvenience for you, since you will not undergo any test or intervention other than those provided by the medical staff for your treatment.

By voluntarily signing this consent, you confirm that you wish to donate the remaining samples from your care and their associated data. You can include restrictions on the use of your samples in the signature sheet and also request the irreversible anonymization of the samples, in which case the relationship between your personal data (those that reveal your identity) and your biological samples and the associated clinical data would be eliminated.

5. Revocation of consent

You may revoke this consent at any time and without needing to give any explanation and without negatively affecting your assistance. In this case, your biological samples and associated data would be destroyed. The effects of this cancellation could not be extended to investigations that had already been carried out. If you wish to withdraw your consent, you must complete the revocation section of the signature sheet and send it to the biobank.

6. Information about research results

The biobank may provide you with information about the investigations in which your samples have been used and the overall results of said investigations, except in the case of cancellation or anonymization.

It is possible that in some of the investigations, information related to your health will be obtained, in particular, genetic data with clinical relevance. If you want this information to not be communicated to you, you must indicate it on the signature sheet at the end of this document. The information obtained may also be relevant to your biological relatives. It is your decision to inform them – something that we advise you to do – so that, if they wish, they can be studied and thus assess their personal risk and their health options in the future.

If you do not wish to receive this information, keep in mind that the law establishes that, when the information obtained is necessary to avoid serious harm to the health of your biological relatives, a Committee will study the case and must decide if it is convenient to inform the affected persons or their legal representatives.

Please ask the medical personnel who requested the donation any questions you may have, now or in the future, regarding this consent. If you want more information, you can get it by calling 961 92 63 21 or via the link: http://www.ciberer-biobank.es/.

We thank you for your selfless collaboration with the advancement of science and medicine. In this way, you are collaborating to improve knowledge about diseases to try to advance in their diagnosis, prognosis and treatment.

INFORMED CONSENT

COPY FOR THE DONOR

To be completed by the donor:

Mr./Mrs. _____ of ____ years old, residing at _____,
DNI _____ and SIP no. _____

Mr./Mrs. _____ of ____ years old, residing at _____,
DNI _____ as representative (in case of legal minority or incapacity) of the patient with DNI _____ and SIP no. _____

I DECLARE THAT:

I have read the information sheet that has been given to me.

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

I have understood the explanations that have been provided to me in clear and simple language.

I have been able to make observations and all the doubts I have raised have been clarified.

I have understood that the donation of samples to a biobank is voluntary and I can revoke my consent at any time, without having to give explanations and without affecting my medical care.

I authorize the use of excess biological material and/or associated data for biomedical research.

I authorize my medical record to be consulted to manage relevant clinical and health data for use in biomedical research.

I CONFIRM THAT

☐YES ☐NO I want to receive the information resulting from the research that is really relevant and applicable to my health or that of my family:

Telephone number or e-mail address: _____

☐YES ☐NO I authorize to be contacted in the case of needing more information or additional biological samples

Telephone number or e-mail address: _____

I have expressed my wish that the following exceptions be respected regarding the objective and methods of the investigations and/or anonymization of the samples: _____

Signature: _____

To be completed by the health care professional:

Mr./Mrs. _____
Medical licence number/DNI _____
In the capacity of: _____

Signature: _____
At _____, on _____ of 20 ____

INFORMED CONSENT

COPY FOR THE BIOBANK

To be completed by the donor:

Mr./Mrs. _____ of ____ years old, residing at _____,
DNI _____ and SIP no. _____

Mr./Mrs. _____ of ____ years old, residing at _____,
DNI _____ as representative (in case of legal minority or incapacity) of the patient with DNI _____ and SIP no. _____

I DECLARE THAT:

I have read the information sheet that has been given to me.

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

I have understood the explanations that have been provided to me in clear and simple language.

I have been able to make observations and all the doubts I have raised have been clarified.

I have understood that the donation of samples to a biobank is voluntary and I can revoke my consent at any time, without having to give explanations and without affecting my medical care.

I authorize the use of excess biological material and/or associated data for biomedical research.

I authorize my medical record to be consulted to manage relevant clinical and health data for use in biomedical research.

I CONFIRM THAT

☐YES ☐NO I want to receive the information resulting from the research that is really relevant and applicable to my health or that of my family:

Telephone number or e-mail address: _____

☐YES ☐NO I authorize to be contacted in the case of needing more information or additional biological samples

Telephone number or e-mail address: _____

I have expressed my wish that the following exceptions be respected regarding the objective and methods of the investigations and/or anonymization of the samples: _____

Signature: _____

To be completed by the health care professional:

Mr./Mrs. _____
Medical licence number/DNI _____
In the capacity of: _____

Signature: _____

At _____, on _____ of 20____

INFORMED CONSENT

COPY FOR THE CENTER

To be completed by the donor:

Mr./Mrs. _____ of ____ years old, residing at _____,
DNI _____ and SIP no. _____

Mr./Mrs. _____ of ____ years old, residing at _____,
DNI _____ as representative (in case of legal minority or incapacity) of the patient with DNI _____ and SIP no. _____

I DECLARE THAT:

I have read the information sheet that has been given to me.

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

I have understood the explanations that have been provided to me in clear and simple language.

I have been able to make observations and all the doubts I have raised have been clarified.

I have understood that the donation of samples to a biobank is voluntary and I can revoke my consent at any time, without having to give explanations and without affecting my medical care.

I authorize the use of excess biological material and/or associated data for biomedical research.

I authorize my medical record to be consulted to manage relevant clinical and health data for use in biomedical research.

I CONFIRM THAT

☐YES ☐NO I want to receive the information resulting from the research that is really relevant and applicable to my health or that of my family:

Telephone number or e-mail address: _____

☐YES ☐NO I authorize to be contacted in the case of needing more information or additional biological samples

Telephone number or e-mail address: _____

I have expressed my wish that the following exceptions be respected regarding the objective and methods of the investigations and/or anonymization of the samples: _____

Signature: _____

To be completed by the health care professional:

Mr./Mrs. _____
Medical licence number/DNI _____
In the capacity of: _____

Signature: _____

At _____, on _____ of 20 ____

REVOCATION OF CONSENT

VOLUNTARY DONATION OF BIOLOGICAL SAMPLES AND THEIR ASSOCIATED CLINICAL DATA FOR USE IN BIOMEDICAL RESEARCH TO THE CBK

Mr./Ms. _____ with DNI _____
I withdraw my previously given consent, without it being necessary to provide any justification.

Signature: _____

At _____, on _____ of 20___