At the [Name of Hospital], as in most hospitals, biomedical research is done in addition to patient care. The purpose of this research is to advance knowledge of diseases and their prevention, diagnosis, prognosis and treatment. This biomedical research requires collecting clinical data and biological samples from patients and healthy donors, to analyze them and to draw conclusions in order to better understand the diseases and improve their diagnosis and/or treatment.

The samples and clinical data obtained for the diagnosis or control of diseases are, after having been used for this purpose, also useful and necessary for research. In fact, many of the scientific advances made in recent years in medicine are the result of such studies.

We ask your permission to include in the biobank of the hospital all biological material that remains after the tests that have been done or will be done on you as part of the current healthcare process at this center, so that they can be used for biomedical research.

Following the provisions of Law 14/2007 on Biomedical Research, Organic Law 15/1999 on the Protection of Personal Data and their implementing rules, we ask that you carefully read this information document and the informed consent that is appended at the end for you to sign, if you agree to take part in this proposal.

**What is a biobank? An institution to contribute to research and health.**

A biobank is an institution regulated by specific laws that facilitates biomedical research, that is, research aimed at promoting people's health.

The samples included in a biobank may be ceded to medical research, always under the supervision of a scientific committee and an ethics committee. Samples are usually ceded without associated personal information, although sometimes access to medical records or results of other tests may be necessary to complete the investigation.

Biomedical research today is a global phenomenon, so that occasionally these samples may be ceded to research groups outside Spain, provided the requirements of Spanish law are met and the transfer is approved by the relevant committees.

**Biological samples and associated information: in no case will more tests be done than necessary for proper medical attention.**

Excess biological material removed during the healthcare process (blood samples, body fluids and/or tissues) will be saved and made available without this causing you any additional discomfort. Donation of surplus samples of this healthcare process does not prevent you or your family from using them should they be required for health reasons, provided they are available. Samples and information associated with them will be safeguarded and/or stored in the Biobank (bank of biological samples) of the [Name Hospital] until they are exhausted. This biobank is an authorized non-profit establishment registered in the National Register of Biobanks attached to the Carlos III Health Institute with reference [Registration Number].

This biobank houses organized collections of biological samples and associated information under conditions and with quality and safety guarantees required by the legislation referred to above and the codes of conduct approved by the Ethics Committees. Such samples and their associated information are available to researchers upon request to the biobank.

Any research study for which the use of these data or samples is requested must always have been approved by the competent Research Ethics Committee (REC), which will ensure that researchers always develop their studies following the
highest ethical and legal standards. Furthermore, the scientific committee of the biobank will guarantee that the projects are of scientific excellence.

In cases where the investigation requires it, genetic studies will be conducted on the donated samples. From these studies information can be obtained about your health and that of your relatives. Protection of this information is always ensured (see section on data protection and confidentiality).

By signing this consent, officials of the Hospital Biobank are allowed to consult your medical history, but only when this is essential for carrying out the project for which the samples were requested and when it is approved by the corresponding Ethics Committee.

Should any additional sample be required, the health institution may get in touch with you to ask again for your cooperation. In that case you will be informed of the reasons and your consent will be asked again.

**Data protection and confidentiality: Samples are stored using a coding system.**

Personal data will be collected, processed and stored adhering at all times to the obligation of maintaining confidentiality, in accordance with current legislation regarding the protection of personal data.

Identification of the biological samples of the Biobank will be subjected to a coding process. Each sample is assigned an identification code, and this code will be used by the researchers. Only personnel authorized by the biobank will be able to relate your identity with those codes. Using this process, researchers requesting samples from the biobank will not obtain any data that may reveal your identity. Likewise, although the results of the research conducted with your samples may be published in scientific journals, your identity will not be provided. In studies in which no results are anticipated that are potentially of use for your health, samples and data may be anonymized upon approval by the relevant Ethics Committee; that is to say that it will not be possible anymore to associate the sample with your identity.

Your samples and associated clinical data will become part of the file of the Biobank, registered at the Data Protection Agency. The Director of the Biobank is responsible for the custody.

You can exercise your rights to access, rectify, cancel and object, as well as obtain information on the use of your samples and associated data by contacting:

**Director of the Biobank**

Postal Address: [Address of the biobank]
Tel: [Telephone] Email: [Email Address]

**Altruistic nature of the donation. The cession of biological samples by you to the Biobank [Name Hospital] is gratis.**

The donation is by law altruistic in nature, and therefore you will not obtain any financial gain from it now or in the future; you will also not have rights to potential commercial benefits from any discoveries that may result from the biomedical research. However, the knowledge gained from the studies carried out using your sample and many other samples can help medical progress and as a result help other people.

**Voluntary participation. Your refusal to participate will NOT affect your medical care, now or in the future.**

Your participation is completely voluntary. By signing the informed consent you confirm that you want to participate. You may refuse to participate or withdraw your consent at any time after signing without having to give reasons; this will not have a negative impact on your present or future health care.
Withdrawal of consent: If you choose to sign this consent, you can also cancel it freely.

If sometime in the future you want to withdraw your consent, your biological samples will be destroyed and the data associated with them will be removed from the biobank. You may also ask that the samples are anonymized, in which case the relationship between your personal data (which reveal your identity) and your biological samples and associated clinical data will be eliminated. The effects of this cancellation or anonymization cannot be extended to the research that has already been carried out.

If you wish to withdraw your consent, you must send a written request to the Director of the Biobank at the address given above.

Information about the results of the investigation: information will be provided if you wish to receive it.

At your specific request, the Biobank can provide you with information about what research your samples have been used for and about the overall results of these investigations, except in the events of cancellation or anonymization.

The methods used in biomedical research are often different from those approved for clinical practice and therefore should not be considered to have clinical value for you. However, should these investigations provide data that could be clinically or genetically relevant to you and of interest to your health or that of your family, you will be notified if this is considered appropriate. It may also happen that the obtained information is relevant for your family, in which case it will be up to you to decide whether or not to inform them of it. If you want such relevant information to be transmitted to you, you should tick the corresponding box at the end of this document.

If you do not wish to receive this information, please note that the law provides that, when the information obtained is necessary to prevent serious harm to the health of your biological family members, a committee of experts will study the case and shall decide whether to inform the affected persons or their legal representatives.

Please ask the medical staff that has given you this information about any doubts you may have, now or in the future, regarding this consent. You can also discuss your concerns with your doctor, who will put you in contact with the authorized medical personnel.

Thank you for your selfless cooperation for the progress of science and medicine. This way you are collaborating to overcome diseases and are helping many current and future patients.
**INFORMED CONSENT**

**USE OF CLINICAL DATA AND SURPLUS BIOLOGICAL MATERIAL FROM THE HEALTHCARE PROCESS FOR BIOMEDICAL RESEARCH AND THEIR STORAGE IN A BIOBANK**

Full name of the donor............................................................... National Identity Card.......................... Age..........................

Person of the center providing information................................................................. National Identity Card.........................

If you have understood the information you have been given, have resolved any doubts you may have had, and decide to collaborate with the Biobank [Name of biobank] in the terms explained above, please read and sign the form below

The undersigned hereby authorizes the Hospital [Name Hospital] to incorporate into the Biobank [Name Biobank] excess biological material from the tests he or she has undergone or will undergo as part of the current healthcare process, and that this material will be ceded by the biobank for the purpose of conducting biomedical research projects, provided these have the required approval of the competent Research Ethics Committee. This authorization is granted after having been verbally informed and after having read the accompanying information.

I hereby confirm that:

1. I consent that the surplus of biological material used for diagnostic tests and associated clinical information will be used for research on the terms contained in the Donor Information Document:  
   - YES   
   - NO

2. I wish to be given the information derived from the research that is really relevant and applicable to my or my family's health 
   - YES   
   - NO   
   Telephone number or email address.........................................................

3. I consent to be contacted in case further information or additional biological samples are needed 
   - YES   
   - NO   
   Telephone number or email address.........................................................

4. I have expressed my wish that the following exceptions to the research aims and methods are met:

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<th>DONOR</th>
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In ................., at the ...... of.................. of.............
WITNESSED INFORMED CONSENT

USE OF CLINICAL DATA AND SURPLUS BIOLOGICAL MATERIAL FROM THE HEALTHCARE PROCESS FOR BIOMEDICAL RESEARCH AND THEIR STORAGE IN A BIOBANK.

Full name of the donor................................................................. National Identity Card......................... Age.......................  
Full name of the undersigned witness................................................................. National Identity Card.........................................  
Relationship to the donor:.............................................  
Person of the center providing information................................................................. National Identity Card.........................................

If the donor has understood the information he/she has been given, has resolved any doubts he/she may have had, and decides to collaborate with the Biobank [Name of Biobank] in the terms explained above, please read and sign the form below

The undersigned hereby confirms that the donor:

1. Authorizes the Hospital [Name Hospital] to incorporate into the Biobank [Name Biobank] excess biological material from the tests he or she has undergone or will undergo as part of the current healthcare process, and that this material will be ceded by the biobank for the purpose of conducting biomedical research projects, provided these have the required approval of the competent Research Ethics Committee. This authorization is granted after having been verbally informed and after having read the accompanying information.

2. Wishes to be given the information derived from the research that is really relevant and applicable to the donor’s or the donor’s family’s health ☐ YES ☐ NO Telephone number or email address: .................................................

3. Consents to be contacted in case further information or additional biological samples are needed

 ☐ YES ☐ NO Telephone number or email address: .................................................

4. Has expressed the wish that the following exceptions to the research aims and methods are met:
                                                                 ........................................................................................................................
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5. Authorized me to sign on his/her behalf.

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In .................................., at the ...... of ............. of ............

Biobank [Name of Hospital or Biobank]
INFORMED CONSENT FOR MINORS

USE OF CLINICAL DATA AND SURPLUS BIOLOGICAL MATERIAL FROM THE HEALTHCARE PROCESS FOR BIOMEDICAL RESEARCH AND THEIR STORAGE IN A BIOBANK.

Full name of the donor............................................................................................................. National Identity Card.......................... Age......................................

Full name of the undersigned legal guardian............................................................................... National Identity Card..........................

Relationship to the donor:.................................

Person of the center providing information................................................................................. National Identity Card..........................

If you have understood the information you have been given, have resolved any doubts you may have had, and decide to collaborate with the Biobank [Name of Hospital] in the terms explained above, please read and sign the form below

The undersigned hereby authorizes the Hospital [Name Hospital] to incorporate into the Biobank [Name Biobank] excess biological material from the tests the ward has undergone or will undergo as part of the current healthcare process, and that this material will be ceded by the biobank for the purpose of conducting biomedical research projects, provided these have the required approval of the competent Research Ethics Committee. This authorization is granted after having been verbally informed and after having read the accompanying information.

The undersigned hereby confirms that:

1. I have been informed that when my ward comes of age, he/she shall be entitled to revoke or amend this consent, of which he/she shall be duly informed. In the event that he/she does not exercise this right, it shall be deemed that the present informed consent document continues to be in effect.

2. I authorize that the surplus of biological material used for diagnostic tests and associated clinical information will be used for research on the terms contained in the Donor Information Sheet: ☐ YES ☐ NO

3. I wish to be given the information derived from the research that is really relevant and applicable to the donor’s or the donor’s family’s health ☐ YES ☐ NO Telephone number or email address..................................................

4. I consent to be contacted in case further information or additional biological samples are needed ☐ YES ☐ NO Telephone number or email address:..............................................

5. I have expressed the wish that the following exceptions to the research aims and methods are met:

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In .............................., at the ..... of ..........................
WITHDRAWAL OF CONSENT

USE OF CLINICAL DATA AND SURPLUS BIOLOGICAL MATERIAL FROM THE HEALTHCARE PROCESS FOR BIOMEDICAL RESEARCH AND THEIR STORAGE IN A BIOBANK.

BY THE DONOR:

I, Mr./Mrs. ................................................................. with National Identity Card .................................. withdraw the consent granted on the ........ of ........ of 20........ and I do not wish to continue the voluntary donation to the biobank [Name Biobank] as of today.

☐ I REQUEST REMOVAL OF THE SAMPLE ONLY.

☐ I REQUEST REMOVAL OF MY PERSONAL DATA ONLY.

The sample will be irreversibly anonymized and may be used in research projects.

☐ I REQUEST COMPLETE ELIMINATION OF MY DATA AND SAMPLES.

Signed:

In ....................., at the ...... of ........... of 20........

BY THE GUARDIAN/LEGAL REPRESENTATIVE OF THE DONOR:

I, Mr./Mrs. ................................................................. with National Identity Card .................................., as legal representative of Mr./Mrs....................................................... with National Identity Card............................., withdraw the consent granted on the ........ of ........ of 20........ and I do not wish to continue the voluntary donation to the biobank [Name Biobank] as of today.

☐ I REQUEST REMOVAL OF THE SAMPLE ONLY.

☐ I REQUEST REMOVAL OF THE PERSONAL DATA ONLY.

The sample will be irreversibly anonymized and may be used in research projects.

☐ I REQUEST COMPLETE ELIMINATION OF THE DATA AND SAMPLES.

Signed:

In ....................., at the ...... of ........... of 20........