

INFORMED CONSENT DOCUMENT

CLINICAL USE OF BIOLOGICAL MATERIAL AND PROCESS FOR SURPLUS OF CARE BIOMEDICAL RESEARCH AND CONSERVATION IN A BIOBANK.

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

Samples and clinical data for the diagnosis or disease control, once used with this purpose, are also useful and necessary for research. In fact, many of the scientific breakthroughs in recent years in medicine are the result of such studies.

We request permission to collect the excess of biological material taken by your hospital as part of your current care process, so that they can be used in biomedical research.

Following the provisions of Law 14/2007, of Biomedical Research, Law 15/1999 of Data Protection, and its implementing rules (Spanish legislation), ISBER “2012 Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research” , “OECD Best Practice Guidelines for Biological Resource Centers”(Global Standards) , we ask that you read this document and sign down the informed consent attached at the end of this document, if you agree to donate your samples.

What is a biobank?: Institution to support research and health.

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

The samples included in a biobank may be provided for research in medicine, under the supervision of a scientific committee and an ethics committee. Samples are handled without personal information associated, although sometimes access to clinical history or the results of other tests to complete the investigation may be necessary.

Biomedical research is today a global phenomenon so these samples may be provided to research groups outside of the country, provided the requirements of European law are met and the relevant committees approved the use of samples.

Biological samples and associated information.

The excess biological material to be removed during the treatment process (blood, body fluids and / or tissues) will be saved without additional discomfort. Samples and information associated with them will be guarded and / or saved in Heracles-Biobank.

This biobank hosts organized collections of biological samples and associated information on the conditions of quality and safety required by the above-mentioned legislation. The samples and associated information are available to researchers who request them to the biobank.

Any requested research study on the use of these data or samples must always have the approval of the Ethics Committee and the Scientific Committee associated to the Biobank, which will ensure that researchers studies always follow the highest ethical and legal standards. In addition, the scientific committee of the biobank ensure that projects are of scientific excellence.

By consenting, the responsible of the Biobank or of the Hospital may consult your medical history, if this is essential for the project for which the samples are going to be used.

Should be required some additional informations, the health institution could request your cooperation again. In this case you will be informed and you asked for consent.

Data protection and privacy: *the samples are encoded.*

Personal data will be obtained, processed and stored in compliance with the duty of secret, according to the legislation on protection of personal data.

The identification of biological samples of the Biobank will undergo a process of coding. Each sample will be assigned an identification code, which will be used by researchers. Only personnel authorized by the biobank may relate the patient identity with such codes. Through this process the researchers applying for biobank samples shall not disclose any information that would reveal your identity. Additionally, if the results of research done with your samples are published in scientific journals, your identity will not be provided.

You can exercise your rights of access, rectification, cancellation and objection, as well as information on the use samples and their associated data from:

Director of Heracles-Biobank: Mar Siles-Lucas

Postal Address: IRNASA, CSIC. Cordel de Merinas, 40-52. 37008-Salamanca. Spain

Phone: Tel.: +34923219606 *Email:* mmar.siles@irnasa.csic.es

Altruistic nature of the donation. *The transfer of biological samples to the Heracles-Biobank of [Name Hospital] is free.*

The donation of samples has an altruistic nature, so you will not get now or in the future any economic benefit or have any rights on commercial benefits of the discoveries can be achieved as a result of biomedical research. However, the knowledge gained from the conducted research can help the medical breakthrough studies and, therefore, you and other people.

Voluntary participation. Refusal has NO impact on your health, present or future assistance

Your participation is fully voluntary. If you sign the informed consent, you may refuse to participate or withdraw consent at any time after the signing without having to explain the reasons, without adversely affect your health, present or future assistance.

Revocation of Consent: *If you choose to sign this consent, you may also cancel it freely.*

If in the future you would like to withdraw your consent, biological samples would be destroyed and the data associated with them would be withdrawn from the biobank. You also may ask the anonymisation of samples, in which case the relationship between your personal data and biological samples and associated clinical data is eliminated. The effects of such cancellation or anonymisation may not include research that has already been done.

If you wish to withdraw your consent, you must ask the Director of Biobank, at the above-mentioned address.

Information on the results of research: *information will be provided if you wish to receive it*

In the event that you specifically requested so, the Biobank can provide information about the overall results of the investigations, except in the event of cancellation or anonymization.

The methods used in biomedical research are often different from those approved for clinical practice, so you do not have to consider these research data of clinical value for you. However, in the event that these investigations provide data that could be clinically relevant to you and for your health, this will be communicated if deemed appropriate. If you want to receive this information, please tick the appropriate box at the end of this document.

If you do not wish to receive this information, please note that the law provides that if the information obtained is necessary to prevent serious harm to your health, a committee of experts will study the case and must decide whether to inform those affected or their legal guardians.

HERACLES Project— Human cystic Echinococcosis ReseArch in Central and Eastern Societies

Human cystic echinococcosis (CE), one of the most widespread helminthic zoonoses, is a chronic disease caused by infection with the larval stage of the tapeworm *Echinococcus granulosus*. This disease is highly endemic in some southern (Spain and Italy), eastern (Bulgaria and Romania) European countries and associated (Turkey) countries, where it still represents a major health and economic problem. In endemic areas the annual incidence of CE ranges from 1 to 200 per 100,000 inhabitants and 2-3 million cases are globally estimated. Case series and small clinical trials show a mortality rate of 2-4% for CE, but this increases markedly with substandard treatment and care. The diagnosis of human CE is mainly based on imaging techniques and serological confirmation. Clinical decision making is difficult and the natural history of the cyst is still poorly known. CE is chronic, complex and still neglected. For these reasons the main objectives of HERACLES are:

- Identify by ultrasound screening the population affected by CE in endemic rural areas of CEE countries.
- Create CEE national registries for surveillance of CE and establish a representative bio-bank of genetic Egg isolates and blood/serum/plasma samples.
- Validate new molecular-based POC-LOC kits for immunological surveillance, diagnosis and follow-up.
- Identify factor/s associated with CE response to therapy or lack thereof through investigation of host-parasite interplay (parasite virulence vs human immunity).
- Increase drug bioavailability in an in vivo model, decreasing the length of antiparasitic (ABZ based) treatment of CE and synthesize a new enantiomeric drug based on ABZ.

The project stakeholders, especially the rural populations in which CE is endemic, as well as SMEs, will be engaged as an integral part of the project. Special events to increase general awareness of CE and training activities for local health care providers will be organized.

INFORMED CONSENT

CLINICAL USE OF BIOLOGICAL MATERIAL AND ASSOCIATED CLINICAL DATA IN A BIOBANK

Name of donorID Age

Individual reporting center. ID

If you understand the information that has been provided and decide to collaborate with the *Heracles-Biobank* AS explained in the above terms, please read and sign this form. Then, the undersigned authorizes the Hospital **[Hospital Name]** to donate the excess of biological material from the tests that have been done or are going to be performed as part of your current care process to the *Heracles-Biobank*, for the purpose of conducting biomedical research projects, provided they have the required approval of the competent Ethics and Scientific Committees. This authorization is granted after being informed verbally and have read the attached information.

I confirm that:

1. I authorize the donation and use of the excess of biological material and associated clinical information for research on the terms contained in the Donor Information Paper:
 YES NO

2. I wish to have communicated the information derived from research that is relevant and applicable to my health
 YES NO Phone or E-mail address

3. I agree to be contacted should you require further information or additional biological samples
 YES NO Phone or E-mail address:

DONOR	REPORTING PERSON
Signature	Signature

Signature Inthis..... of of(three copies: for giving; for hospital / facility; for biobank)

Please ask the medical staff any questions you may have, now or in the future, about this consent. You can also discuss your concerns with your doctor, who will put you in touch with authorized medical staff.

Thank you for your generous collaboration with the advancement of science and medicine