

PATIENT FACT SHEET FOR MINORS

INFORMATION ON KIDNEY STONE DONATION, STORAGE AND USE AT THE UNIVERSITY OF THE BALEARIC ISLANDS KIDNEY STONE BIOBANK

In addition to undertaking morpho-compositional analysis on kidney stone, the activities of the Renal Lithiasis Research Laboratory include biomedical research in the field of renal lithiasis. This research aims to advance knowledge about this disease and, therefore, about diagnosis, treatment and prevention. In order to do this, clinical data and biological samples from kidney patients are required. The samples and clinical data obtained through morpho-compositional analysis are useful and necessary for research. In this sense, biological sample donation is essential to make progress in biomedical research.

PURPOSE OF THE DONATION

The procedure you are invited to join comprises the voluntary donation of kidney stones to the University of the Balearic Islands Kidney Stone Biobank (BICUIB). Therefore, we kindly **request your permission to include the kidney stones or excess fragments from the morpho-compositional analysis to the BICUIB, which as part of the diagnosis and/or care process will be undertaken by the Renal Lithiasis Research Laboratory, for the purpose of biomedical research use.**

We kindly request that you carefully read the attached information and informed consent document for you to sign, if you agree to take part in this procedure.

Moreover, the information related to the donation is explained to minors in understandable language in the presence of their parents or guardians, who sign the IC form (see INFORMATION PROVIDED TO MINORS section).

BICUIB is a non-profit kidney stone storage centre providing researchers with access to samples for study through a transfer agreement. Its operation is governed by what is set out in Royal Decree 1716/2011 of 18th November. The samples that you donate may only be used for scientifically guaranteed research projects that have been approved by external committees, such as the Clinical Research Ethics Committee and the Research Commission.

All personal data generated or collected as part of the sample donation process at the Biobank shall be protected, in line with current legislation, Regulation (EU) 2016/679 on General Data Protection and Spanish regulations on personal data protection (Organic Law 3/2018 of 5th December on Personal Data Protection and Digital Rights Guarantee). Associated data from your clinical history or other tests to round out the research shall always be encoded for transfer, maintaining your identity confidential

DESCRIPTION AND INFORMATION ABOUT THE DONATION:

As a general rule, the kidney stones will be stored alongside a minimum set of personal data (age, gender and clinical data, health data, physiological status, pharmacological treatment).

Samples and associated data shall be held indefinitely at BICUIB until the stored sample is fully used, in accordance with the quality and safety conditions and guarantees required by the aforementioned legislation. Storage shall be open-ended given the physical and chemical features of the sample, to ensure samples do not deteriorate.

Your consent will be requested for your sample to undergo the following procedures:

- 1.- **Storage** of the sample for an open-ended period at BICUIB, as long as this consent is not withdrawn
- 2.- **Analysis and scientific studies** using the samples and associated data via transfer from the Biobank to Researchers, which may lead to fruitful knowledge for public health.

By signing the attached consent form, you authorise BICUIB to store and use your relevant clinical data and sample to carry out research projects that comply with applicable ethical and legal principles. Where due to the nature of the research project additional clinical data on the source subject are required, the Biobank or collection supervisor shall coordinate with the centre where the sample was taken to obtain this information, as long as the information has not been anonymised.

EXPECTED BENEFITS:

By legal requirement, the donation is made pro bono, meaning you waive any financial, equity or facultative right over the potential benefits that may directly or indirectly arise from the research undertaken with the sample you transfer for research purposes. Nonetheless, and notwithstanding what is set out in Article 7 of Act 14/2007 of 3rd July, financial compensation may be set for physical complaints, expenses and other inconveniences that may arise from taking the sample.

BICUIB undertakes to not trade samples or associated personal data. Nevertheless, the information generated from research undertaken on samples transferred from the Biobank to researchers may be the source of commercial benefits.

PERSONAL DATA PROTECTION AND CONFIDENTIALITY:

Personal and health data associated with your samples shall be included and processed in a database, in accordance with the guarantees set out in health and personal data protection regulations, for which the UIB as owner of the Biobank is responsible. Both personal data (age, gender, race) and health data, such as the sample for research, shall be collected by using an encoding procedure. Each biological sample held by BICUIB is identified by an individual code. Solely personnel authorised by the Biobank may link the code assigned to your sample to your identity (personal data provided in the consent form), which is responsible for safeguarding the consent document and ensuring compliance with your wishes regarding the use of the kidney stones you transfer for research. Samples are transferred to researchers and identified solely by a code. In this sense, researchers who request samples from BICUIB shall not be made aware of your identity and, therefore, may not disclose it, ensuring confidentiality of the information obtained, in compliance with current legislation.

CONSENT WITHDRAWAL RIGHT:

You may withdraw your consent at any time without having to specify a reason. You may exercise your rights to access, rectify, erase, restrict and object with regard to processing your information, by writing to the organisation that provided this document to you and requesting the withdrawal form available to you. You may also make this request to the Head of the Biobank, by using the contact details provided at the bottom of this page. Samples that have not been used at the time of withdrawal shall be anonymised or destroyed, depending on your choice; anonymisation leads to the irrevocable destruction of the link between the sample and associated data and you as a donor, impeding you to be identified but enabling your sample to continue to be used for research; destruction represents the elimination of your samples at the Biobank, as well as your clinical and personal data associated with them. Nonetheless, the effects of withdrawal shall not extend to the data arising from research that has already been carried out on samples. The owner of the Biobank is legally liable for compliance with the LOPD personal data protection act, and the file officer shall deal with requests to exercise the rights of access, rectification, erasure and objection. More information on data protection may be viewed at the following website: <https://www.uib.es/es/Contacte-DPO/>.

It is hereby ensured that in the event that the Biobank closes or its licence is withdrawn, the information on sample destinations shall be available to you at the National Registry of Biobanks for Biomedical Research, so that you may find out where they are held and used.

In the case of storage of samples from minors, access to information about the sample is guaranteed for subjects when they reach the age of 18. It is hereby stated that the Biobank is not legally obliged to contact minors when they reach the age of 18 to inform them about the existence of their samples and rights. It is the responsibility of their parents or guardians to inform minors about this when they reach the age of 18.

INFORMATION PROVIDED TO MINORS

The procedure that you are invited to join comprises a voluntary donation of the kidney stones that you have generated at the University of the Balearic Islands Kidney Stone Biobank (BICUIB). These samples will be used by researchers at the university and other scientifically accredited research centres in Spain and other countries, so that they may make advances in knowledge about this illness and, subsequently, propose more effective diagnosis, treatment and prevention procedures than current ones.

Personal and health data associated with your sample shall be included and processed in a database, in accordance with the guarantees set out in health and personal data and confidentiality protection regulations, for which the UIB as owner of the Biobank is responsible. The samples and information associated with them shall be held at the Biobank for an open-ended period until the stored sample is fully used, whilst ensuring access to the information about your sample for when you reach the age of 18.