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Informed Consent Form for the authorisation for the use of human tissues. Allograft recipient

Hospital:
Accreditation date (transplants):

I, Mr/Ms …… of adult age, with registered address in …….. National Identity Document number ……. and born on…… …… ……. in full use of my mental faculties, in my capacity of patient, state:

I, Mr/Ms …… of adult age, with registered address in …….. National Identity Document number…… and born on…… …… ……. in full use of my mental faculties.

In the capacity of…….. (FATHER, MOTHER OR LEGAL REPRESENTATIVE)

of……. (PATIENT'S NAME AND TWO SURNAMES)

DECLARE that

I have been satisfactorily informed of the consequences of my decision to accept the implant of tissues coming from a human donor (allograft) and **I freely and consciously provide my consent**, authorising the medical Traumatology team of …… with authorisation to perform osteotendinous transplants.

Furthermore, **I authorise the necessary serological analyses and tests** (hepatitis B C, syphilis and AIDS virus) to be conducted for the safety and follow up of the donation.

The bone tissue which will be implanted comes from the donation of another human being (alive or deceased), this graft is known as an **allograft**. The donor has been meticulously selected and their donation has been conducted with strict sterilisation and safety measures, the allograft has been stored in a **Bone and Tissue Bank**, which is the Technical Unit in charge of obtaining, processing, preserving and storing human tissues in order to distribute them for their clinical application as grafts and which has as its mission to guarantee the quality of the tissues from when the tissues are obtained until they are used clinically as a graft. These institutions are non-profit in order to respect the ethics concerning the human origin of the tissues which they process and which are later implanted in the patients who need them, receiving clinical benefits from this donation. Prior to the use of the allograft, the bacteriological and serological tests conducted on the donor and the donated tissue will be analysed in detail to decrease the risk of transmitting diseases to the recipient to the greatest extent possible. The activities carried out in these banks are subject to strict quality controls to prevent the probability of transmitting diseases to the greatest extent possible.

The use of bone and/or ligament grafts for transplant during an osteoarticular procedure may be necessary based on replacing the lack of bone or ligament tissue and due to the impossibility of obtaining it from the patient with a sufficient guarantee of functional efficacy.

Due to the patient's right/left …… affected by a diagnostic process of …… and having exhausted other surgical and non-surgical treatments, it is recommended to undergo surgery which consists of …… and which requires an allograft.

The alternatives to this treatment are …… (non-surgical or surgical without the allograft implant) ……. in the second case (surgical) it will be necessary …… (to extract it from the patient, to place a massive metallic prosthetic or to not reconstruct the bone defect)……..

The **general risks** inherent to any surgical procedure together with the specific risks of this procedure can be considered **mild and moderate**, which may occur in up to 10% of procedures (haematomas, superficial infections, thrombophlebitis, wound dehiscence, non-incorporation of the graft), or serious risks, which may occur in up to 15% of procedures (deep infections, vascular and nervous lesions, fat or pulmonary embolism, fractures). Among the possible risks are also the instrument or surgical equipment error.

The principal **specific complications** of an allograft implant are infection, fracture and non-incorporation of the graft in the donor bone, estimated at approximately 10-15% of procedure, and it may be necessary to re-intervene to remove the graft, exchange the osteosynthesis or provide a graft taken from the patient.

The **specific risk of being a recipient** of a human disease is the minimal theoretical possibility of contracting a transmittable disease (hepatitis, AIDS, among others). To avoid this risk, we hereby guarantee all the pertinent studies necessary to rule out the presence of known transmittable diseases have been carried out on the tissue to be implanted.

The general and specific risks inherent to the scheduled surgical procedure are detailed in the specific informed consent form for the surgery. _____

I declare that I have been amply and satisfactorily informed orally, I have read this document, **I have understood and I am in agreement** with the explanations of the procedure that have been provided to me, that this information has been provided and that I give my consent in order to proceed to conduct the cited procedure (Article 10.6 of the General Healthcare Act).

Furthermore, I am informed of the possibility to withdraw my consent.

Date of the Surgery ... .

I AGREE

Signed (Patient, family member or legal representative ……

Physician who informs patient about the transplant
Name:
Medical Licence No.:
Signature

Physician who performs the transplant
Name:
Medical Licence No.
Signature

REFUSAL/WITHDRAWAL OF CONSENT

Signed (Patient, family member or legal representative .....
Date: .....

Note Two (2) copies must be signed. One (1) will be sent to the Bone and Tissue Bank and the other will be stored in the patient's clinical history.