Informed consent for genetic analysis of peripheral blood and/or tumorous tissue for clinical use

ONCOLOGY

1. Identification and description of procedure

The proposed procedure is
.....
.....and consists of conducting genetic analysis/analyses using excess tissue from the histopathological diagnostic process and/or a blood sample
to detect the presence, absence or variants of one or more genetic material segments. This may include indirect tests to detect gene products or specific metabolites indicative of certain genetic modifications.

2. Purpose

The purpose of all the analyses proposed, as well as any that could be done in the future, is mainly, to detect possible mutations, analyse the family-related risk and proceed to accurately characterise/diagnose

the cancer affecting you and optimise the clinical management of your illness.
In any event, you must be aware that you will be verbally informed of the results of the analyses.

The samples used for the genetic analysis, including the indirect tests to detect gene products or specific metabolites indicative of certain genetic modifications, shall be done at the various laboratories approved for such purpose by the institution that is treating you for your illness: pathological anatomy, clinical analysis, haematology, microbiology, genetics and molecular biology.

Once they are processed, the samples will be stored at the ..... centre during the period needed to conduct the entire analysis process described. After that, they will be destroyed unless they are considered appropriate for other uses, which shall require your consent once again.

If the genetic analyses must be done at another institution besides the one treating you, your personal identification details will be duly encoded.

3. Expected benefits

The results of the genetic analysis will be evaluated with your personal and family medical background, the results of the physical examination, complementary testing and clinical interpretation of by the head physician in mind. At all times, you will be duly informed of the repercussions that the genetic analyses could have on the clinical management of your illness.

If you are shown to be a carrier of a gene variation that could be hereditary, and therefore could be transmitted to your offspring, you will be offered the option of receiving genetic counselling.

4. Predictable consequences of the PROCEDURE

The studies conducted with your samples may provide relevant information for your health or that of your family. You have the right to be informed or to decline to be informed of your genetic data and other personal details attained in the study. To such end, it shall be assumed that you wish to receive this information unless you state otherwise, by using the form available to you at the centre where you are being treated.

These data may affect certain members of your family, and therefore you must assess whether it is advisable to transmit this information to them.

5. Predictable consequences if not performed and right to withdraw consent

The decision to refrain from performing the genetic study is completely voluntary, and you are entitled to refuse to do so. You may even withdraw your consent at any time without providing any explanation, and this shall have no effect whatsoever on the medical assistance you receive at the Centre.

This shall have no repercussions on the medical assistance you receive or that you or your family members may in the future receive at this centre. To withdraw your consent, you must contact the same physician who signed this consent form.

6. Personal data protection and confidentiality

The data resulting from the analyses will be stored in the archives of the genetic counselling unit. The centre's health professionals shall have access to the data included in your medical record to the extent that it is relevant for the treatment they provide you. Staff members who have access to genetic data in the course of their duties shall be bound to permanent secrecy.

You must be aware that the information on your personal and health details will be incorporated into a computerised database and processed in compliance with the guarantees established in the Personal Data Protection Law and applicable health legislation.

Genetic data of a personal nature shall be kept for a minimum period of 5 years, after which time you may request that they be cancelled. To request the cancellation, you must do so in writing by contacting the medical management department of the centre that treated you for your illness. If you do not request such cancellation, the data will be kept indefinitely.

7.-. Declarations and signatures

The patient's declaration:

I, Mr/Ms..... of ..... years of age, of (address) ..... ID no. ..... and SIP No.....

I, Mr/Ms....., of.....years of age, with home address at ....ID No.....acting as the representative (in the event of underage or disabled patients) of the patient....., with ID No..... and SIP No.....

HEREBY DECLARE:

That Dr....., the primary contact for the procedure with the assistance team (according to article 10.7 of the Spanish General Health Law), has explained to me that cancer is a genetic disorder, and that therefore genetic alterations occur which are the cause of the development of tumours. Such tumours respond to certain drugs.

He/she has also informed me that we may be carriers of genetic variants that may predispose us to develop cancer or that condition the response to the treatment that I am to receive.

I hereby declare that I am satisfied with the information received, that I have been verbally informed of the genetic analysis procedures that I am to undergo, that I have been able to ask the questions I considered appropriate and have received adequate responses to these questions, and that I understand the scope of the procedure, and thus, in such conditions, I FREELY AND VOLUNTARILY GRANT MY

CONSENT TO THE GENETIC ANALYSIS OF PERIPHERAL BLOOD AND/OR TUMOROUS TISSUE FOR CLINICAL USE.

In..... on .... , 20.....

Signed:

Mr/Ms.....

Declaration by the health professional:

I have duly informed

Signed: Dr.....ID No.....Professional Association No.....

In..... on ...., 20.....

8. Withdrawal of consent

I, Mr/Ms....., as the interested party, of ..... years of age, of (address) ..... and ID no. ..... withdraw my consent given on ..... , which I terminate on this date, with no need to provide explanations and without this affecting in any way the medical assistance I receive or that my family may receive at the centre.

Signed:

In..... on .... , 20.....

I, Mr/Ms.....with ID No. ....., as legal representative of Mr/Ms ....., with ID No....., withdraw the consent given on .... 20..... and I do not wish to continue the voluntary donation, which I terminate on this date.

Signed:

In..... on .... , 20.....

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FORM

Patient statement:

I, Mr./Mrs.....years old, residing in

.....

ID number ..... and SIP number .....

HEREBY DECLARE THAT

Dr. ....., has explained to me that my illness is a genetic disease, understanding as such, that genetic alterations occur that are responsible for the disease developing and/or responding to certain drugs. I have also been informed that we may be carriers of genetic variants that could predispose to the development of the disease or condition the response to the treatment(s) that I will be undergoing.

I declare that I am satisfied with the information received, that I have been verbally informed of the genetic analysis procedures that I will be undergoing, that I have been able to ask the questions that I deemed necessary, which were suitably answered, and that I understand the scope of the procedure. Nevertheless,

I DO NOT WANT TO BE INFORMED OF THE GENETIC RESULTS ALTHOUGH I AM ENTITLED TO RECEIVE SUCH INFORMATION.

In .....on the.....of.....20.....

Signed.:

Mr./Mrs. .....

ONCOLOGY