MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
DE USO HUMANO

Annex VIIIB

Paragraphs to be included in the Informed Consent Form for the collection and use of biological samples in clinical trials

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Clarifying note: The paragraphs proposed in this document refer to the information that the patient must receive regarding the collection and use of biological samples and possible future use of excess samples, and should preferably be included in the general information sheet for the clinical trial (see Annex VIIIA to the document "Instructions for conducting clinical trials in Spain"). Therefore, this guide document does not include the patient's signature or the date. In the event of biological samples being obtained specifically for sub-studies or future studies, it is recommended that specific PIS/ICFs are created for this.

COLLECTION AND USE OF BIOLOGICAL SAMPLES

Objectives

Your participation in this clinical trial involves the collection and use of biological samples for research purposes, during which Law 14/2007 on biomedical research and Royal Decree 1716/2011, regulations that ensure that your rights are respected, will be observed. By signing this document, which has been reviewed and given a favourable opinion by the Ethics Committee that approved this clinical trial, you agree to the use of your samples for the purposes of this study. *Describe which samples will be collected and used, for what purposes (if genetic analyses or complete genomic sequencing are going to be performed), unless it has already been specified in the "Study objectives" section: safety analysis, study on how the drug is distributed through your body [pharmacokinetics], how the drug works in your body [pharmacodynamics], etc.*

Sampling procedures, discomfort, and possible risks

Some samples are obtained during the routine follow-up of your disease or process; others are requested because they are necessary for fulfilling the objectives of this study. Below we explain what they are and the risks associated with the procedures used for obtaining the samples *(in the case of samples that are not leftover from diagnostic procedures or clinical follow-up of the donor)*:

(Add the different samples that are obtained and the risks; the most common examples are shown below).

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Blood samples: XX blood samples will be collected and the quantity of blood taken in each analysis will be XX ml of blood. For most people, needle punctures for blood drawing are not a problem. However, on occasions they may cause bleeding, bruising, discomfort, infections and/or pain at the blood draw site. You may also feel dizzy.

Urine samples: XX urine samples will be collected. You will be asked to urinate into a small jar. This test will not cause you any discomfort.

Tumour samples: you will be asked to donate part of a tumour sample from a biopsy or surgical intervention that you underwent during the care process.

If specific biopsy/biopsies are required during the trial, this fact, and the risks associated with the biopsy, must be detailed in this document. If the biopsies are optional, the patient must be given the option of authorising their performance at the end of the document. If they are required by the protocol, this information should be given in the following paragraph.

If you agree, you will undergo a new tumour biopsy in... (in case of progression, at visit …). This biopsy is/these biopsies are specific to participation in this clinical trial.

A biopsy is a fragment of tumour tissue extracted for examination under a microscope or for tests to look for specific molecules. The most common risks of a biopsy are: pain during the procedure, bleeding and infection. For example, biopsy of a specific location: with lung biopsies, there is also a risk of pneumothorax (collapsed lung); often a chest x-ray is taken immediately after biopsy to see if this has occurred, and, if necessary, a chest tube is inserted to re-expand the lung. If you have trouble breathing or your heart rate increases after you are discharged from hospital, it is important to call your study doctor or the emergency department immediately. There may be other risks, depending on the location of the tumour being biopsied, such as the puncture of a nearby organ. Your study doctor will discuss these aspects with you.

The possible risks derived from the procedure performed for the collection of these samples will be covered by the insurance of the clinical trial.

Samples will be assigned a code that may only be linked to your identity by authorised personnel (explaining the profile of these personnel) as previously explained for the data obtained during the trial. The data obtained from the use of these samples will be processed in the same way as the other data that are collected during this trial (see section on personal data protection).

The samples and associated data will be kept under appropriate security conditions, and it will be guaranteed that it will not be possible to identify the subjects using media considered reasonable by people other than those authorised.

Additional samples or information may be required. In that case, your doctor will contact you to request your collaboration again. You will be informed of the reasons and asked again for your consent (see option yes/no at the end of the document).

Expected benefits

No direct benefit is expected from your participation in the study. However, the knowledge gained from studies carried out based on your samples and many others may contribute to medical progress and, therefore, other people. You will not receive any financial benefit from donating samples or for the transfer of the data provided, nor will you have any rights to potential commercial benefits from the discoveries that may be achieved as a result of the research.

Place of analysis and storage of samples

Your samples may be analysed in various laboratories during the conduct of the trial and will be stored for X years, in case it becomes necessary to repeat an analysis related to the trial objectives. During this process, the person responsible for the samples will be the sponsor of the trial.

In the event of storage for the future use of the samples, the samples will be stored in ..... for .....

Future use of the samples

Once the trial has finished, any remaining samples will be destroyed, unless you agree to them being stored and used in future research (see yes/no option at the end of the document). These samples are stored so that they can be used in research projects in the future.

Three options for future use are proposed, depending on the clinical trial:

Option (A): biobank registered in Spain:

The samples will be stored in the XXX biobank *(include biobank details).* From there, they will be transferred for authorised projects, possibly also abroad, subject to a favourable opinion from the scientific committee and the ethics committee of the biobank. You may contact the biobank to obtain information on the projects in which your samples have been used.

Option (B): collection registered in Spain:

The samples will be stored in the XXX collection (*include details of the collection).* They will not be transferred to third parties, and will be used in projects given a favourable opinion by a Research Ethics Committee and related to *... describe line of research, disease or process...* In the event that the use or transfer of your samples to different research is proposed, your consent will be requested. You may contact (person responsible for the collection or principal investigator) to obtain information on the projects in which your samples have been used.

Option of storage in a repository abroad:

Samples will be stored in the XXX repository (*write format according to the Spanish legislation if applicable – collection or biobank – and location), explain if they will be transferred to third parties or not and, if so, under which conditions,* and if they will be used in projects related to the following research purposes: disease or process, determination of disease biomarkers, aspects related to response to, and safety of, the investigational medicinal product, aspects related to the disease's mechanisms of development... If the future studies to be performed with your samples are not related to these objectives, you will be asked for your consent again and the studies will be assessed by a research ethics committee (in the event that the aims of the research are not described and the material is stored for undefined future research, there is no need for re-consent but there does have to be an evaluation by a research ethics committee). You may contact (person responsible for the repository or principal investigator) to obtain information on the projects in which your samples have been used.

The data obtained from the use of these samples in future research will be processed in the same way as the other data that are collected during this trial (see section on personal data protection).

Right to withdraw consent

If you change your mind with regard to the donation of biological samples and the transfer of the data provided, you have the right to request their destruction or anonymization, via your doctor/researcher/principal investigator of the collection/biobank. However, you should know that the data obtained in the analyses performed up to that time may be used for the purposes requested and may be stored in compliance with the corresponding legal obligations.

Implications of the information obtained through the analysis of the samples

If you request it, you may be provided with information on the research studies in which your samples have been used, as well as the general results of this trial.

If data, that could be clinically or genetically important for you, and concern your health or your family's health, are collected during this study, you may request for these data to be communicated by your trial doctor if you request this by marking the box at the end of this document. However, if the patient had indicated that they do not want this and when this information, in the opinion of the responsible doctor, is necessary to avoid serious harm to the patient's health or that of their blood relatives, a close relative or a representative will be informed, following consultation with the site's healthcare ethics committee. This information will be communicated by professionals who will be able to adequately explain its significance and the options that may arise. In the event of clinically important genetic information, you can receive the mandatory genetic guidance.

If the donor is a minor, once they reach legal age they will have the right to receive this information and to withdraw their consent. If they do not exercise this right, the current document will be considered to be still valid.

Talk to your doctor about the possibility of establishing restrictions so that your biological sample is not used in specific research *(In this case, there should be an option in the general consent for the type:*

If you want to establish any restriction regarding the future use of your samples, please specify in this section which: (if the patient does not complete this section, it shall be understood that there are NO restrictions).

These options should be listed in the general study consent:

With regard to optional biopsies: I consent to the performance of the specific biopsy/biopsies explained in the information sheet (where applicable due the characteristics of the trial):

□ YES □ NO

I want the study doctor to provide me with the information obtained from the research (genetic or non-genetic, to clarify depending on the case) that may be significant and applicable for my health or my relatives' health:

□ YES □ NO Contact telephone number or e-mail…….

I consent to the storage and use of biological samples (leftover or not, can be specified in each individual case) and the associated data for future research under the conditions described in this information sheet.

□ YES □ NO

I consent to being contacted in the event that further information or additional biospecimens are required.

□ YES □ NO Contact telephone number or e-mail…….