CONSENT FOR ELIGIBLE PERSONS

OPERATIVE UNIT Thoracic Surgery

DATE AND ISSUE 1 No of 03.12.2022

FACT SHEET

Dear all,

In this University Hospital, there is a medical-scientific research program titled "LANTERN" **(CANCER MULTI-OMICS** AVATARS FOR INTEGRATED PRECISION MEDICINE). This research is multicentric, that is to say, several hospitals and treatment centres abroad are involved.

To carry out this research, we need the cooperation and availability of people who like you, meet the scientific requirements for the evaluation that will be carried out. However, before you make the decision to accept or refuse to participate, please read this document carefully, taking all the necessary time and ask us for clarification if you do not understand or need further clarification. In addition, if he/she so wishes, he/she may seek advice from his/her family members or from his/her trusted doctor before making his/her decision.

WHAT THE STUDY PROPOSES

The general objective of this study (which is purely observational, does not involve changes to its diagnostic and therapeutic path) is to accumulate clinical information on pathological anatomy, radiology and genomics of the pathology you are affected by, in order to develop through sophisticated technologies based on artificial intelligence, prediction models to be applied to future patients. In particular, we intend to obtain data on lung neoplasms/tumors that in recent times, represent a pathology of great clinical importance and of considerable socio-sanitary impact. Overall, the final aim of this project is to contribute to the development of a personalized medicine that allows to choose increasingly effective and individualized therapies based on these models of prediction.

WHAT YOUR PARTICIPATION IN THE STUDY ENTAILS

If you choose to participate in this study, the observational design of the research will imply the collection of various information about you, both clinical, i.e. demographic aspects, lifestyle habits, etc., and other details related to the disease you are affected by (radiological features, pathological and genomic features)

The study will overall last for 3 years and we plan to enroll 300 patients in this hospital with the same medical conditions.

If you agree to take part in the study, you will need to attend an initial visit to check that your condition meets the criteria for the study

You are not obliged to be available or to participate in any specific cooperation, except for signing this consent form, as the study is purely observational. There are no additional costs for you to participate in the study, these costs will be borne entirely by this research program

RISKS ARISING FROM PARTICIPATION IN THE STUDY

There are no reasonably foreseeable risks or discomforts to the subjects, as the study does not include drugs/treatments/devices or specific investigations.

The confidentiality of the records identifying the data subject is safeguarded. Data on subjects or biological samples collected as part of research, including data where identifiers have been removed, are not used or disclosed for future research.

If data becomes available that may influence your willingness to continue participating in the study, you will be informed/informed in good time.

WHAT ARE THE BENEFITS YOU WILL RECEIVE BY PARTICIPATING IN THE STUDY

As a participant in the study you will not benefit directly, but this research aims to benefit society and specifically patients with the same disease by providing new knowledge to prevention, early detection and treatment of the disease.

INVESTIGATIONS TO BE PERFORMED DURING THE STUDY

The study involves carrying out the normal laboratory and imaging investigations provided for the clinical management of their pathology. The study might include genome sequencing as well. Researchers will simply record all the information that will be produced in the course of their care and store it in a private and secure "virtual data platform" from which analyses will be performed and prediction models developed.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

You are free not to participate in the study. In this case, however, you will receive all the usual therapies for your condition without any penalty, and the doctors will continue to follow you with due diligence, even if no other therapy is available.

WHAT HAPPENS IN CASE OF DAMAGE

Please note that this study *is insured* with the (name of the Insurance Company) _____ _____. The European Commission is currently preparing a proposal for a Council Directive on the approximation of the laws of the Member States relating to the transport of sensitive materials.

The policy is only applicable to damages that have occurred no later than months after the end of the trial for which a claim for compensation will be made within months of the end of the study

In any case, the above statement does not affect your right to claim compensation directly from the person responsible for the damage. By signing this informed consent, you do not waive any of your legal rights.

Before taking part in the trial in question, if you have taken out an insurance policy, you will have to check with your insurer that your participation has no impact on it.

STUDY INTERRUPTION

Your participation in this research program is completely voluntary and you can withdraw from the study at any time.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you so request, at the end of the study you will be informed of the results of the study in general and in particular, those concerning you.

MORE INFORMATION

For further information and notification on the research, please contact:

Filippo Lococo (0630156064)

Charles-Davies Diepriye (0630154393)

In case of questions about research subjects' rights please contact:

Filippo Lococo (0630156064)

Charles-Davies Diepriye (0630154393

The protocol of the study that has been proposed to you has been drawn up in accordance with the Standards of Good Clinical Practice of the European Union and the current review of the Helsinki Declaration and has been approved by the Ethics Committee of this structure.

DECLARATION OF CONSENT[1]

I, the undersigned: _____

I have received from the Doctor[2] _____

The Committee on Environment, Public Health and Consumer Protection has been asked to give a full explanation of the request for participation in the observational study in question, as stated in the attached fact sheet, a copy of which I have previously been given.

I also declare that I have been able to discuss these explanations, that I have asked all the questions that I considered necessary and that I have received satisfactory answers, and that I have had the opportunity to inquire about the details of the study with a person I trust.

I therefore freely agree to participate in the study, having fully understood the meaning of the request and having understood the risks and benefits involved.

Moreover, I have been informed of my right to have free access to the documentation relating to the study (clinical-scientific]) and the evaluation by the Ethics Committee.

_____	_____
Date	Patient's signature
Date	Signature of the doctor who informed the patient

[In case the patient cannot read and/or sign][3]

I, the undersigned: _____

I testify that the Doctor _____

explained in detail to Mr. _____

the characteristics of the observational study in question, as reported in the fact sheet attached hereto, and that the same, having had the opportunity to ask all the questions it deemed necessary, voluntarily agreed to join the study.

_____	_____
Date	Signature of the independent witness

[1] This declaration of consent must be signed and dated personally by the patient and by the person who conducted the discussion on informed consent.

[2] Indicate the name of the doctor who informed the patient about the proposed trial.

[3] If the patient is unable to read or sign, an independent witness from the experimenter and sponsor shall be present during the entire discussion of informed consent. The witness must personally sign and date the informed declaration of consent after the form itself and any other written information has been read and explained to the subject and the subject has expressed verbal consent to participate in the study.