Fondazione Policlinico Universitario A. Gemelli
Università Cattolica del Sacro Cuore

CONSENT FORM

UOC Radiotherapy – Gemelli ART

03/09/2016

ULISSE: Umbrella protocoL ISSue for oncological patiEnts

Patient Information

Dear Sir/Madame,

A clinical trial with the title *ULISSE* is scheduled at this University Hospital*: Umbrella protocoL ISSue for oncological patiEnts.* The trial involves the participation of different centres and hospitals.

To carry out research, we need the cooperation and availability of people who, like you, meet the scientific inclusion criteria required for the evaluation to be performed. However, before you decide to participate, please carefully read this document, taking as long as necessary to fully understand it. Please, ask if you have any doubts or need any further clarifications. Moreover, before deciding to participate in the trail, you may seek the opinion of your family or GP.

PURPOSE OF THE TRAIL

The purpose of this trail is to promote data collection to allow for the creation and validation of predictive models. These models cover different aspects of oncological treatment allowing us personalized clinical care both from an efficacy and toxicity control aspect. Models could even be used to compare new approaches and technique in Radiation Oncology and Clinical Oncology (target therapies and /or chemotherapy scheme) with standard patient care. In particular, we would obtain data regarding your disease, the treatment provided and the outcomes.

POSSIBLY DISAVANTAGES

Participation in this trail involves no additional risks related to treatments already provided as it is an observational trail on clinical practice. You will be informed about any findings that may influence your decision to continue participating in the trail.

POSSIBLY BENEFIT

You will not benefit personally from taking part in the trail. However, future patients may benefit from the results.

WHAT PARTICIPATION INVOLVES

If you decide to participate in the trail, you will receive the appropriate treatment for your clinical condition and will undergo any planned clinical evaluations (telephone or outpatient).

The trail will last five years in total and follow-up will be for a minimum of one month and a maximum of 5 years. All patients who are suffering from the same illness as you will be offered participation in research at this hospital.

If you agree to participate in this trail you will undergo a preliminary clinical examination to check the presence of the inclusion criteria.

We require the following interaction: telephone or outpatient contact before, during and after treatment to monitor symptoms and your quality of life.

Participation in the trail will not involve any increase in expense for you. Any costs will be borne by this hospital.

EXAMINATIONS YOU RECEIVE DURING THE TRAIL

Being an observational study of clinical practice, the trail requires the implementation of standard examinations only.

WHAT HAPPENS IF YOU DO NOT PARTICIPATE?

You are free to not participate in the trail. If you choose not to participate, you will still receive all the standards therapies provided for your condition, without any penalty, and doctors will continue to take good care of you, even if there are no other available therapies.

INTERRUPTION OF THE TRAIL

Your agreement with this trail is completely voluntarily and you may end participation at any time.

INFORMATION ABOUT TRAIL RESULTS

If you ask, results in general and those that concern you in particular will be shared at the end of the trail.

FURTHER INFORMATION

For further information, please seek advice from your GP.

Doctor for referrals:

Prof. Vincenzo Valentini

Tel: (+39) 06 3015 6054

Fax: (+39) 06 3550 1928

Email: vvalentini@rm.unicatt.it

The trail proposed has been prepared in accordance with EU Good Clinical Practice standards and the current Declaration of Helsinki. The trail and was approved by the Hospital's Ethics Committee. You can highlight any relevant facts concerning the trail to the Hospital's Ethics Committee.

CONSENT FORM[1]

I, _____declare to have received from

Dr[2]_____ information to participate in this clinical trial, as reported in the enclosed information note, a copy of which I have received.

To have had information explained to me & have been given the opportunity to ask questions.

To have had the opportunity to inform a trusted person.

To voluntarily accept to participate in this clinical trial, having read and understood the possible benefits and disadvantages of participating.

To have been informed that I can examine documentation (scientific-clinical) and the evaluation expressed by the Ethical Committee.

_____ _____

Date Patient's Signature

_____ _____

Date Doctor's Signature

(If the patient cannot read and / or sign)[3]

I _____ attest that

Dr _____ explained to

Mrs/Mr_____about the procedures of this clinical trial, as reported in the information note enclosed, and that the same patient has been given the opportunity to ask questions and has voluntarily accepted to participate in the clinical trial.

_____ _____

Date Independent witness signature

_____

[1]This consent form must be signed and dated by the patient who intends to take part in the trail.

[2] The Doctor that informed the patient about the trail.

[3]If the patient cannot read or sign, an independent witness appointed by the researcher or the sponsor must be present during the whole discussion about informed consent. The witness has to sign and date the consent form after reading and explaining all written information to the patient and after the patient has expressed his/her oral consent to participate in the trial.