Fondazione Policlinico Universitario A. Gemelli
Università Cattolica del Sacro Cuore

UOC Radioterapia – Gemelli ART

ULISSE: Umbrella protocoL ISSue for oncological patiEnts

03/09/2016

CONSENT FORM FOR PERSONAL DATA USE IN A NON-PROFIT CLINICAL TRIAL

Information note for personal data use for non-profit clinical trials

[D.Lgs. 196/2003 "Codice in materia di protezione dei dati personali"]

Pursuant to Legislative Decree n.196 passed on 30 June 2003, ["Codice in materia di protezione dei dati personali"], the "**Università Cattolica del Sacro Cuore", located in Largo Francesco Vito, n. 1 – 00168 – Rome, as the data owner, informs you that your data, as included in this note, will be used as follows.**

1. AIM OF THE DATA USE AND TYPE OF DATA

The management of your *personal data* (relating to any personal information including a personal identification number), both *sensitive* (i.e. related to health status) and possibly *genetic* (data concerning the hereditary characteristics of an individual), will be held for:

1. Clinical trials, as defined by Legislative Decree n. 196/2003, national and international laws and regulations on standards of ethics and codes of good conduct issued for medical and health measures by the relevant Authority and Guarantor.

2. Scientific and statistical research aimed at general health care in the medical, biomedical and epidemiological fields.

3. Health care with particular reference to genetic diseases and protection of identity.

4. Compliance with specific obligations or tasks required by International and European norms, as well as by the laws and regulations governing material.

2. NATURE OF COLLECTED DATA

The acquisition of your personal data is necessary to achieve the above mentioned purposes. Participation in the trial is on a voluntary basis. Therefore, a lack of consent to data processing will in no way influence the treatment or medical care you receive in this hospital.

3. DATA PROCESSING MODALITY

The abovementioned trail requires the collection, recording, storage and modification of personal data by hand or computer, strictly related to the purposes stated above and, under all circumstances, in a way that guarantees the privacy and confidentiality of data.

Persons designated to data processing will pay special attention in differentiating data collected for medical / clinical purposes from that collected for experimental purposes so respecting patients' rights and dignity.

Your data may be managed with the help of third parties expressly appointed by the owner, managers or those in charge of Data Processing.

4. COMMUNICATIONS AND DISSEMINATION

Your data may be disclosed to third parties, if the facilities and the equipment of the University became inadequate for the purposes of its management or in cases expressly provided by laws or regulation.

The Ethics Committee and Italian and foreign health authorities, may access data concerning you, also contained in your original clinical documentation, to guarantee the confidentiality of your identity.

If necessary, your data can be transmitted to third party countries either in the European Union or outside it, even if they cannot guarantee an adequate level of data protection (i.e. USA). The diffusion of your data outside of the circumstances stated above will only be anonymously.

Data that emerges from analysis of results, even future data, if implicating a practical and direct benefit in terms of treatment, prevention or awareness of your future choices, will be communicated directly to you. Only with your consent, will it be shared with other persons as indicated below.

5. DATA STORAGE

The information you provide will be kept for a period no longer than necessary to achieve the purposes for which it was collected and processed.

In particular, data emerging from the trial will be kept within the limits established by laws governing the matter.

6. RIGHTS

We inform you that in accordance to the law, the data owner is "Università Cattolica del Sacro Cuore", located in Largo Francesco Vito n. 1-00168 - Rome.

As per Article. 7 of Law 196/2003, you may obtain confirmation of data, know contents and origin, verify accuracy, request integrations, updates or corrections, as well as obtain an updated list of the Data Handlers by contacting the Secretary of the University's Ethics Committee at the above address.

You can stop participation in the trial at any time without giving any reason. In this case, no additional data will be collected on you, without prejudice to the use of that already collected to determine, without altering it, the research results.

If stopping treatment, any biological samples collected will be destroyed.

Consent Form for Personal Data Use
as per Legislative Decree n. 196/2003

Declaration of Consent Form for Personal Data Use in Clinical Trial
[Consenso al trattamento dei dati per scopi di sperimentazione]

Pursuant to atr.13 of Legislative Decree n.196/2003, the undersigned (name and Surname)

_____,

born in_____, on _____/_____/_____,

Residing at_____,

Tel.n. _____

In his/her capacity as:

☐ The person concerned

or

☐ The parents/guardian of minors (both parent's personal details)

Father (Name and Surname)_____,

born in_____, on the _____/_____/_____,

residing at _____

Mother (Name and Surname) _____,

born in_____, on the _____/_____/_____,

residing at _____

or

☐ Support Administrator / Attorney _____,

born in_____, on the _____/_____/_____,

residing at _____

AGREES □ YES □ NO

to the use of personal data for the clinical trial aims.

AGREES □ YES □ NO

to the processing of data and its transfer to third parties within the European Union or outside it within the experimental/research purposes indicated in this document.

AGREES □ YES □ NO

to the possible transfer of data anonymously to pharmaceutical companies or other entities that use the same for the purpose of study or research.

AGREES □ YES □ NO

to share the results of the analysis and any unexpected discoveries that concern you that emerge during the experimental activities to:

□ Myself

□ Relative (Name and Surname)_____)

□ Cohabitant / partner (Name and Surname)_____)

□ General Practitioner (Name and Surname)_____)

Section to be completed in case of genetic data experimentation

- In the event that the outcome of tests and results of research involving a concrete and direct benefits in terms of treatment, prevention or awareness of reproductive choices

DECLARES

□ that she/he wants to know this information

□ that she / he does not want to know this information (*only if the unknown information will not be dangerous for herself/himself or others*)

- In the event that the outcome of *tests* and results of research involving a concrete and direct benefits in terms of treatment, prevention or awareness of **reproductive choices**, even for members of his/her own genetic line.

DECLARES

□ to agree to the disclosure of information to the those indicated above, if they should request it.

□ to **not** agree to the disclosure of that information to those indicated above, if they should request it.

- If the "Università Cattolica del Sacro Cuore" does not carry out the required analysis at its laboratories

DECLARES

□ to agree to biological sample dispatch to (name of lab)_____, outside the **"Università Cattolica del Sacro Cuore", for the following examination (name of examination)**

_____

□ to **not** agree to biological sample dispatch to (name of lab)_____, outside the **"Università Cattolica del Sacro Cuore", for the following examination (name of examination)**

_____

Date_____ Signature_____