Institutul Clinic Fundeni

FISA DE CONSIMTAMANT LIBER EXPRIMAT

Titlul proiect: "Mecanisme patogenice si tratamentul personalizat in cancerul de pancreas utilizand tehnologii multi-omice"

Cod PACIENT:

Subsemnatul(a)……. certific ca doctorul ……

mi-a propus participarea la proiectul de cerectare **"Mecanisme patogenice si tratamentul personalizat in cancerul de pancreas utilizand tehnologii multi-omice", cod proiect complex: PN-III-P1-1.2-PCCDI-2017-0797,** care are drept scop caracterizarea moleculara a probelor biologice prelevat si identificarea mecanismelor biologice implicate in boala mea, cu identificarea unor noi markeri de diagnostic/prognostic si depistarea unor noi tinte terapeutice

Am fost bine informat(a) atat privind obiectivele si conditiile de realizare ale acestui studiu cat si despre riscurile implicate de acesta. Am primit raspunsuri la toate intrebarile mele referitoare la acest studiu.

Imi exprim consimtamantul in mod liber pentru participarea la acest studiu si am fost informat(a) cu privire la dreptul de retragere a participarii mele in orice moment, fara a suferi nici un fel de prejudiciu.

Pentru realizarea in bune conditii a acestui proiect, sunt de acord ca promotorul si/sau autoritatile medicale competente sa aiba acces direct la documentele mele medicale originale pentru verificarea procedurilor clinice si/sau a datelor, cu rezerva pastrarii confidentialitatii.

Imi dau acordul in vederea prelucrarii informatice a datelor medicale inregistrate cu ocazia acestei cerecetari de catre/in folosul promotorului. Am fost informat ca, in orice moment imi pot exercita dreptul de a accesa informatiile care ma privesc, conform legii Nr. 677/2001 pentru protectia persoanelor cu privire la prelucrarea datelor cu caracter personal si libera circulatie a acestor date (articolul 13 si urmatoarele) si Regulamentului (UE) 2016/679 privind protecţia persoanelor fizice în ceea ce priveşte prelucrarea datelor cu caracter personal şi privind libera circulaţie a acestor date (Regulamentul general privind protecţia datelor), prin intermediul medicului responsabil. De asemenea imi pot exercita si dreptul de rectificare a datelor prin intermediul aceluiasi medic.
Am primit o copie a prezentului document si am fost informat(a) ca o alta copie va fi pastrata in arhiva proiectului, cu garantarea confidentialitatii si sunt de acord cu aceasta.
Consimtamantul meu nu absolva de responsabilitatile lor pe organizatorii cercetarii.
Imi rezerv toate drepturile garantate de lege.
Declar ca am primit raspuns la toate intrebarile referitoare la acest studiu, ca am raspuns la randul meu la toate intrebarile ce mi-au fost adresate in particular privind antecedentele medicale si ca voi urma toate sfaturile si instuctiunile, descrise detaliat in nota de informare, ce imi vor fi acordate de catre echipa medicala.
Declar ca nu am primit nici o remuneratie de orice natura ar fi aceasta (directa sau indirecta) in schimbul consimtamantului sau participarii mele la acest studiu.

Numele si prenumele pacientului:

.....

.....

Data: ..... Semnatura:

Numele medicului care a cerut consimtamantul:

.....

Data: ..... Semnatura:

NOTA DE INFORMARE

In vederea participarii la acest studiu biomedical este important sa cititi acest document care va furnizeaza informatiile necesare cu privire la desfasurarea lui.
Puteti semna consimtamantul dupa o perioada de gandire.
Prin participarea la acest studiu contribuiti la eforturile de cercetare care au drept scop ajutorarea altor persoane.
Tratamentul maladiei dumneavoastra va necesita o interventie chirurgicala.
Va propunem participarea la proiectul de cercetare cu titlul: "Mecanisme patogenice si tratamentul personalizat in cancerul de pancreas utilizand tehnologii multi-omice", condus de Prof. Univ. Dr. Irinel Popescu, din Institutul Clinic Fundeni, avand drept obiectiv caracterizarea moleculara a tesutului prelevat si depistarea mecanismelor biologice implicate in boala dumneavoastra. O mai buna intelegere a acestor mecanisme ne va putea permite identificarea unor noi markeri de diagnostic/prognostic si depistarea unor noi tinte terapeutice. Aceasta va permite ameliorarea ingrijirii bolnavilor care vor suferi de aceeasi boala ca dumneavoastra.
Ati fost informat de catre medicul curant ca piesa operatorie (tesutul extras) va fi trimisa la serviciul de anatomie patologica din .Institutul Clinic Fundeni. O parte din tesut va fi folosita de catre medicul anatomopatolog la stabilirea diagnosticului, iar restul, in mod normal, este considerat deseu operator si este distrus prin incinerare. Va cerem consimtamantul pentru colectarea unor fragmente de tesut din aceste deseuri operatorii si folosirea lor in proiectul de cercetare **"Mecanisme patogenice si tratamentul personalizat in cancerul de pancreas utilizand tehnologii multi-omice"** Pentru realizarea interventiei chirurgicale este necesara prelevarea unor probe de sange. Va cerem consimtamantul pentru prelevarea a 5 esantioane de sange suplimentare. Pentru urmarirea bolii dumneavoastra vor fi necesare si alte prelevari de sange. In vederea realizarii proiectului de cercetare va cerem consimtamantul pentru prelevarea suplimentara a unor esantioane de sange.

Medicul care va propune participarea la acest studiu va va acorda un timp de gandire. Sunteti liber sa participati sau nu la acest proiect. Va puteti rezerva dreptul ca in orice moment sa intrerupeti participarea la acest studiu, fara a fi nevoit sa precizati motivele care v-au determinat sa luati aceasta decizie. Aceasta nu va afecta in nici un fel ingrijirile medicale oferite.Informatiile medicale inregistrate in cadrul acestui studiu vor fi anonime si confidentiale; aceste informatii pot fi consultate de catre reprezentantii autoritatii contractante (ANCS) precum si de catre serviciile in drept ale autoritatilor medicale romane si straine. Identitatea dumneavoastra nu va fi mentionata in nici un moment si esantioanele biologice prelevate vor fi anonime pe parcursul desfasurarii tuturor proiectelor de cercetare.

Institutul Clinic Fundeni va avea permisiunea sa foloseasca aceste probe pentru orice proiect de cercetare cu urmatoarele obiective descrise (o mai buna intelegere a mecanismelor implicate in aceasta boala, ceea ce ar face posibila identificarea unor noi markeri de diagnostic/prognostic, precum si identificarea unor noi tinte terapeutice) fara ca dumneavoastra sa puteti impune restrictii in ceea ce priveste folosirea lor, cu conditia pastrarii anonimatului.
Aceasta cercetare este conforma recomandarilor declaratiei de la Helsinki (1964) si amendamentelor sale.
Datele dumneavoastra medicale, necesare acestui studiu, sunt prelucrate informatic si nu vor fi transmise decat autoritatiilor sanitare indreptatite in conditiile garantarii confidentialitatii lor. In orice moment va puteti rezerva dreptul de a accesa si de a rectifica aceste informatii prin intermediul medicului responsabil de acest studiu. In orice moment aveti dreptul de a va retrage participarea la acest protocol printr-o simpla cerere scrisa. Aceasta renuntare atrage obligatia Institutul de a retrage din colectie esantioanele biologice prelevate si de a le distruge prin incinerare.
Conform legii, daca acceptati sa participati la acest studiu, va rugam sa semnati fiecare pagina a acestei note informative precum si foaia de consimtamant atasata.

Fundeni Clinical Institute

INFORMED CONSENT DECLARATION

Project title: "Pathogenic mechanisms and personalized treatment in pancreatic cancer using multi-omics technologies"

Patient Numerical Code:

I, the undersigned, ……., certify that ..... MD has asked me to participate in the research study "**Pathogenic mechanisms and personalized treatment in pancreatic cancer using multi-omics technologies" complex project code: PN-III-P1-1.2-PCCDI-2017-0797,** that intents to establish a molecular characterization of the biological samples and identify the biological mechanisms of my disease, as well as identifying new diagnostic/prognosis markers and discovering new potential therapeutic targets.

I have been fully informed of the aims of this study and how it will be implemented, as well as any risks it may involve. I have received answers to all my questions about the study.

I freely give my consent to participate in this study and I understand that I have the right to withdraw from it at any time without incurring any prejudice.

I agree that for the purpose of the study the promoter and/or the health authorities may have direct access to original medical documents in order to check all the clinical procedures and/or data, but without violating their confidentiality.

I agree that the medical data recorded during this research study may undergo computer processing by the promoter or by others acting on its behalf.

I have noted that my right of access, provided by the law "Law Nr. 677/2001- Romania regarding the people protection concerning the personal data processing and their free spreading (article 13 and follows) and Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) may by exercised at any time through the study physician. I can also exercise my rights to correct data through the same physician.

I have received a copy of this document and I have been informed that another copy will be kept in the project archives under conditions which guarantee confidentiality, to which I consent.

My consent does not discharge the organizer of the research study of their responsibilities. I retain all my rights as guaranteed by the law. I hereby declare that I have received answers to all the questions I asked about the study and I have answered all the questions concerning my medical history.

I state that all the questions I asked about this study have been answered, while having answered myself to all questions on my medical history that were addressed to me in private and I undertake to follow all the advice and instructions I will be given by the medical team and which are described in detail in the information sheet.

I hereby declare that I did not receive any payment of any type (directly or indirectly) in exchange for my participation in this study.

First and last name of the patient:

.....

.....

Date: ..... Signature:

First and last name of the MD in charge with filling in the forms:

.....

Date: ..... Signature:

INFORMATION SHEET

Before you participate in this biomedical research study it is important to read this document, which will inform you about the implementation of the study.

Please take all the time that you need before giving your consent.

By participating in this study you will contribute to research that could help other people.

The treatment of your disease will necessitate a surgical intervention.

We are asking you to participate in the research project "Pathogenic mechanisms and personalized treatment in pancreatic cancer using multi-omics technologies" being carried out by Prof. Irinel Popescu MD PhD at Fundeni Clinical Institute, that intents to establish a molecular characterization of the biological samples and identify the biological mechanisms of my disease. A clear understanding of these mechanisms would allow the identification of new diagnostic/prognostic markers and of new potential therapeutic targets. This will provide an improvement in the management of patients suffering from this disease in the future.

You were informed by your treating MD that the surgical sample (extracted tissue) will be sent to the Pathology Department of the Fundeni Clinical Institute. A part of this tissue will be used for establishing the histopathological diagnosis and the other one would normally be destroyed by incineration as operatory waste. We are asking for your consent to take fragments from this operatory waste and use them in the research project **"Pathogenic mechanisms and personalized treatment in pancreatic cancer using multi-omics technologies".**

For the surgery, blood samples must be collected. We ask your consent to collect 5 additional blood samples in order to use them in the research projects of the Fundeni Clinical Institute. For your disease follow-up other blood samples will have to be collected periodically. We ask your consent to take additional blood samples which will be used in the research programs of the Institute.

The MD asking you to participate in this study will allow you plenty of time to think about it. You are free to take or not to take part in this study. You have the right, at any time, to withdraw your participation without having to give any reasons. This will not affect the medical care you are given in any way.

The medical information collected for this study will be processed under anonymous and confidential conditions; it may be consulted by the representatives of the promoter or by relevant representatives from the Health Authorities in Romania or other countries. Your identity will never be mentioned and all biological samples will remain anonymous throughout the implementation of any research project.

The Institute will be permitted to use these samples for any research project having the following objectives: a better comprehension of the mechanisms involved in my disease which could make it possible to identify new diagnostic/prognostic markers and to identify new potential therapeutic targets) without you being able to place any restrictions on their use, except concerning preservation of your anonymity. Any research will be carried out in compliance with the recommendations of the Declaration of Helsinki (1964) and its amendments. Medical data concerning you and necessary for this research will be the subject of computer processing and will only be transmitted to the promoter and if necessary to the appropriate health authorities under conditions which guarantee their confidentiality. You can at any time exercise your right of access to and correction of this data, through the MD in charge with the study. You are free to withdraw at any time from this protocol simply by a written request. Such a withdrawal will mean that the Institute will remove your samples from the collection and ensure their destruction by incineration. As required by law if you agree to participate in this study we will ask you to sign every page of the consent form.