

## **CONSENT FORM AFTER INFORMATION**

**Responsible researcher:**

Lampros Vagiotas

Nurse

PhD candidate

Transplant Surgery Clinic of Aristotle University of Thessaloniki

General Hospital of Thessaloniki "Ippokrateio"

Tel. 2310 89 2068

E-mail: lampisv@yahoo.gr

**Please read this form carefully and ask the person in charge of the study to answer your questions.**

Kidney transplantation is the treatment of choice in end-stage renal failure patients, as it improves their quality of life and prolongs the survival of patients. The immune system has the ability to distinguish the "same", that is, its own from the foreign molecules, which after recognizing them, it treats them in order to protect the body from pathogens. In the case of renal transplantation, the body recognizes molecules in the graft cells (allograft) resulting in the initiation of an immune response that, if not regulated, leads to the rejection of the graft.", which is carried out by the Transplant Surgery Clinic of the Aristotle University of Thessaloniki, the Laboratory of Biological Chemistry of the Medical School of A.U.Th., in collaboration with the National Regional Center of Histocompatibility, at the General Hospital of Thessaloniki "Ippokratio", as well as the Nephrology Clinic of A.U.Th. Your choice as suitable for the study was based on the fact that you recently underwent a living or cadaver renal transplant. The purpose of the above study is to determine whether there is an association of immunophenotype changes in your peripheral blood sub-populations of T and NK lymphocytes at certain times with transplant function and

any dismissive episodes (i.e. shortening of the survival of the transplant), but also whether it is possible to adjust your immunosuppressive regimen in relation to the fluctuations of the specific subpopulations

## **1. WHAT IS THE PROCEDURE?**

In order to participate in the study, you will not need to attend any additional clinical-laboratory appointment, nor to modify your medication.

The procedure involves taking about an additional 10 ml of blood during your scheduled laboratory test, initially on the day just before the start of the renal transplant and then on the scheduled blood sampling on your arrival at the 3-month, 6-month and post-transplant . Histocompatibility entrenchment, while there will be close cooperation and information of the treating nephrologists. The additional blood sampling procedure does not burden you at all in time, since it is scheduled to be done together with the rest of the routine laboratory tests provided by the protocol of the Surgical Transplant Clinic of A.U.Th.

## **2. POSSIBLE INCONVENIENCES, UNDESIRABLE ACTIONS AND RISKS**

As the blood collection will be performed upon your arrival for your scheduled clinical-laboratory examination, you will not need to undergo additional venipuncture. The inconveniences and risks from the above procedure are minimal.

## **3. POSSIBLE BENEFITS**

However, you will not have any cost, nor any financial or material benefit from your participation in the study, but there is the opportunity for a specialized examination of your immunological profile, as was done at regular intervals and before your transplant. Also, in the future it is possible that other patients will benefit from the results of this study.

## **4. WITHDRAWAL FROM THE STUDY**

You have every right not to participate, or to discontinue your participation in the study at any time you wish, at no cost to you. You will not need to justify your decision. The

treatment of any of your health problems by the attending physician does not depend on your participation in the study.

## **5.CONFIDENTIALITY**

The data and results of the study we collect will be processed after codification, while only the researchers conducting the study will have direct access to them. You have the right to be informed about your personal data recorded, the way in which they were collected and the persons to whom they have been disclosed. The blood samples that will be stored for further analysis will not mention your personal information but will be encoded.

If you have any questions or would like additional information about the survey you can contact the investigator in charge.

## **CONSENT OF A PARTICIPANT IN THE RESEARCH**

Full name



1.I have read the updated consent form for this study. I received an explanation of the purpose, duration and potential benefit of the study and what I would be expected to do. My questions were answered satisfactorily.

2. I agree to take part in this study, as well as biological samples (blood) as well as clinical and epidemiological information concerning the course of my disease to be used for research purposes in the hope of offering useful scientific conclusions and provided that absolutely sensitive personal data are ensured and the rules of ethics and ethics are observed in accordance with the Helsinki Treaty.

3. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any justification, without affecting my medical care or my legal rights.

4.The Ethics Committee or local regulatory authorities in accordance with local regulations may wish to review my medical record to verify the information gathered. By signing this document, I give permission for this examination of my file.

Full Name:

[REDACTED]

Signature:

[REDACTED]

Date: 10/03/2021

Declaration of the investigator obtaining the consent of the subject.

I confirm that I have personally explained the nature, purpose, duration, and foreseeable effects and risks of the study on the person mentioned above. I confirm that the participant was given the opportunity to ask questions about the study and that all the questions posed by the participant have been answered correctly and in the best possible way.

A copy of the consent form has been given to the participant

Full Name: Lampros Vagiotas



Signature:

\_\_\_\_\_

Date: 10/03/2021