INFORMED CONSENT FORM FOR PARTICIPATION IN A STUDY

University Hospital of Ioannina (U.H.I.)

Last updated/approved: 17 November 2023

STUDY TITLE: "Immunophenotyping profiling in patients with primary nephrotic syndrome: Emphasis on the diagnostic and prognostic value of immune cells across the different phenotypes of nephrotic syndrome."

INTRODUCTION

Your participation in this research will be greatly appreciated and, of course, ***the rule of anonymity will be strictly maintained.*** *The personal data collected within the framework of the study will be recorded anonymously and used solely for the purposes of the study. The information collected will not reveal your name or any other details (e.g., address, social security number, etc.) that could reveal your identity. The scientific conclusions and results arising from the study will be published in medical journals and/or presented at scientific conferences, without naming the individuals who participated.*

We inform you that participation in the study is voluntary. In any case, neither you nor your public or private insurance provider will incur any cost as a result of the study procedures. Before you decide to take part in the study, please discuss any questions you may have with us.

Duration of the study: 1–3 years.

Protection of Personal Data: The scientific investigator confirms that she is aware of, has understood, and strictly adheres to the applicable national and international legislation for the conduct of research and the protection of the personal data of participants; that the informed-information documents are binding upon the participants; and that the principles of research ethics and deontology will be followed. Any modification to the terms under which the research is conducted must be reported to the Scientific Council.

Your personal data will be processed in accordance with the EU General Data Protection Regulation (Regulation (EU) 2016/679, "GDPR") and the applicable Greek national legislation. The only person who will have access to, and who will be responsible for handling your personal data — including any request to access it — is the primary investigator Christos Georgopoulos.

PURPOSE OF THE STUDY

The purpose of this study is to investigate cells of the immune system and their potential use as a biomarker in patients with primary nephrotic syndrome, with respect to response to treatment or disease relapse.

STUDY METHOD

The above study will be carried out in the Nephrology Clinic and in the hospital's hematology laboratory using flow cytometry. What is required of you is to attend to the routine follow-up schedule within the context of your kidney disease. Patient follow-up will take place in the Nephrology Clinic as well as in the Nephrology Outpatient Clinic. In addition to the blood sampling required for your routine follow-up, two (2) additional complete blood count samples and two (2) additional biochemistry samples will be collected.

Any blood samples collected for the purposes of the study that are not fully analyzed at the time of collection will be stored (bio-banked) at −80 °C. In addition to the analyses described in this study, these stored samples may also be used for future exploratory analyses of additional biomarkers (for example, further markers of inflammation, coagulation, or lipid metabolism) related to your kidney disease.

CONSENT

The undersigned …… hereby responsibly declare that I have been fully informed by Mr. Christos Georgopoulos regarding the purpose of the present study in which I will take part, and I give my consent to participate in it. I understand that my participation in this study is free and voluntary and that I may withdraw my consent at any time without any consequences for the medical care to which I am entitled. I have been informed about the protection of the personal data concerning me.

Participant

Full name (in block letters): ……

Signature: …… Date: ……

Person obtaining consent

Full name (in block letters): ……

Signature: …… Date: ……

Legal representative

To be completed only when the participant is unable to provide consent in person (e.g., is unable to sign). By signing below, the legal representative provides consent on the participant's behalf.

Full name (in block letters): ……

Relationship to participant / legal capacity: ……

Signature: …… Date: ……

Thank you in advance for your participation.

For any questions or clarifications, please do not hesitate to contact me:

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