A sample of the research consent form is given here:

Research Study Number:

Patient Identification Number for this study:

CONSENT FORM

Title of Project: The immunomodulatory effects generated by Extracorporeal Photopheresis on antigen presenting cells and lymphocytes

Chief Investigator, Photopheresis Unit: Robert Whittle

Photopheresis Research Director: Dr Peter Taylor

Please initial box

1. I confirm that I have read and understand the information sheet dated version .....) for the above study. I have had the time and opportunity to consider the Information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records ☐

4. I confirm I am fully aware that the research associated with this study is newly performed at Rotherham Hospital and the results will not affect clinical care by my doctor ☐

5. Having been assured of total anonymity, I consent to the collected data being used for analysis, presentation and publication ☐

6. Knowing all the facts, I agree to take part in the above study. ☐

Name of Patient Date Signature

Name of person taking consent Date Signature

Copies: 1 for patient; 1 for researcher site file; 1 (original) to be kept with medical notes

SAMPLE

A sample of the research information sheet is given here:

Study title:
The immunomodulatory effects generated by Extracorporeal Photopheresis on antigen presenting cells and lymphocytes

Invitation
We would like you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read this information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Purpose of Study
The Photopheresis Unit at Rotherham has an ongoing program of research which has led to important publications in this area. This study is designed to understand how the treatment works by monitoring changes to the immune system that may occur in response to the therapy. This information will be used to examine whether these changes are associated with different outcomes of the Photopheresis treatment. The long term aim is that this information will contribute to improving this treatment for patients.

Why have I been invited?
Your doctor has referred you for Photopheresis treatment of your symptoms and an assessment is made by the Photopheresis unit to examine whether this is an appropriate therapy option for you. This will involve a detailed history taking and relevant physical examination, after which we may arrange further tests (blood tests, lung function, dry eye test, grip assessment, medical photography).
These tests are performed as part of your clinical assessment and are carried out regardless of whether or not you choose to participate in the study.

It is highly likely that the condition and symptoms you are experiencing are appropriate for this area of research and including you as a participant will contribute toward the study goal.

The Photopheresis Unit at Rotherham has a long tradition in research and is a pioneering centre for the use of the treatment. Previous research here at Rotherham has aided understanding in the field and has led to significant medical and scientific publications.

Do I have to take part?
No, it is up to you to decide. It is entirely optional and deciding not to participate or to withdraw from the study will not affect your healthcare in any way.

What will happen if I agree to take part?
During the course of your therapy a small amount of blood will be taken before and after each round of treatment as part of your necessary routine observations.

SAMPLE

1. To perform the study 2 or 3 additional blood samples are needed; 1 prior to starting your 1st treatment and the second sample at a later time point to be determined by your treatment schedule. Occasionally a third sample may be required. These are all small volume samples and will be taken at the same time as other blood tests to minimize inconvenience.

2. The study will not change your current healthcare. The results of the study will be analysed by the Research team but will not influence the treatment you receive.

3. As this is a new study, the results and clinical data will be used for analysis and publication. Your anonymity is of course assured.

What are the possible benefits, disadvantages and risks I should know about before taking part?
Taking part in the study will result in you providing a small amount of additional blood on 2 or 3 occasions at the same as other routine samples are being taken.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the Researchers who will do their best to answer your questions (contact details overleaf). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

If in the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against Rotherham NHS Foundation Trust but you may have to pay legal costs.

Will my taking part in the study be kept confidential?
All information that is collected about you for the study will be kept confidential. Any results from the study that are published will be completely anonymous and will have all personal information removed so that you cannot be identified in any way. All information will be held securely in strict accordance with hospital policy and will only be accessed by authorized personnel.

What will happen to the results of the study?
It us intended that the results will be published. You will not be identifiable in any report or publication. You can request a summary of the results if you would like them once the study has been published.

Who has reviewed the study to ensure it is correctly conducted?
The York Research Ethics Committee has reviewed this study. A Research Ethics Committee is a body that is appointed by the Strategic Health Authority. It consists of a number of members both medical and non-medical who review proposed research within the health district. Their role is to consider the ethical merits of the research which consists of reviewing whether the potential advantages of the proposed research outweigh any risks to which the participants may be exposed. Research projects are not undertaken unless REC approval has been granted.

The research has also been reviewed by the Research and Development Governance Committee here at Rotherham to ensure that the project is performed with due care and attention to the responsibilities of Researchers in healthcare.

Thank you for your participation and cooperation.

Dr P C Taylor
Consultant Haematologist
Director of Photopheresis

Mr. R M Whittle
Research Scientist
Photopheresis Unit

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Independent advice may also be obtained from: **Patient Advice and Liaison Service (PALS)**
Level D, Rotherham General Hospital
Moorgate Road
Rotherham S60 2UD
Telephone: 0800 953 1303