Guy's and St Thomas' NHS
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET "HEALTHY VOLUNTEER BLOOD DONATION"

Title of the Study: **Immunopathogenesis of Psoriasis**
Version and Date of Subject Information Sheet and Informed Consent: Version 3, 19/07/2007
Guy's Research Ethics Committee
Ethics Committee Code: 06/Q0704/18

PART1

INTRODUCTION

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

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.

This research project will improve our understanding of the role of the immune system in psoriasis, and aims to develop new treatments. Psoriasis is a common chronic inflammatory skin disease that affects about 1 million people in Britain. No cure is available at the moment. Present treatments alleviate the symptoms but are often accompanied by considerable side effects. What causes psoriasis is not known at present, but recent data indicate that a dysregulation of the immune system plays a major role in psoriasis development. There is also accumulating evidence that treatments targeted at components of the immune system in psoriasis might be beneficial to patients.

Our research group has been working for many years in the field of understanding the causes of psoriasis and finding new treatments.

We aim to better understand the differences between normal skin/blood and psoriatic skin/blood, e.g. which cells of the immune system can be found in psoriatic plaques that are absent in normal skin. We also want to find new targets for treatment in psoriasis and test them in relevant model systems. For this reason we need to obtain blood samples from healthy volunteers.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this research study is to better understand the role of the immune system in psoriasis in comparison to healthy volunteers, and to develop novel treatments.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you are a healthy volunteer.

DO I HAVE TO TAKE PART?

No, it’s up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will have no impact on your work relationship (e.g. if you are a member of the research group of the principal investigator).

WHAT WILL HAPPEN TO ME IF I TAKE PART?

In order to participate in this study you will need to donate a blood sample of no more than 50 ml possibly at different time points.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART IN THIS STUDY?

Taking blood samples might cause discomfort and bruising.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The information obtained from this study will not benefit you personally.

DO I GET ANY MONEY FOR TAKING PART IN THIS STUDY?

No.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

WHO CAN I CONTACT FOR FURTHER INFORMATION ON THE STUDY?

If you have any questions concerning the study please don’t hesitate to contact Professor Frank Nestle on 0207 1889038.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

WHAT HAPPENS IF I DON’T WANT TO CARRY ON WITH THE STUDY?

Your participation is entirely voluntary. You may refuse to be in this study, or withdraw at any time. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

WHAT IF THERE IS ANY PROBLEM?

If you have a concern about any aspect of this study, you should ask to speak with the researchers, who will do their best to answer your questions (Tel: 0207 1883713)
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.

In the event that something does go wrong and you are harmed during the procedure there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence then you may have grounds for a legal action for compensation against the Guy's and St Thomas' NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanism will be available to you (if appropriate).

WHO WILL HAVE ACCESS TO THE DATA GENERATED?

We guarantee you data security. All information resulting from this study will be coded and anonymised and will be only accessible for medical research staff involved in this study for scientific analysis of the data.

All staff will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

WHAT WILL HAPPEN TO THE SAMPLES I GIVE?

Blood samples that we obtain from you will be further processed using cell culture, flow cytometry protein biochemistry, molecular biology, genetic and genomic analysis (including microarrays).
DNA samples will be coded and stored (potentially forever) until use. Samples used will be anonymised. Data will be held in protected data bases.

The samples will be used in the studies described above. If samples are used in future studies, not covered by the present research proposal, the approval of the local Research Ethics Committee will be sought. Blood that isn’t used immediately will be stored. Only researchers involved in the study will have access to the blood samples. The samples will be coded and will not be directly marked with your name.

It is possible that commercial partners may become involved in this research in the future. This would mean that both patient samples and results may be used by commercial partners in the development of new treatment, diagnosis etc. In this instance all samples and research would be anonymised. By participating in this research you are agreeing to the potential future use of your samples and results by commercial partners. There will be no financial benefit for you if samples collected during the study are passed on to commercial companies.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results of the research study will be discussed at scientific meetings and published in a scientific journal. You will not be personally identified unless you have consented to release such information.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This research project is funded by various funding organizations including the Wellcome Trust and the National Institutes of Health.

WHO HAS REVIEWED THIS STUDY?

This study was given a favourable ethical opinion for conduct in the NHS by the Guy's Research Ethics Committee

If you have understood all the information above and wish to participate in this study, you will be asked to sign an INFORMED CONSENT FORM. You should keep a copy of the information sheet yourself.

Thank you for considering taking part in this study and taking time to read this information sheet.