**PARTICIPANT INFORMATION SHEET**

**Bio-markers and Stratification To Optimise outcomes in Psoriasis (BSTOP)**

**Chief Investigator: Professor Catherine Smith**

**NRES Committee London - Westminster**

**REC Ref: 11/HO802/7**

You are being invited to take part in the BSTOP study. Before you decide to take part, it is important to understand why the research is being done and what it will involve. Take time to decide whether or not you wish to take part. Please ask the study doctor or nurse to explain anything you do not understand.

**WHAT IS THE PURPOSE OF THE STUDY**

The purpose of this study is to identify genetic or other markers (biomarkers) that will enable us to give the right medicine, to the right patient at the right time. We will investigate genes, and how they are expressed and ‘translated’ into actions within the body. We will do this by sampling blood, and in some people, other samples such as skin. We will use cutting-edge science to investigate differences between people with different kinds of psoriasis and associated health problems, and before and during treatments. This information will help us to select individuals most likely to respond well to the treatments available already, and to design better, safer, treatments (***the right medicine***). It will also help us to select individuals more likely to develop severe psoriasis and/or health problems such as arthritis for early treatment (the right medicine ***at the right time***). By comparing our findings in skin with inflammation in other organs of the body, we will also contribute to vital research into health and disease more generally. A second, major aim is to make this information and samples available to the research community to understand the causes of psoriasis, and to help design better treatments. We will prioritise research questions that matter to people with psoriasis.

**WHY HAVE I BEEN INVITED**

You have been invited to take part because you have psoriasis. You may also be taking part in “The British Association of Dermatologists Biologics and Immunomodulators Register - BADBIR”. This research study is being run alongside, and with the approval of, BADBIR and we would like your permission for us to access data that you have already given to BADBIR. This way we will not need to ask you twice for the same data.

**DO I HAVE TO TAKE PART?**

No. Taking part is entirely voluntary and your clinical care will not be affected by your decision to participate or not participate in this study.

**WHAT DO I HAVE TO DO?**

**You will be asked to sign a consent form**

We will ask you to sign a consent form, to confirm you are happy to participate in the study. A study doctor or nurse will go through the consent procedure with you and explain the study in detail.

**You will be asked to provide medical (clinical) information**

We need to collectbasic medical (clinical) information from you regarding your general health, family history, medications, how you are responding to treatment and whether you have developed any side effects. To minimise the amount of time you need to spend at appointments to participate in this study with your permission, data will be collected from the BADBIR registry (if you are taking part in this) and your medical records by the research nurse or study doctor where ever possible. The study nurse will also measure your height, waist and weight.

**You will be asked to complete patient questionnaires**

You will be asked to complete the questionnaires and other survey forms about your health. You should note that some of the questions on these questionnaires may be of a sensitive or personal nature. You do not have to answer all the questions.

**You will be asked to provide a sample of your blood**

You will be asked to donate a blood sample (up to 7 tablespoons i.e., 100ml) to look at your genes (often called "DNA"), proteins, RNA (which is related to DNA) and immune cells. In exceptional circumstances when blood samples cannot be collected, we can isolate DNA from saliva, in which case you will be asked to spit 2ml (half a teaspoon) into a plastic pot.

**Are they any additional things that I might be asked to do?**

You may be asked to make additional visits and you may be asked to provide additional samples. **These extra visits and/or samples are all optional and you can still take part in BSTOP if you do not want to take part in these optional extras.** Here is more information about these optional extras:

**You may be asked whether you would be willing to make further visits to the clinic**

We may ask you to come back to the clinic to provide follow-up data and samples, including a further blood sample (up to 7 tablespoons i.e. 100ml) and/or optional samples (skin and/or tear fluid, as detailed below) and/or medical photographs. If you have been invited to provide samples over time, we will aim to collect follow up data and blood samples from you at your regular clinical visits. We will do so every 6 months and annually for 5 years after your initial “baseline” study visit, or for as long as you are involved in the study with which we collaborate, ‘BADBIR’, whichever is longer.

Participants starting, switching or stopping treatment may be asked to return to clinic for other additional follow up visits on day 3, day 14 and month 3 after starting treatment. This is because treatments often have significant effects in the early stages, and we want to get a "snapshot" of these changes during this important stage.

This is an optional request. You can take part in the study if you do not wish to provide follow-up data or samples. Every effort will be made to coordinate BSTOP study visits with scheduled clinic appointments so that additional trips to the hospital are not required.

 **You may be asked to provide optional samples (skin)**

These are highly valuable samples. You can still take part in the study if you decide not to provide these samples and it will not impact your medical care.

* **Skin samples**

Skin samples are usually taken from the back or buttock. The skin sample may be a skin biopsy, skin swab or a tape strip depending on the needs of the study and the research capacity of your study site. It will always be carried out by a trained doctor or specialist nurse.

* + **A skin biopsy** involves removing a piece of skin about the size of the end of pencil (6mm) using a small round bladed instrument. We ask for a sample before you start your treatment, and then on day 3, day 14 and month 3 after you have started your treatment. It takes 20-30 minutes. We will use a small injection of local anaesthetic to numb the area. The biopsy area will require 2 to 3 stitches and will be covered with a dressing. You will need to have the stitches removed after 10-14 days. This can be done at your GP surgery or by the research team. You will have a scar at the site of the biopsy. This will fade over time but will not disappear completely. Participants must not use topical treatments (except for emollients) at the site of biopsy for at least 48 hours before the biopsy.
	+ **A skin tape strip** only samples the very top layer of the skin. We ask for a sample before you start your treatment, and then on day 3, day 14, month 3 and month 6 and annually after you have started your treatment. It involves applying some sticky tape about the size of a 10 pence coin on the skin and peeling it off around 5 times. It takes 15-20 minutes. It does not involve any injections or stitches.

**You will be asked whether you would be willing to have medical photographs taken**

We will ask if you are willing to have photographs taken of your skin. This will help us to monitor changes before and during treatment. We ask for photographs before you start your treatment, and then on day 3, day 14, month 3 and month 6 after you have started your treatment. All photographs will be stored safely and protected in accordance with Data Protection Act 2018. The photographs will be used for the purposes of scientific and medical research in the public interest. De-identified photographs may be published in scientific reports, journals, used in clinical presentations and educational materials, and/or in future research. This is an optional request. You can still take part in the study if you decide not to have photographs taken and it will not impact your medical care.

**You will be asked if you are willing to be recalled for future investigations**

Psoriasis research is a rapidly changing field and there are frequent advances in our analytical techniques. In the event that new discoveries are made or new aspects to explore, the researchers are requesting permission to contact you again to invite you to participate and/or provide further samples (e.g. finger prick samples or skin biopsies). You are agreeing only to be contacted at this point – you will again have the chance to say yes or no. This is an optional request and if you don't wish to give consent to be contacted for future investigations and studies, it will not impact your participation in this study nor will it impact your clinical care.

**BENEFITS OF TAKING PART IN THE STUDY**

You will not receive any financial benefit for taking part in this study and the results of the study will not be of any direct clinical benefit to you. However, by taking part in this study you will be providing vital information to the research team which we hope will lead to better management and treatments for people with psoriasis.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

Blood tests can sometimes be uncomfortable and cause bruising at the site. We will always try to take research blood samples from you when you are having your routine blood tests taken.

Skin biopsy is a routine investigation. There is a small risk of bleeding, bruising and infection of the sample site. There will be a scar at each biopsy site that will fade over time but not disappear. Tape stripping may be uncomfortable and may leave a temporary red mark. We will discuss all procedures in further detail before we ask you to sign the consent form and you will have the opportunity to ask questions.

**WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

Yes. You will be assigned a study number, which will used for all study-related material (including data) and data analysis. Only the approved delegated members of the study team will know which study number relates to you.

**WHAT WILL HAPPEN TO MY DATA?**

**How will we use information about you?**

We will need to use information from you and your medical records for this research project. This information will include your initials, date of birth, NHS number, name, and contact details.  People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Some of your de-identified information will be sent within this country and abroad. They must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

The information you provide will be even more valuable if you give us permission to link your data with additional sources including NHS digital and UK Public Health Organisations. To do this, in addition to the above identifiers we would like to collect your postcode. If you do not know your NHS number, we can use your name, date of birth and postcode to find it. We will ask for your consent to collect this extra information. It really helps us if you can provide your confidential information, but it is not essential. You can still participate in the study if you do not provide this information. You have the right to have your confidential information removed at any time. We will also ask your permission to link your data to other national research databases.

**What are your choices about how your information is used?**

⦁ You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

⦁ If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital. If you do not want this to happen, tell us and we will stop.

⦁ We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

⦁ If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

⦁ at www.hra.nhs.uk/information-about-patients/

⦁ our leaflet available from: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx (For GSTT) and www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (for KCL)

⦁ by asking one of the research team (contact details included below)

⦁ by contacting the Data Protection Officer: (For GSTT: Nick Murphy-O’Kane DPO@gstt.nhs.uk; For KCL: Olenka Cogias info-compliance@kcl.ac.uk)

⦁ by emailing dermatologytrials@gstt.nhs.uk

**WHAT WILL HAPPEN TO MY SAMPLES?**

All samples will be stored securely in accordance with the Human Tissue Act and according to national and local NHS Research Governance guidelines and will only be used for scientific research.

We may investigate your blood/skin for the purposes of the study; you will not have any financial benefits or rights over these samples. We plan to store your samples for as long as this and future studies continue at the main study (St. John’s Institute of Dermatology, Guy’s Hospital, London).

**WILL ANY GENETIC TESTS BE DONE?**

We will use the samples you provide to look at genes related to our research only (psoriasis and treatment outcomes). We will not use your DNA for any genetic tests to learn about personal risk of developing any other diseases.

**WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?**

When the study has been completed we will aim to publish the results in scientific journals/publications. We will also publicise our findings in patient information leaflets and on request. You will not be identified in any publication.

**WILL THE COST OF MY TRAVEL BE REFUNDED?**

Yes, if you attend study visits outside routine clinical care you will be reimbursed for reasonable travel costs incurred. You will also receive up to £60 per visit if you donate skin biopsies or up to £30 per visit if you donate tape strip or skin swab samples. Please ask a member of the research team who will provide more details on claiming expenses.

**WHAT HAPPENS IF I WISH TO WITHDRAW FROM THE STUDY?**

If at any time you wish to withdraw from the study we will provide you with a form to complete and return to us asking us to withdraw you from the study. On the withdrawal form, you will also be asked whether you are happy for us to continue accessing (i) your BADBIR record and/or (ii) your healthcare records. We will keep all samples and clinical information that we have already obtained, but will not contact you for further studies, if you do not want us to. Your participation in the study is voluntary. This will not affect your medical care in any way.

**WHAT IF THERE IS A PROBLEM?**

If you have a concern about any aspect of this study, please ask to speak to the researchers who will do their best to answer your questions. Please contact the study team using the contact details below.

If you have a complaint, you should talk to your research doctor who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure.  Details can be obtained through the Patient Advisory Liaison Service (PALS)

How to contact PALS:

* Visit us at St Thomas' Hospital in the main entrance (Monday-Friday, 9am-5pm), or at Guy's on the ground floor of Tower wing - in the main reception area (Monday to Friday, 9am-5pm).
* Telephone 020 7188 8801. You may get an answering machine if the team is busy. Please leave a message and we will return your call within 24-48 hours.
* Email: pals@gstt.nhs.uk
* Write to the PALS lead at the following address:

PALS

St Thomas' Hospital Westminster Bridge Road

London SE1 7EH

In the event that something does go wrong, and you are harmed during the research you may have grounds for legal action for compensation against Guy’s and St Thomas’ NHS Foundation Trust and/or King’s College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). This study has been reviewed and given favourable opinion by *the NRES Committee London – Westminster Ethics Committee (Ref: 11/H0802/7).*

**If you have understood all the information above and wish to participate in the study, you will be asked to sign a Consent Form. You should keep a copy of this Information Sheet for yourself.**

|  |
| --- |
| **CONTACT DETAILS** |
| **Principal Investigator: Prof Catherine Smith****Research Nurse:**John Gregory, April Neville, Louise Griffiths, Katherine TeatherTel : 07717 697 435 |
| **BSTOP Study Team**Skin Therapy Research Unit9th Floor, Tower Wing,Guys Hospital,London, SE1 9RTdermatologytrials@gstt.nhs.uk**In emergencies please contact your study doctor/nurse or local emergency services**  |