**Patient Information Sheet v5.1, 16 Jul 2019**

**TAKING PART IN PSORIASIS RESEARCH**

**Bio-markers of Systemic Treatment 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 a research study. Before you decide it is important to understand why the research is being done and what it will involve. 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. Please ask the study doctor or nurse to explain anything you do not understand

**What is the purpose of the study?**

There are a large number of drugs available for psoriasis but not all of these work for every person. We know that the genetic and biological make-up of each person is very important in determining how they will respond to treatment. We also know that not all patients who need to get treatment for their psoriasis receive it early enough in their disease journey. The overall research aim of this large, multi-centre study is to identify genetic or other markers that will enable us to give the right medicine, to the right patient at the right time. We will do this by systematically investigating genes, and how they are expressed and ‘translated’ into actions within the body by sampling blood and in some patients other biological samples (such as skin or hair pluck samples) as well as looking at how drugs are handled in the body. Once discovered, doctors will be able to use the genetic and biological blueprint of each patient to identify which treatments are most likely to work (and be the safest or least likely to cause side effects). This would be a major step forward compared to our current approach which is 'try it and see'. A second, major aim of our study is to create a clinical, sample and data resource for investigators to use for research that relates to any aspect of psoriasis.

**Why have I been invited?**

You have been invited to take part because you have psoriasis and are taking, or are about to start systemic or biological therapy for your psoriasis, or you have taken systemic therapy in the past. You may have also taken part in the ‘PSORT-D’ study.

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.

**What are the 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?**

There are no important risks to taking part in this study. Blood tests can sometimes be uncomfortable and cause bruising at the site. However we will try to take any research blood samples from you when you are having your routine blood tests taken to minimise discomfort.

You may also be invited to provide a skin biopsy. This will be optional, and agreeing to be contacted doesn’t mean you have to provide a sample. Skin biopsy is a routine investigation and would be performed by a trained member of staff who would take all safety measures to reduce the risk of any complications arising from the procedure. If you choose to provide skin biopsy samples there is a small risk of bleeding at the site of the sample, bruising around the site, and infection of the skin where the sample has been taken. You will be provided with this information again at the point you are invited to provide the sample.

**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 will taking part involve?**

**YOU WILL BE ASKED TO SIGN A CONSENT FORM**

In order to participate in the study we will ask you to sign a consent form. A study doctor or nurse will go through the consent procedure with you and explain the study in detail. If you are invited to give a skin biopsy sample, you will be asked to sign a separate consent form for this too.

**YOU MAY BE ASKED TO MAKE ADDITIONAL VISITS TO CLINIC**

For most participants, 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 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 new treatment (or returning to treatment after being off treatment for a long time) may be asked to return to clinic for other additional follow up visits at the first week, the fourth week and between 12-16 weeks 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. If you are invited to return to clinic outside of your routine clinical care to give additional samples, you may be eligible for reimbursement of reasonable travel expenses, on provision of receipts. Please confirm with your local team if you are eligible.

If you have been invited to participate in a one-off visit, you will likely not be required to return to clinic for a follow up at all. However, there is a small chance we may require a second sample at a later date, if there is any problem with your original sample. You will be asked again if that happens, and you will have another chance to say yes or no.

We can collect valuable information from you regardless of your stage of treatment or the frequency of your visit. Talk to the study nurse or doctor if you are unsure how often they would like to follow up with you.

**YOU WILL BE ASKED TO PROVIDE CLINICAL INFORMATION**

We need to collectclinical information about how you are responding to treatment and whether you have developed any side effects to the drug that you are on for your psoriasis. We also need to know your ethnic group, your current medical condition, the history of your psoriasis and whether you are taking any other medication. We aim to collect this information (along with samples, see below) during your normal clinical appointments to minimise the number of times you come to hospital. 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 are not compelled to answer all of the questions.

**YOU WILL BE ASKED TO PROVIDE BIOLOGICAL SAMPLES**

You will be asked to donate at least one blood sample for DNA (up to 12ml, or just over 2 teaspoons). In some circumstances it may be possible to donate DNA from saliva by spitting into a plastic pot (2mls approximately half a teaspoon). Your local research team will advise if this option is available. If you are taking part in the one-off visit, you will only donate a sample for DNA.

To help us investigate how your treatment is being affected by your body, and how your body is being affected by the treatment, you may be asked to donate additional blood samples at each visit (for RNA, plasma or serum). The volume requested at a standard follow-up visit would be 5 teaspoons if you are on Methotrexate, 4 teaspoons for all other treatments.

A smaller group of patients may also be invited to give additional samples during the first 12-16 weeks after starting a new medication, or at later points during your study participation. The total blood taken per visit including these additional samples will not exceed 100ml (20 teaspoons) in addition to any routine clinic bloods, which is completely safe. For reference, blood donors give around 470ml. You may also be invited to give skin samples, of either or both skin biopsies, or skin microbiome samples (swabs). All samples are optional and you do not have to agree, and it will not affect your participation in the wider study or your clinical care. The skin biopsy procedure involves taking a 6mm punch biopsy from either normal skin, or skin affected by psoriasis, or both. The skin microbiome swabs are a non-invasive method of gently collecting skin cells from the surface of your skin. The trained team member who would take the sample(s) will talk you through the procedure before you give consent.

**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.

**Will my taking part in the study be kept confidential?**

Yes. When you consent to take part in the study you will be assigned an anonymised study number. This number will used for all study-related material (including data) and data analysis. No person-identifiable information will be used in any correspondence. Only the coordinating centre study team and your local research team will know which anonymised number relates to you.

**What will happen to my data?**

All your data will be stored and managed in accordance with the General Data Protection Regulation (GDPR; 2018) and the International Conference on Harmonisation for Good Clinical Practice. Your data will be held on secure, confidential databases for the purpose of this study, to which only the Chief Investigator and approved delegated members of the study team will have access. The database may be one developed and maintained by Guy’s and St Thomas’ NHS Foundation Trust, held on a secure server behind the NHS Trust firewall, known as CAPTURE. Identifiable information about you (e.g. name, date of birth and NHS number) entered on this database will only be accessible to the Chief Investigator and approved delegated members of the study team, and will only be used locally for the purposes of participant tracking and, if you have given permission, for recall to invite you back for further investigation or samples.

By consenting to take part you are agreeing that, in the event of an inspection or audit by the sponsor or Regulatory Authorities, authorised staff and CAPTURE administrators will also have access to your identifiable information and study data.

By signing the consent form, you are agreeing that your anonymised study data (including clinical information, samples and research data arising from samples taken) can be shared with the research team including study collaborators, who may include industry partners, and who may be located outside of the country or region (e.g. the European Union) in which you live. Your study data will always be kept confidential, secure and anonymised and used only for the purposes of research on psoriasis for this and future studies.

**ADDITIONAL INFORMATION ON GENERAL DATA PROTECTION REGULATION (GDPR)**

Guy’s & St Thomas’ NHS Foundation trust (GSTT) is the sponsor for this study, based in the UK. We will be using information from you and your medical records in order to undertake this study, and will act as the ‘data controller’ for this study. This means we are responsible for looking after your information and using it properly. GSTT will keep identifiable information for up to 12 months after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep some information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out how we use your information here:

<https://www.guysandstthomas.nhs.uk/research/patients/about.aspx>

GSTT will collect information about you from the trust at which you are being treated. This information will include your name, and may include your hospital number and NHS number. These details are used for the purpose of patient management, which include recording who is taking part in the research, and making sure we can identify the data and samples that belong to you. The information is only accessed by the study team at your local hospital, and key personnel at the sponsor site, as described above. The local hospital may also provide some contact details if you have consented to being recalled (an optional item on the consent form, q11). The team will also share some health information related to your participation, which is regarded as a special category of information. We will use your health information to answer our research questions, summarised above.

**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 your personal risk of developing any other diseases.

**What will happen to my DNA, RNA and my other samples?**

All samples, including the DNA extracted from your blood cells, saliva or skin, 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 related to skin disease.

We plan to store your biological samples and data for the duration of this study and for future research into skin disease in an ethically approved research bioresource and database at St. John’s Institute of Dermatology, Guy’s and St Thomas’ NHS Trust.

**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 via our website, in patient information leaflets and on request. . You will not be identified in any publication.

**Who can I contact for further information on the study?**

Please contact the research 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) [insert local details].

**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. All samples and clinical information we have obtained up until the point of withdrawal will continue to be used, but we will not collect any further information at study visits. Your participation in the study is voluntary. None of these actions will affect your future treatment.

**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.**

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| **CONTACT DETAILS** |
| **Principal Investigator:**  **Research Nurse:**  (Insert Local Research Name & Address)  Tel : (Insert Local number) |
| **BSTOP Study Team**  Skin Therapy Research Unit  9th Floor, Tower Wing,  Guys Hospital,  London, SE1 9RT  [dermatologytrials@gstt.nhs.uk](mailto:dermatologytrials@gstt.nhs.uk)  **In emergencies please contact your study doctor or local emergency services** |

**Research Team at Guy’s and St. Thomas’ NHS Trust (Coordinating centre):**

**Professor Catherine Smith**: Chief Investigator and Consultant

**Professor Jonathan Barker:** Co-investigator and Consultant