

**PATIENT INFORMATION LEAFLET**  
**Patients with pustular psoriasis and disease controls**

**STUDY TITLE: Pustular psoriasis, eLucidating Underlying Mechanisms (PLUM)**

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. Please ask the study doctor or nurse if there is anything that is not clear or if you would like more information.

**WHAT IS THE PURPOSE OF THE STUDY?**

Pustular psoriasis is a rare but very severe skin disease. Current therapies have limited efficacy and may cause significant side effects, partly because the cause of the disease is not fully understood. With this study, we seek to identify the genetic defects that cause pustular psoriasis and understand how they alter immune responses and result in disease. We are also seeking to establish whether pustular psoriasis and autoinflammatory disorders (a group of inherited diseases that manifest with recurrent fevers and skin rashes) are caused by similar disease mechanisms. This knowledge will help to guide the development of more effective, less toxic treatments.

**DO I HAVE TO TAKE PART?**

No. Taking part is entirely voluntary and your future medical 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. 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 clinical information**

We need to collect basic clinical information from you regarding your general health, family history and whether you are taking any medications. To minimise the amount of time required for you to participate in the study, data will be collected from 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 provide a sample of your blood**

You will be asked to donate some blood samples (up to 7 teaspoons i.e. 35ml) to look at your genes (often called "DNA"), and RNA, which is related to DNA. Finally, we will perform a full blood count. If the latter was to reveal any anomalies in the numbers of your blood cells, we will contact you to discuss these results. 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 (approximately half a teaspoon) into a plastic pot.

**You will be asked whether you want to provide a skin sample**

We will also ask if you are willing to provide a small skin sample, as this would help us to determine the function of the genes contributing to psoriasis. You can still take part in the study if you decide not to provide a skin sample and it will not impact your clinical care.

If you are willing to donate a small (2mm) sample of your skin, we will use a punch biopsy, which is a small round bladed instrument. It takes 20-30 minutes and will be carried out by a doctor or specialist nurse. A 2mm 'microbiopsy' sample is taken under local anaesthetic and may require a stitch, although for such a small sample a stitch is usually not necessary. The dressing/plaster will

need to be kept dry initially to make sure it stays in place but healing should be straightforward. You may have a small scar at the site of the skin sample.

**You will be asked whether you would be willing to make another visit to the clinic**

Depending on the results of your DNA analysis, we may ask you to come back to the clinic to donate a further blood sample (no more than 7 teaspoons, i.e. 35ml) and/or ten hair plucks, which we would gently pick from your scalp, using tweezers. These are important samples that would help us understand how genetic defects cause disease. This is an optional request. You can still take part in the study if you do not wish to be contacted again.

All participants will attend at least 1 study visit. If further information or samples are required, you may be invited to attend on up to 4 further occasions. Every effort will be made to coordinate study visits with existing scheduled clinic appointments so that additional trips to hospital are not required. Each study visit is expected to last about 30 minutes.

**BENEFITS OF TAKING PART IN THE STUDY**

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 and less toxic treatments for people with pustular psoriasis in the future.

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

Blood tests can sometimes be uncomfortable and cause bruising at the site. Potential risks of a skin microbiopsy include local discomfort, bleeding, and/or rarely infection. Although the microbiopsy is not large (2mm), a small scar will be left. It is a routine investigation performed within the dermatology department and our experienced staff will take all safety measures to reduce complications from the procedures performed. 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 an anonymised study number, which will be used for all study-related communications. No person-identifiable information will be used in any correspondence. Only the Chief Investigator and approved delegated members of the study team will know which anonymised number relates to you. With your permission, we will notify your GP that you are participating in this study.

**WHAT WILL HAPPEN TO MY DATA?**

All your data will be stored in accordance with the Data Protection Act 2004 and the International Conference on Harmonisation for Good Clinical Practice. Your data will be held on a secure, confidential database for the purposes 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 (eg 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 for future studies. 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.

All study data and samples used and analysed in the research will be anonymous and identified by a unique study identification number.

Our team collaborate on pustular psoriasis research throughout the world. By signing the consent form, you are agreeing that your anonymised study data and your biological samples can be shared with research collaborators and industry partners who may be located outside of the country. Study data will be retained within the department for as long as this and future studies of pustular psoriasis continue, and for at least 25 years.

#### **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 related to psoriasis. We may culture cells from your blood/hair/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 of pustular psoriasis continue at the main study site (St John's Institute of Dermatology, Guy's Hospital, London). With your agreement, we will store your samples for future research into skin disease in a research bio-bank at St. John's Institute of Dermatology, Guy's and St Thomas' NHS Trust: Ethics Approval Ref: 07/H0712/106; HTA License number 12521 and related data (e.g.name and ID number) on our database (described above).

#### **WILL ANY GENETIC TESTS BE DONE?**

We will use the samples you provide only to look at genes related to our pustular psoriasis research. We will not use your DNA for any tests to learn about your risk of developing any other disease.

#### **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. Please let us know if you wish to be informed of the publication of the study and we will aim to keep you fully informed. You will not be identified in any publication.

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

If you need to make an extra visit to the hospital specifically for the study, we will reimburse reasonable travel expenses, e.g. for a recall visit. Please ask a member of the research team who will provide more details on claiming expenses and will provide you with an expense form.

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

You can withdraw from the study at any time without having to give a reason. This will not affect your medical care in any way. We will keep all samples and clinical information that we have obtained up until the point of withdrawal, but will not contact you for further studies, if you do not want us to.

#### **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. 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) [insert local details].



**PLUM**  
PUSTULAR PSORIASIS: ELUCIDATING  
UNDERLYING MECHANISMS

This study is sponsored by Guy's and St Thomas' NHS Foundation Trust. The sponsor will at all times maintain adequate insurance in relation to the study independently, through its own professional indemnity (Clinical Trials) and no fault compensation. This study has been reviewed and given favourable opinion by the London Bridge Research Ethics Committee (Ref: 16/LO/2190).

**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.**

<b>CONTACT DETAILS</b>
<b>Principal Investigator:</b> <b>Research Nurse:</b> (Insert Local Research Name & Address) Tel : (Insert Local number)
<b>PLUM Study Team</b> Skin Therapy Research Unit 9th Floor, Tower Wing, Guys Hospital, London, SE1 9RT  <a href="mailto:dermatologytrials@gstt.nhs.uk">dermatologytrials@gstt.nhs.uk</a>  <b>In emergencies please contact your study doctor or local emergency services</b>