

## PARTICIPANT INFORMATION SHEET

**Title of Study: Understanding inflammatory skin diseases over the long-term: MySkin, a longitudinal cohort study**

**(Phase 2 - Frequently Asked Questions)**

*Ethics Ref: 22/NI/0193; Date of Approval: 19/12/2022*

We would like to invite you to participate in the MySkin study, which forms part of our programme of skin disease research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

### **What is the MySkin study?**

MySkin is an online survey for people with psoriasis who live in the UK. It takes about 10 minutes to complete. We will ask you to log your progress in shorter follow up surveys every 3 months.

### **Why do we need the MySkin study?**

Psoriasis is a lifelong skin disease that changes over time – some days are worse than others. The MySkin study will uncover how everyday behaviours, physical health and mental wellbeing impacts psoriasis. This knowledge will help us to understand how to reduce the risks of psoriasis, so that people with psoriasis can live healthier lives for longer.

We are asking for people with psoriasis to regularly enter data about their skin and health into MySkin so that we can build a detailed picture of how psoriasis can change over time, and why. By contributing to MySkin you will help improve scientific understanding and ultimately treatments for people with psoriasis.

### **Who should take part in the MySkin study?**

Any adult with psoriasis who lives in the UK can take part, whether you have lived with psoriasis for some time or are newly diagnosed. We are keen to hear from everyone, whether you have a small area of skin affected or widespread psoriasis.

You can complete MySkin if you are aged 16 years and over.

### **What do I need to do?**

Please complete the online survey, which is found online at [www.myskin.org](http://www.myskin.org).

We will ask you to create a login to MySkin before we collect any information. Please keep your username and password safe.

We will ask for your consent to collect information from you. We will ask you to provide an electronic signature ('e-consent').

### **What information are you collecting?**

We are collecting information about you and your psoriasis, including any treatments that you are using. We will ask about your physical health, mental wellbeing and everyday behaviours such as your diet and physical activity.

### **Are you collecting photographs of psoriasis from everyone?**

We will ask you to take photos of your skin using your own phone and upload the photos to our secure database. This is optional and does not affect the rest of your participation in the MySkin study.

If you can provide photos, we will use the photos to assess how active your psoriasis is, and to help develop accurate digital skin assessment methods. Your photos will be confidentially uploaded to our secure database. Your photos will be stored safely and protected in accordance with UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, and used for the purposes of scientific and medical research in accordance with the existing ethical approval of our study. De-identified photos from the study may be published in scientific reports, on the study website, used in clinical presentations and educational materials, and/or in future research.

### **I do not want to provide photographs of my skin for confidential upload to the secure MySkin study database. Can I still take part in the MySkin study?**

Yes, providing photos is optional and does not affect the rest of your participation in the MySkin study.

### **Are you linking my data with my NHS healthcare record or other datasets?**

The information you provide will be even more valuable if you give us permission to link your data with additional health records including NHS, UK Public Health organisations, homecare companies who provide biologic/injection treatments, and other research studies that you may have contributed to (e.g. BSTOP). To do this, we need to collect your date of birth, NHS number, name and postcode. If you do not know your NHS number, we can use your name, date of birth and postcode to find it.

### **How often do I need to complete MySkin?**

We will invite you to log your progress in follow up surveys every 3 months. We will ask you to tell us about your skin and how you feel, including any changes to your health. You will need to enter your username and password before you can enter this information.

### **How will I know when a follow up survey is required?**

We will ask for your phone number or email address so that we can let you know when to complete a follow up survey.

### **What happens if I miss one of the follow up surveys?**

It really helps us if you can regularly log your progress in follow up surveys every 3 months so that we can build a detailed picture of how psoriasis can change over time, and why. If you have missed a follow up survey, please complete it as soon as you are able to.

### **What if I forget my username and password?**

You can ask for your username and password to be emailed to you by contacting us. Please contact us if you require further support.

### **What happens to my information and how is it protected?**

We will be collecting your information through a secure website. The information that we collect from you is stored safely on a secure, confidential database at King's College London, UK and protected in accordance with UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018. All study data will be identified by a unique study identification number and only approved delegated members of the study team will know which study number relates to you. The study team will analyse the information and it will only be used for the purposes of scientific and medical research, in accordance with our ethical approval. The MySkin study has been formally approved by an independent ethical review board (REC reference 22/NI/0193).

Personal identifiable information that you entered in MySkin (e.g. name, date of birth, NHS number, telephone and email contact) will only be accessible to approved delegated members of the study team. It will not be provided to any third parties. Personal identifiable information will be used locally for the purposes of participant tracking, linkage of your data to relevant datasets held by national providers of healthcare data or existing research datasets and, if you have given permission, for recall for future studies. In the event of an inspection or audit by the sponsor or regulatory organisations, authorised staff will have access to your medical and research records to check the accuracy of the research study. Study data will be retained for as long as this and future studies continue, and at least 5 years.

Our team collaborate on research throughout the world. By signing the consent form, you are agreeing that your de-identified study data can be shared with research collaborators running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies (e.g. industry partners) involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. Sharing de-identified information with researchers will always be under relevant data protection and information governance regulations. Your information will not be used for commercial purposes. The MySkin study is a not-for-profit initiative.

Please contact us if you have any questions or would like to find out more.

### **Can I view a summary of the information collected in the MySkin study?**

Yes, you can view a summary of information from everyone who has completed MySkin online ([www.myskin.org](http://www.myskin.org)). This summary is freely available to everyone, and you do not need to log in to view it.

### **What if I decide to withdraw from the study?**

You have the right to withdraw from participating in the MySkin study at any time. Please contact us to let us know that you do not wish to continue your participation in the MySkin study. After you withdraw from the study, we will not contact you again for follow up surveys. You may also be withdrawn if you lose capacity to consent during the study.

In view of the nature of the study, identifiable information or samples that have been submitted prior to withdrawal will be kept by the research team for the purposes of scientific and medical research, in accordance with our ethical approval (REC ref 22/NI/0193). The information will be protected in accordance with UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, and stored securely at King's College London, UK.

### **I have other health conditions in addition to psoriasis and have already reported my experience in other surveys. Should I still complete MySkin?**

Yes, please still complete MySkin. By telling us about your skin and how you feel, you will providing valuable information for research into psoriasis. Your information will help us find out how everyday behaviours, physical health and mental wellbeing impacts every aspect of psoriasis. This knowledge will help us to understand how to reduce the risks of psoriasis over the long term and ultimately improve treatments for people with psoriasis.

### **How can I get support to complete the MySkin survey?**

If you are unclear about how to answer any questions, please contact us.

### **Is the MySkin survey only available online?**

Yes, the survey is only available online at [www.myskin.org](http://www.myskin.org). No paper versions are available.

### **My circumstances have changed since I last completed the MySkin survey, can I add new information?**

Yes, please log into MySkin and add a new health update. Please contact us if you have any questions about this.

### **My skin was worsened (flared) since I last completed the MySkin survey, can I log this new information?**

Yes, we would like to hear from you if your skin has worsened. Please log into MySkin and complete a flare follow up survey. Following this submission, we will invite you to submit short weekly follow up surveys

for the next 4 weeks so that we can build a complete picture of how psoriasis affects physical health, mental wellbeing and quality of life. We will not be informing your medical team - please contact your medical team if you need help with your skin treatment.

### **I live outside the UK. Can I still take part in the MySkin study?**

The study is currently running in the UK. Please email us to join our contact list so that we can let you know about other opportunities to contribute to psoriasis research.

### **Should I tell others that I am taking part in the MySkin study, for example my dermatologist?**

Yes, you can inform anyone that you are taking part in the MySkin study, including your dermatologist.

### **Are you collecting blood or saliva samples?**

We are collecting self-taken blood or saliva samples from a subset of people who have participated in the MySkin study. This will help us to build a more detailed picture of the factors that change a person's risk of psoriasis. We will ask you if you are happy to be contacted in the future for this purpose. This is entirely optional and does not affect the rest of your participation in the MySkin study.

If you can provide a blood sample, we will ask you to collect a finger prick blood test in a small plastic tube. We will use your blood sample to look at your genes (often called "DNA") and proteins. We can also isolate DNA from saliva, in which case you will be asked to spit 2ml (half a teaspoon) into a plastic pot. We will use the samples you provide only to look at genes related to psoriasis and other inflammatory disease research. We will not use your DNA for any tests to learn about your risk of developing any other disease. We will post the blood or saliva kit to you. Blood tests can be uncomfortable and cause bruising at the site. The kit will contain full instructions on how to take the sample safely and we will provide a transport pack so that you can return your sample to us. Please contact us if you require further support.

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 accessible to approved designed members of the research team and used for scientific research. We plan to store your samples securely for as long as this and future studies 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 in a research biobank 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 secure database.

You may have previously provided blood, saliva and/or skin samples for other research studies (e.g. BSTOP). We will use your personal identifiable information (e.g. name, date of birth, NHS number) to link your MySkin data to these existing research studies so that we can build a more complete picture from all of the information that you have provided for research.

### **Who designed the MySkin study?**

The MySkin team is a group of doctors and scientists at St John's Institute of Dermatology at Guy's Hospital, King's College London, and patient representatives from the Psoriasis Association. We co-designed MySkin with patients and professionals involved in the care of people with psoriasis. We collaborate with patient and professional organisations and leading researchers globally, so that our research can rapidly advance scientific understanding and improve healthcare, for the benefit of people with psoriasis.

### **Who is funding the MySkin study?**

We receive funding from a number of sources including the National Institute for Health and Care Research and the Psoriasis Association.

### **Where will I find the results of the MySkin study?**

We aim to publish the results in scientific journals and will publicise our findings via our website, research partners (e.g. Psoriasis Association), in patient information leaflets and on request. You will not be identified in any publication. Please visit our publications page online ([www.myskin.org](http://www.myskin.org)) for updates.

### **What if there is a problem?**

If you have a concern about any aspect of this study, please contact our study team, who will do their best to answer your questions.

If you have a complaint, you should contact our study team, 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) (020 7188 3514). 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. This study has been reviewed and given a favourable opinion by the Health and Social Care Research Ethics Committee B (Ref: 22/NI/0193).

**Thank you for taking the time to read this information sheet. We are very grateful for any support you feel able to give to this study. Our hope is that with your help, the care available to people with psoriasis can be improved.**

**If you have understood all the information above and wish to participate in the MySkin study, please proceed to the online survey, which is found at [www.myskin.org](http://www.myskin.org). We will ask you to create a login to MySkin before we collect any information. We will next ask for your consent to collect information from you. You should keep a copy of this information sheet for yourself.**

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