Supplementary Document 1: Adult Participant information sheet and consent form

Guy's and St Thomas' NHS
NHS Foundation Trust

Understanding Ultraviolet Protection in Xeroderma Pigmentosum (XP): A Research Study

PARTICIPANT INFORMATION SHEET
ADULT

Invitation

We invite you to take part in a research study at Guy's and St Thomas' NHS Foundation Trust. 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 this if you wish. 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.

Information

1. **WHAT IS THE PURPOSE OF THE STUDY?** Avoidance of ultraviolet from sunlight and daylight is the only way to reduce the number of skin cancers and eye problems in patients with XP. However, it is very difficult and not very pleasant to have to avoid all ultraviolet exposure and some patients find it harder than others to avoid ultraviolet. We want to try to make it easier for people with XP to protect their skin and eyes from ultraviolet. To do this we are first trying to measure how much ultraviolet people with XP do get exposed to, and to find out what patients find most difficult about having to avoid ultraviolet.
We hope that information gained from this study will help us to improve the help we give to patients who are having difficulty avoiding ultraviolet.

2. **WHY HAVE I BEEN CHOSEN?** You have been asked to help because you have Xeroderma Pigmentosum (XP).

3. **DO I HAVE TO TAKE PART?** No, it is 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 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 not affect the standard of care you receive.

4. **WHAT WILL HAPPEN TO ME IF I TAKE PART?**
The researchers will arrange to visit you in your home at a time convenient to you. There will be up to 3 visits.

   Over the 3 visits they will:

   A. Have a guided conversation with you about your XP, your ultraviolet (UV) protection, including the problems you experience and the ways it affects

you and your family's life. This will be conducted by a specially trained researcher. It is likely that the conversation will be done at one visit and the rest done at another time. The conversation will take about an hour.

We would like to record this conversation to make it easier to analyse, but if you prefer not be to be recorded the researcher will take notes instead. We will type out the recorded conversation to learn from the research. The audio recording will be kept safe, and we will delete it as soon as it has been typed out.

B. Ask some questions which are tests to assess memory and other neurological function.

C. Ask you to complete a short questionnaire about your XP, your UV protection, how you and your family cope with XP, your thoughts about your XP, and about the financial burden that the XP is putting on you and your family.

D. Leave with you some tubes of sunscreen, a UV detecting wristwatch, and an activity diary for you to record when your activities and your UV protection when outside.

You will wear the wristwatch for 3 weeks and fill in the short daily activity diary every day for 50 days. The research nurse will come back after 3 weeks to collect the tubes of sunscreen and the UV wristwatch.

5. **WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?** There are no foreseeable disadvantages or risks.

6. **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?** There are no immediate benefits to you for taking part. However, we want to use the results from this research to find new ways of making it easier for patients with XP to protect themselves from ultraviolet. If we manage to do that, we may be able to offer that to you in future years. However we can provide study updates and feedback on your activity diary if you would find this interesting.

7. **WHAT IF YOU HAVE A QUESTION ABOUT THE RESEARCH**? It is usual to have comments or questions about research. Contact our research nurse Lesley Foster on 07775111823 or e-mail her at Lesley.Foster@gstt.nhs.uk who will be happy to answer your questions. She can also pass on your query to other members of the team.

8. **WHAT IF THERE IS A PROBLEM?** If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions. Contact our research nurse Lesley Foster on 07775111823 or e-mail her at Lesley.Foster@gstt.nhs.uk or Dr. Sarkany on Robert.sarkany@gstt.nhs.uk. If you

wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the patient advice and liaison service (PALS) tel: 020 7188 8801 email: pals@gstt.nhs.uk.

9. **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?** Yes, only members of the Research team will have access to patient identifiable information. If you participate, members of the chief investigator's team may also need to obtain the relevant medical records from Guy's and St Thomas' NHS Trust and from other hospitals where you have been treated or had skin surgery. All information will be kept strictly confidential and individuals will be given a code. If at any time in the future data from this study is shared, presented or published, all information will be anonymised and individuals will not be identifiable.

10. **WHAT WILL HAPPEN IF I WISH TO WITHDRAW FROM THE STUDY?** You can withdraw from the study at any time. With your consent any data collected up to the point of your withdrawal may still be used in the study. However if you choose we will destroy any data collected for the research only. Withdrawal from the study will not affect your clinical care in any manner.

11. **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?** We aim to publish the results of these studies in scientific journals and give presentations at academic meetings. It will not be possible to identify any individual patient from the published data. We can provide you with a summary of our findings if you would find this interesting.

12. **WHO HAS REVIEWED THE STUDY?** All the research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable ethical opinion by Camden and Kings Cross Research Ethics Committee

13. **CONTACT DETAILS:**

Nurse Lesley Foster, National Xeroderma Pigmentosum Service
Floor 2, Block C, South Wing
St. John's Institute of Dermatology
St Thomas' Hospital
Westminster Bridge Road
London SE1 7EH

Nurse Lesley Foster
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E-mail: Lesley.Foster@gstt.nhs.uk
Fax: 020 7188 1621

Thank you for taking the time to read this information sheet. Should you decide to take part in the study you will be given a copy of the information sheet and signed consent form for further reference.

Study Number: Patient ID No:

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CONSENT FORM

	Please initial box	
	Yes	**No**
1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐	☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals at Guy's and St. Thomas' NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐	☐
4. I give permission for the conversation with the researcher to be tape recorded and understand that the tapes will be deleted once the conversation is written up.	☐	☐
5. I hereby consent to take part in the study	☐	☐
6. I agree that any data may be retained in the study if I lose the capacity to consent, though no further data will be collected	☐	☐

Name of Patient *Date* *Signature*

Name of person taking consent *Date* *Signature*

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.