THESEUS

TREATMENT OF HIDRADENITIS SUPPURATIVA EVALUATION STUDY

COHORT PATIENT INTERVIEW INFORMATION SHEET

You are being invited to take part in an interview study that is part of the THESEUS research study, being run by Cardiff University and the University of Nottingham. Before you decide, it is important for you to understand why this research is being done and what it would involve for you. 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. Take time to decide whether or not you wish to take part.

Thank you for reading this.

WHAT IS THE PURPOSE OF THE STUDY?

To strengthen the study and to support the clinical aspects of the THESEUS study we would like to interview people with HS to gain an understanding of your experience of those treatments used to manage Hidradenitis Suppurativa (HS). We are also interested to find out about your experience of taking part in the THESEUS study, and about the impact that the study has had upon those involved in the research.

Insight from people with HS with regard to their experience of HS treatment and about taking part in THESEUS will help us to make recommendations about the focus and design of future HS research.

WHY AM I BEING ASKED TO TAKE PART?

We are inviting you to take part as you are already taking part in the THESEUS study. We are inviting you because you have previously indicated that you might be interested in taking part in a THESEUS study interview.

We want to find out a range of people's attitudes about HS treatment and the THESEUS study. We are including people from different parts of the country and people who have experienced the different treatments which are included in the THESEUS research.

WHAT WILL I HAVE TO DO IF I TAKE PART?

On the consent form that you signed at the start of the study, you agreed that you would be happy for a research team member to contact you via telephone or email to see if you would like to take part in an interview. When you receive this phone call or email the researcher will confirm with you if you are interested in taking part. If you are interested, then you will be provided, via email, with an information sheet (PIS) and a copy of the consent form. You will also be asked when would be a convenient time for you to do the interview. Due to the COVID-19 pandemic, these interviews would be over the telephone and not in person. If you are happy to take part after reading the PIS you will be asked to provide your consent. The researcher would ask if you are happy to provide your consent over the telephone, the researcher will complete the consent form on your behalf and the consent taking process will be audio recorded. Once a researcher receives your consent to take part, the interview will then take place.

During the interview the researcher will talk to you about your personal experience of HS treatments, about the treatments that you have used during the THESEUS study, and about your experience of the research processes involved in THESEUS. There will be an

opportunity for you to raise issues or topics which you think are relevant to HS treatment and/or HS research.

The interview will last approximately 30 to 60 minutes, and will, with your permission, be recorded using a digital recorder and kept confidential. A copy of the recording will be stored securely at the University of Nottingham. A written account of the interview recording (a transcript) will be made by a transcription service company and this will be shared with the University of Nottingham. The transcripts will also be transferred onto a secure server on the Cardiff University network. The transcript will not contain any information that could identify you. If you do not wish to have the interview recorded, you can indicate this on the consent form and the researcher will take handwritten notes during the interview.

DO I HAVE TO TAKE PART?

No. It is for you to decide whether you wish to take part or not. Even if you initially decide to take part and consent, you are free to withdraw from the study at any time, without giving a reason. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. Whether or not you choose to take part will not affect the standard of care that you receive.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

If you do take part, you will be contributing to our knowledge about people's experiences of HS treatment and helping us to design better HS studies in the future. We hope that this information will help guide practice for the future care of HS patients. You may also find the experience interesting, as you will have the opportunity to tell us, confidentially, what you think about your HS treatment and research.

WHAT ARE THE POSSIBLE DISADVANTAGES OF TAKING PART?

Talking to the researcher will take up a small amount of your time. We do not expect this to happen, but you might be asked questions about certain topics which are sensitive or may upset you. You can refuse to answer any questions which you feel uncomfortable with, or you can stop the interview at any time.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

What you say in your interview will be kept strictly confidential, in that the recordings will not be shared with anyone other than the members in the research team and a transcriber. What you say/communicate in your interview may be typed out by a professional transcriber (external company) to make a transcript. All identifiable information in the transcript will then be anonymised by changing your name and place names for example.

In some instances, authorised persons at Cardiff University (the sponsor of the study) may need to access data for monitoring of the quality of the research. All members of the research team and sponsor are trained in data protection issues and bound by the terms of the General Data Protection Regulation (EU 2016/679).

With your agreement, we may quote some of the things you have said in writing about the research, but these would be anonymous – your name will not appear in any reports.

We will not share anything you have told us with NHS staff, or anyone else, without your permission. However, there may be very rare circumstances where confidentiality may need to be breached. Such a breach would only occur in the most extreme cases, if, for example, information disclosed related to criminal activity or implied that an individual has been, or is, at risk or harm.

WHAT WILL HAPPEN TO MY PERSONAL INFORMATION?

Cardiff University, based in the United Kingdom is the sponsor for this study. Cardiff University will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cardiff University will keep identifiable information about you for 15 years 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 the 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 more about how we use your information at: https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection or by contacting the THESEUS Trial Manager: THESEUS@cardiff.ac.uk/ 02920 687616

WILL MY GP BE INFORMED?

If you choose to be interviewed, your GP does not need to be informed.

WHO HAS REVIEWED THIS STUDY?

Before any research goes ahead it has to be checked by an independent group of people, called a Research Ethics Committee, to make sure that the research is fair. This study has been approved by the National Research Ethics Service. In addition, people with HS have been involved in designing this study and their suggestions have been added to this leaflet.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is funded by the 'National Institute for Health Research' Health Technology Assessment programme. The sponsor is Cardiff University. Interviews will be undertaken by the University of Nottingham.

WHAT DO I DO NOW?

If you are interested in taking part please initial all the boxes in the consent form and sign and date the consent form. There is a section on the consent form for you to provide your contact details in order for a member of the research team to contact you about the interview. Please return the consent form in the freepost envelope provided.

WHO CAN I CONTACT FOR MORE INFORMATION?

If you do not understand anything on this information sheet, would like more details or if you are unhappy with any aspect of this study please contact:

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THANK YOU FOR READING THIS INFORMATION SHEET AND FOR CONSIDERING WHETHER TO TAKE PART.

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