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**Audio-recording discussions and interviews**

**Patient Information Sheet**

We would like to invite you to take part in a research study that looks at how doctors and nurses explain research studies to patients, and to help us with how we present information about Topic 2. This is part of the main Topic 2 study and is being undertaken by researchers from the University of Bristol. Before you decide if you would like to take part, 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 and talk to others about the study if you wish. One of the team will go through this leaflet with you and answer your questions.

What is the purpose of this study?

We are inviting you to take part in a study, which looks at how people make decisions about participating in clinical studies like Topic 2. Currently we know little about how people make decisions about whether or not to take part in clinical studies. One way to improve our knowledge is to audio-record the conversations you have with hospital staff about your possible participation in the Topic 2 study. This will help us to understand better how the information about the study is presented to you, and how we could improve the way we discuss the study with patients in the future. Interviewing you after you have made your decision about whether or not to take part in the Topic 2 study will also help us to understand how you came to your decision.

Why have I been invited?

We are inviting you to take part in this study because you have had discussions (or will soon have discussions) with your doctors and nurses about joining a clinical study called **the TOPIC 2 study**. We would like to improve the way doctors and nurses explain clinical research to patients such as yourself.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision not to take part or a decision to withdraw will not affect the standard of medical care you receive or your legal rights. You can still take part in the Topic 2 study without taking part in this particular study.

**What will happen to me if I take part?**

Taking part in this study will involve two main things:

1. We will ask your permission to audio-record appointments during which doctors and nurses explain the Topic 2 study and what taking part entails. We would like to record these discussions to understand how clinical staff communicate information about the Topic 2 study.
2. After you have made a decision about whether or not to take part in the Topic 2 study, we may invite you to be interviewed by the Topic 2 Qualitative Researcher at a location of your choice (or over the telephone, if you wish). If you agree, your interview with the researcher will be audio-recorded. The researcher will ask about your views on the information conveyed to you by doctors and nurses, and how you came to a decision about whether or not you would like to take part in the Topic 2 study. Before the interview starts, we will ask you to sign a consent form. (NOTE – ONLY A SMALL NUMBER OF PATIENTS WILL BE INVITED TO TAKE PART IN AN INTERVIEW).

You will be asked to sign a consent form indicating whether or not you give permission for each of the above activities. You do not have to agree to all or any of these activities.

What are the possible risks or disadvantages of taking part?

There are no physical risks to taking part. It is possible that talking about issues related to health and clinical care can cause some people anxiety. If this happens, the interview can be paused or stopped at any time, and there will be no obligation to continue.

## What are the possible benefits of taking part?

We cannot promise the study will help you directly, but the information we get will help us to improve the ways we communicate information about the Topic 2 study and similar clinical studies in the future.

**What if there is a problem?**

Because this study does not involve any medical interventions, it is extremely unlikely that you will be put at any risk by taking part. However, if something goes wrong and you are harmed by taking part in this research, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will still be available to you. You are also free to contact the individuals named at the bottom of this information sheet.

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

All information collected about you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and care research and will be kept strictly confidential. Birmingham University is the Sponsor for this study and Birmingham Clinical Trials Unit (BCTU) is where the study co-ordination team are based. The audio-recording and interview data will be recorded on an encrypted device (password protected) and stored by researchers at the University of Bristol. These organisations are responsible for looking after your information and using it properly. To allow the results of the study to be verified if needed, information will be help about you by the data controllers of this study (University of Birmingham and University of Bristol) for at least 25 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.hra.nhs.uk/information-about-patients>.

Your local recruiting hospital will collect information from you and your medical records for this research study and will transfer it securely to the coordination team at the University of Bristol. Data relating to the patient audio-recording and interview study will be stored securely on a server at the University of Bristol.

Your local recruiting hospital, researchers at the University of Bristol or the University of Birmingham will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the Sponsor and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local recruiting hospital and researchers at the University of Bristol and University of Birmingham will keep your name and contact details strictly confidential.

All audio-recorded data will be securely transferred to the University of Bristol to be used for research and training. Only the researchers and those employed on the study will have access to the recordings. Responsible members of the University of Birmingham or Birmingham Clinical Trials Unit may be given access to data for monitoring and/or audit of the study to ensure we are following regulations.

All audio-recordings will be named with a reference number (not with your name) to hide your identity. Audio-recordings will be recorded on an encrypted device and stored on a password protected computer for the duration of this study and up to a maximum of ten years, after which they will be wiped.

We may wish to play parts of recordings or use quotes, for example as part of teaching or presentations at academic meetings. If we do use any of your recordings, all the quotes will be anonymised so that you cannot be recognised from any of the information we present. We may also use the data collected (interview and audio-recordings) in our future research looking at common issues across studies. Please indicate on the consent form if you are happy for us to use your recordings in the above ways.

You can find out more about how we use your information by contacting the Topic 2 Study research team.

**What will happen if I don’t want to carry on with the study?**

You are free to withdraw from any aspect of this study at any point. If you withdraw, we will ask you whether we can use your audio-recordings which were made before your withdrawal. If you wish, any audio-recordings that can still be identified as yours will be destroyed.

**What will happen to the results of this research study?**

The results of this study will be reported in scientific journals and presented at conferences and meetings. Results may also be used for teaching and training purposes. No individuals will be identified in these outputs.

**What will happen to my data?**

At the end of the study, any transcriptions made of your recordings will be made “Controlled Access”. This means that transcripts will be stored in an online database, which can be accessed by approved individuals who are interested in conducting their own analyses of the data. These individuals will have to submit an application to do this, which will be assessed by an independent committee. We will therefore have no control over how these data are used in the future. However, all data will be anonymised before they are made available, and there will be no way to identify you or any other individuals mentioned in your interviews/appointments. Sharing access of research data and findings is considered good research practice and is a requirement of many funding bodies and scientific journals. Sharing data helps to maximise the impact of money invested into conducting research studies and can encourage new avenues of research.

**Who is organising and funding the research?**

The research is being coordinated by researchers at the University of Bristol, under the supervision of the study Sponsor, the Trials Unit at Birmingham University. The research is funded by the National Institute for Health Research Health Technology Assessment Programme (project number).

**Who has reviewed the study?**

This study has been reviewed and given a favourable opinion by South East Scotland REC 01 research ethics committee.

**Who do I contact if I want further information or have concerns?**

The Patient Advice and Liaison Service (PALS)/ Advice & Complaints Team (ACT) [delete as appropriate] should be contacted for any complaints. Your local PALS/ACT [delete as appropriate] can be contacted by [insert contact details]

If you have any concerns or queries, you are welcome to contact the qualitative researchers below:

**Dr Caroline Wilson:** Caroline.wilson@bristol.ac.uk; 0117 331 3954; Room 4.07 Canynge Hall, 39 Whatley Road, University of Bristol, BS6 2PS.

**Dr Marcus Jepson**: Marcus.jepson@bristol.ac.uk ; 0117 331 3930; Room 4.03 Canynge Hall, 39 Whatley Road, University of Bristol, BS8 2PS.

**Thank you for taking the time to read this leaflet.**