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PRoCuRe
Partial Rotator Cuff Tear Repair Trial

PRoCuRe Information Study
Patient Information Sheet

We would like to invite you to take part in some research that looks at how doctors and nurses explain the PRoCuRe Study *(the 'main' study)* to patients, that will help us with how we present study information.

This part of the PRoCuRe Study (*the 'Information Study'*) 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 information study if you wish. One of the team will go through this leaflet with you and answer your questions.

1. What is the purpose of the Information Study?

This *Information Study* is to help us to understand better how the main PRoCuRe study is described to you, and how we could improve the way we discuss the main study with patients in the future in order to improve recruitment to the main study. This should ensure that patients have the right information to make an informed decision about taking part in the main study.

2. Why have I been invited?

We are inviting you to take part in the *Information Study* because your clinical team believe that you are eligible for the *main PRoCuRe study*. We are interested in how your clinical team describe participation in the main study to you, whether or not you choose to participate in the main study.

3. Do I have to take part?

No, it is up to you to decide whether or not to take part in the *Information Study*. 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 choose to either:

- take part in the *main PRoCuRe study* AND the Information Study

or

- take part in the *main PRoCuRe study* only

or

- take part in the *Information Study* only

or

- **not** take part in the *main PRoCuRe study* or the *Information Study*

4. What will happen to me if I take part?

The *Information Study* will involve up to two main things:

(i) **We will ask your permission to audio-record appointments during which doctors and nurses explain the PRoCuRe Study to you.** Recording these discussions helps us to understand how clinical staff communicate information about the PRoCuRe Study.

(ii) After you have made a decision about whether or not to take part in the PRoCuRe Study, **we may ask you to take part in a short telephone interview (approx. 30 minutes) with the PRoCuRe Qualitative Researcher.** 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 PRoCuRe Study. (NOTE – THIS WILL ONLY APPLY TO AROUND 20 PATIENTS IN TOTAL)

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.

5. 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.

6. 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 to patients about the PRoCuRe Study and similar clinical studies in future.

7. What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact your local Principal Investigator:

[Insert Local Team Details]

or

Dr. Marcus Jepson, Information Study Lead, University of Bristol:

at Marcus.jepson@bristol.ac.uk or by telephone on 0117 331 3930

or

The PRoCuRe office in Oxford

at procure@ndorms.ox.ac.uk or by telephone on (01865) 227684

or

The University of Oxford Clinical Trials and Research Governance (CTRG) office at:
ctrg@admin.ox.ac.uk or telephone: 01865 616480

8. What if I am concerned about the care I receive?

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact

insert relevant NHS site phone number and email from the PALS website xxxxxxxxx

9. Will my taking part in this study be kept confidential?

Yes, you will be allocated a study number and all patient information will be stored securely in accordance with data protection law.

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.

All audio-recordings will be named with a reference number (not with your name) to hide your identity. Audio-recordings will be transcribed by staff at the University of Bristol. Both the audio-recording and the transcript will be stored securely on a password protected computer for the duration of this study. 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, no identifiable content (like names of people or hospitals) will be included, and voices will be changed so that you cannot be recognised by it or from any of the information we present. At the end of the study, only the de-identified audio and transcripts will be retained securely by the University of Bristol for 20 years. We may use this de-identified 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. We may also use de-identified data collected (interview and audio-recordings) in our future research looking at common issues across studies.

Responsible members of the University of Oxford, the University of Bristol, regulatory authorities or your NHS trust, may be given access to data for monitoring and/or audit purposes of the study to ensure the research is complying with the applicable regulations.

10. 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. To do this, please contact the Trial Manager at procure@ndorms.ox.ac.uk or Tel (01865) 227684. Please have your study ID to hand (this can be found at the top of the consent form that you signed) as without it, we may not be able to identify your audio-recordings.

11. What will happen to the results of the Information 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.

12. What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford and the University of Bristol are the data controllers ('Joint Controllers') and are responsible for looking after your information and using it properly.

If you agree to take part in an interview, your local hospital PRoCuRe team will share your name, and contact details with researchers the University of Bristol who will contact you to organise the interview. They [researchers at the University of Bristol] will keep identifiable information about you from this study until the end of the study when it will be destroyed. Non-identifiable data will be held on the University of Bristol's secure research data storage facility (RDSF) for 20 years. Your Information Study consent form will be archived at the NHS Hospital Trust site as per local Trust policy for medical notes retention for at least 5 years after the end of the PRoCuRe study. Your agreement to participate in this Information Study will be logged in the PRoCuRe study database at the University of Oxford where it may be held for up to 5 years.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting procure@ndorms.ox.ac.uk or going to procure.octru.ox.ac.uk

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.

13. Who is organising and funding the research?

The study is sponsored by the University of Oxford. The Surgical Intervention Trials Unit (SITU) at Oxford will manage the study with Oxford Clinical Trials and Research Unit (OCTRU). The National Institute of Health Research, Health Technology Assessment programme, has funded this national study.

14. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London - Central Research Ethics Committee

If you have any concerns or queries about the Information Study, you are welcome to contact the lead below:

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

Thank you for taking the time to read this leaflet.