Trust Letterhead Paper

Information Sheet for Patients

ROAM Information Study
Version 1.0 26th November 2014

You are being invited to take part in a research study. Before you decide please take time to read the following information and talk to others about the study if you wish.

- Part 1 tells you the purpose of the study and what will happen if you take part.
- Part 2 gives you more detailed information about the study.

Please ask if there's anything that isn't clear or if you would like more information.

Part 1

What is the purpose of the study?

We know that patients have a lot to take on board when they are invited to consider a clinical study like ROAM. The ROAM Information Study will look at how patients and health professionals communicate about ROAM and their experience of this. We'll use what we find out to improve how information is provided for future patients in ROAM and similar clinical studies.

Why have I been chosen?

You've been chosen because your doctor has invited you to participate in ROAM. Your viewpoint is very important to us. We want to include patients with different experiences so we are inviting patients from different treatment centres. We're also hoping to include patients who've declined to participate in ROAM, as well as those who've consented. We don't mind whether you said "yes" or "no" to ROAM – we're just interested in how information was provided and your views of this.

In all, we'll be asking about 40 patients to take part in the ROAM Information Study.

What will happen if I take part?

The doctor or researcher who spoke to you about ROAM will have asked your permission to switch on an audio-recorder before he or she discussed ROAM. We'd like to include the audio-recording in our Information Study. We'd also like to invite some patients to be interviewed by an Information Researcher.

The Information Study Researcher <Name> will contact you and ask to interview you in your home or in a private room in the treatment centre, as you prefer. The interview with <name>will take place a few weeks after your appointment and last about 1-1 ½ hours.

During the interview s/he will ask your views about what and how information on ROAM was provided and how well this addressed your needs. S/he will also ask you about any other discussions you've had about ROAM and your overall thoughts about clinical studies like ROAM. If there are any questions you don't want to answer just tell <Name> and s/he'll move to the next topic. You can stop the interview at any point. With your permission we'll audio-record the interview.

We will also be interviewing some of the doctors and nurses involved in ROAM.

Do I have to take part?

No – it is your decision entirely. If you decide to take part, you'll be given this information sheet to keep and asked to sign a consent form. If you decide not to take part in an *interview*, we would still like to include the audio-recording of your discussion with the doctor about ROAM. But if you don't want this to be included it will be deleted.

You can withdraw from the Information Study at any time and without giving a reason. All information we have collected from you will be destroyed if you wish.

Any decisions you make about the Information Study will not affect your clinical care.

What about confidentiality?

Information collected during this study will be kept confidential. Apart from the Information Study researchers, no one, including your doctors and nurses, will know what you have said in the interviews. We may play back sections of the audio-recording that the doctor did when discussing ROAM to help the doctors and nurses involved improve how information about ROAM is provided.

Each audio-recording will be typed out but we will take out identifying details like names. The audio-recordings will be marked with a number only, and stored securely. You will not be identified in any reports of the Information Study. We may include brief quotations from in our reports, but we will always change details such as names and places so nobody can be identified. We will not be looking at your medical records for this study.

What are the possible risks and benefits of taking part?

We do not anticipate any major risks, though sometimes interviews can cover upsetting topics. If you feel upset after an interview and want to talk things over, you can contact <researcher name> (see telephone number are at the end of this sheet).

We hope this study will benefit future patients approached to take part in ROAM. We cannot promise that you benefit directly, but many people find that taking part in studies like this is useful because they can air their views and reflect on things.

What if there is a problem?

Any complaint about the way you have been dealt with during this follow-up study or any possible harm you might suffer will be addressed. Further information on this is given in part 2.

Who can I contact for further information?

If you have any questions at all, at any time, please contact:
<researcher contact details>

S/he is based at in the Institute of Psychology, Health and Society, University of Liverpool, Liverpool, L69 3GB.

Alternatively, you may prefer to contact Dr <local contact details>.

The person supervising this study is Professor Bridget Young, University of Liverpool (byoung@liv.ac.uk).

Thank you for reading Part 1 of this Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making your decision.

Part 2

What if I there is a problem or I have a complaint about the study?

If you have a concern about any aspect of this study, you should speak to the researchers (see contact details on page 3). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details of this procedure can be obtained from your local hospital.

This study is covered for harm due to negligence by The Walton Centre. In the event that something goes wrong and you are harmed during the study due to someone's negligence then you may have grounds for legal action against the Walton Centre, but you may have to pay your legal costs. There are no special compensation arrangements for non-negligent harm, though the normal NHS complaints mechanisms will still be available to you.

How will the data collected about me be stored and used?

All data collected for this study will be kept safely and securely on computer. Professor Bridget Young will be custodian of all study data. With your permission, audio-recordings will be stored at the University of Liverpool for up to 10 years in case queries arise and it is necessary to check the data. If you do not wish your audio-recordings to be stored they will be destroyed at the end of the study.

After all identifying details have been removed from the typed audio-recordings these will be analysed by the study team. The results will be published scientific journals, but it will not be possible to identify any individuals from these reports. We will send you a summary of the results at the end of the study if you would like one.

Who is organising and funding the study?

The National Institute for Health Research (Health Technology Assessment) have provided the funds to carry out this study and The Walton Centre is sponsoring and organising the study.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by XXX.

Thank you very much for taking time to read this information sheet.

Study Number:
Participant Identification Number for this study:

Patient Consent Form

Title of Project: ROAM Information Study

Name of interviewer:

		Please initial box
1.	I confirm that I have read and understand the information sheet dated …….. (version …….) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my care or legal rights being affected.	
3.	I understand that audio-recordings will be made as part of this study, and that brief quotations from some interviews or consultations may be included in study reports. I understand that nobody will be able to identify any participants in these reports.	
4.	I agree to audio-recordings of my ROAM consultation and/or Information Study interview being stored at the University of Liverpool for up to 10 years for checking purposes. I understand that these will be held securely and marked with a number only.	Yes / No
5.	I would like to receive a summary of the findings at the end of the study.	Yes / No
6.	I agree to take part in the above study.	

Name of participant	Date	Signature
Name of interviewer	Date	Signature

When completed, 1 for participant, one for interviewer file, 1 original to be kept in patient's medical notes