

## **The PREPARE Study:**

### **ImPRoving the PrepARation of ResEarch Information ShEets**

PhD Student: Kirstie Shearman, Warwick Medical School

Supervisors: Professor Heather Draper and Dr Greg Moorlock

We would like to invite you to take part in a research study. Before you decide if you want to be involved, it is important that you understand why we are doing this research and what you would need to do to take part. Please read this information sheet and contact us if you have any questions about the study or would like to discuss anything in this sheet further.

#### **What is the purpose of the research?**

The aim of this study is to find out what information you think is important to include in information sheets and why. Information sheets used in clinical research are often very long and complicated because different groups of people, like PPI groups, R&D, and NHS Ethics committees, ask researchers to include lots of different information. The information you give us will be part of a wider PhD study looking at what information researchers are asked to include and why this is, and whether all information added to information sheets needs to be included.

#### **Why have I been invited?**

You have been invited as you have recently been involved in the design of an information sheet for clinical research, and the lead researcher of that study has also agreed to take part in this study. We are interested in your views on what information potential research participants considering taking part in a study need to be told before giving informed consent.

#### **Do I have to take part?**

No. It is up to you whether you take part or not. If you read this sheet and decide you want to participate, you can sign and initial the consent form

attached and send this back to us. If you decide later that you don't want to participate, you can withdraw without giving us any reason up until 48 hours after your telephone interview.

### **What will I be asked to do if I take part?**

If you decide to take part you will be invited for a short telephone interview, during which you'll be asked some questions about the content and overall purpose of information sheets. The interview will be audio-recorded so that it can be transcribed word for word and analysed.

### **What will happen to my details and the information I give?**

Your personal details and involvement in the study will be kept confidential. The interview will be recorded on a portable audio recording device and will be transferred to University servers as soon as possible afterwards, at which point it will then be deleted from the device. The recording will be transcribed and stored on a university server. The recording also needs to be kept for 10 years as this study is part of a PhD project. The transcript of your interview will be anonymised – we may use quotes from your interview in the write up and any publications, but any information that might identify you will have been removed. Your consent form and contact details will be stored on a university server for 10 years before being securely deleted.

### **Will I benefit from taking part?**

You won't personally benefit from taking part in this study, but you might find it helpful and interesting to reflect on ethical issues relating to the content of information sheets when you are helping to design them in the future.

### **What are the risks of taking part?**

We do not anticipate that there will be any risks to you by participating in this study. You will not be asked any sensitive or embarrassing questions in the interview so we do not expect that you will become upset, but if you do want to

stop the interview at any time you can do so without giving a reason. If you change your mind after the interview has taken place, you can withdraw up to 48 hours later without telling us why.

### **Who is organising and funding the study?**

Kirstie Shearman, a PhD student at Warwick Medical School, is organising the study. It will be supervised by Professor Heather Draper and Dr Greg Moorlock, also from Warwick Medical School. The study has been funded by the university.

### **What if I want to complain?**

If you have any concerns about the study, you should speak to the PhD student who will help with any worries you have. If you want to complain formally, you can contact the Deputy Director/Head of Research Governance, Research and Impact Services, University House, University of Warwick, Coventry, CV4 8UW or by email/telephone: [researchgovernance@warwick.ac.uk](mailto:researchgovernance@warwick.ac.uk), 024 76 522746.

### **How do I agree to participate?**

If you want to ask any questions please contact Kirstie Shearman. If you'd like to participate, please sign and initial the attached consent form and send it to us by email ([k.shearman@warwick.ac.uk](mailto:k.shearman@warwick.ac.uk)).