UNIVERSITY OF LIVERPOOL

Participant Information Leaflet

Perspectives Study

(Perspectives on enhancing consent and recruitment in intensive care studies)

We are inviting you to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read this leaflet carefully and feel free to ask if you would like more information or if there's anything that you don't understand.

Feel free to discuss this with your colleagues if you wish. We would like to note that you do not have to accept this invitation and should only agree to take part if you want to.

Who is doing the study?

This study is being led by researchers at the University of Liverpool and funded by the Economic and Social Research Council (http://www.esrc.ac.uk/). An Advisory Group of people who have experience of intensive care units (ICUs) as clinicians, researchers, patients or relatives, are advising on the study.

What is the purpose of the study?

This study is exploring the perspectives of research teams on the recruitment and consent of patients to studies in ICUs. We are doing the study because we want to develop good practice guidance on the recruitment and consent of ICU patients to clinical research studies. We think it is important to understand the perspectives of all research team members - whether they are researchers or patient/public research partners[1]. The study will run until November 2017.

Why have I been chosen to take part?

[1] By this we mean we mean people who have roles providing a public, patient or carer perspective on research in ICUs (rather than as participants in the research). This would include, for example, people who have provided input in the planning, development, design, running or dissemination of an ICU research study. This could be on an informal basis, or it could be via a trial/study management group, steering committee, advisory group or panel. We have based this explanation on advice from INVOLVE – see http://www.invo.org.uk/

You have been invited to take part because you are/have been involved in developing, designing, running or advising on an ICU research project. We are interested in hearing about all types of ICU studies, including observational studies and well as clinical trials. Learning about your experiences of developing the patient recruitment and consent process for your study (including resources such as patient information leaflets), will help us a greatly in developing the good practice guidance for future ICU research.

As part of this study we will also be interviewing ICU patients and their relatives, and the ICU researchers, nursing and medical staff who recruit patients to research projects.

Do I have to take part?

It is completely up to you. If you do decide to take part we will ask you to sign a consent form to say that you agree to participate. If you decide later on that you wish to withdraw then you can leave the study at any time and you do not have to give a reason.

What will happen if I take part?

You will be asked to take part in an interview. This will last about an hour and involve you talking with an interviewer about your experiences as a researcher/research partner within your ICU research project. The interviewer will ask about the recruitment and consent process within your ICU research project, any challenges that arose, what solutions were developed and how well these worked. With your permission, the interviews will be audio-recorded.

Are expenses and/or payments provided?

We do not anticipate that participants will incur any costs from participating in this study, aside from the time being interviewed. As a token of appreciation we will offer patient/public research partners a £25 shopping voucher for taking part.

Where will the research take place?

The interviews will usually be carried out over the telephone at a date and time of your choosing.

Are there any risks in taking part?

We do not expect there to be any risks or discomfort from being interviewed in this study. If there are any questions that you do not wish to answer please just let the interviewer know and s/he will move on to the next question. You can also stop the interview or leave the study at any point – you do not need to give a reason.

Are there any benefits in taking part?

You will be helping us to better understand patient recruitment and consent in lCU research projects. This will enable us to make sure that the good practice guidance is well informed and realistic.

What if I am unhappy or if there is a problem?

If you are unhappy or there is a problem, please let us know by contacting the lead researcher, Bridget Young, at University of Liverpool on 0151 794 5525 (byoung@liv.ac.uk). Bridget will try to help. If you are still unhappy or prefer to speak to someone else, then you should contact the University of Liverpool's Research Governance Officer at ethics@liv.ac.uk . Please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

Will my participation be kept confidential?

All the information that you give us will be kept strictly confidential. Interview transcripts will have all identifying information removed (e.g. person, place or study names) before being analysed and stored, and only authenticated researchers will have access to them. The information you provide will be stored in locked filing cabinets or password protected computers. Anything about you, including any quotes which are used in the write-up of the study, will have all identifying details removed so that you will remain anonymous.

At the end of the study the research data (consent forms, anonymised interview transcripts, study notes, and your contact details) will be kept in locked filing cabinets and/or password protected University of Liverpool computers for up to ten years. With your permission, data from this study will also be archived with the UK Data Archive for use by future researchers. Before archiving all identifying information will be removed, and only authenticated researchers will have access to the data.

What will happen to the results of the study?

After the study has finished, the results will be written up and published in academic journals and presented at conferences. We will make a summary of the findings available to you at the end of the study if you would like us to. The researcher will ask you about this as part of the interview. You can also have a copy of the full research report if you would like it.

What will happen if I want to stop taking part?

If you decide at any point that you no longer wish to be part of the study, then you can stop and do not have to give a reason. You can also ask for your data to be destroyed if you wish.

How can I find out more?

Just get in touch with the researcher, Katie Paddock, who will be happy to answer any questions you might have:

Tel: 0151 795 5421
Mob.: 07498 082383
Email: Katie.paddock@liverpool.ac.uk

Thank you for reading this. This information sheet is for you to keep