

## **Risk, safety and consent in blood services: information for interviewees**

### **Invitation to participate**

We are conducting an interview study about risk, safety and consent in blood services in the UK. We would like to conduct interviews with professionals, policy makers and staff and committee members of patients' organisations about these issues. You have been invited to participate because of your expertise in this field. This information sheet is designed to help you decide whether you would like to participate in this study.

### **Background: why this research now?**

Modern medicine depends on the use of donated human biological materials, as an increasing number of patients globally receive treatments based on these materials. Amongst these, blood and products derived from it, are widely and commonly used, both in routine treatments and in medical emergencies. Blood transfusions and blood derived products used in these circumstances are often life-saving and life-enhancing. Although receiving blood has become progressively safer, some risks are involved.

There is a debate in policy and professional communities about how best to provide patients with appropriate information about risks and benefits associated with these treatments, and about informed consent in this context.

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

This study is being led by Dr Helen Busby from the University of Leicester. The project team also includes Professor Julie Kent, who is Professor of Sociology of Health Technology at the University of the West of England and Dr Anne-Maree Farrell, who is Associate Professor in Law at the University of Monash. The project has been funded by the Economic and Social Research Council (ESRC), a government funded research body.

### **Who has reviewed the study?**

This study has been reviewed by an NHS Research Ethics Committee (REC), which considers the interests of people taking part in research. The Nottingham 2 REC have reviewed the study and agreed that it may go ahead.

### **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 change your mind at any time and you don't have to give a reason.

### **What will happen to the results of the study?**

We expect to publish papers about the research in academic journals. At the end of the project we shall send out a summary of our findings to everyone who has asked for one. Please tell Helen Busby if you are interested in receiving this summary. We shall also publish a summary report on the ESRC website.

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

We would like to ask you some questions about your views on blood services. Interviews will take place at a convenient time and place for you. (This will often be at the interviewees' office or workplace or at the University.) We would especially like to know about your views on safety and risk in the blood supply; patient information and informed consent; contemporary blood services; and the procurement of blood and plasma products. If you feel that it is not appropriate for you to address some of these issues, then we can leave these out of the interview.

**What are the possible risks and benefits of taking part?**

There are no direct benefits to participants who take part in this research but we hope that the research will help to inform policy decisions about blood services. We do not anticipate any major risks to taking part in these interviews. We do acknowledge the sensitivity of exploring issues about blood safety, and we shall take care to ask questions in an appropriate and sensitive way, and to keep information confidential.

**Confidentiality and data protection**

All information that is collected in the course of the research will be kept strictly confidential. Data will be stored either in locked filing cabinets or in password protected databases which are only accessible by members of the research team. The names and contact details of people involved will be deleted from our records at the end of the project.

**What will happen to the information during and after the study?**

We would like to record what is said in the interviews and to make a written transcript. This will allow us to conduct a thorough analysis of the data. The names of people interviewed will be removed from the transcript as well as any other identifying details (such as the names of patients, colleagues, or hospitals). Because we think that your views are important, we would like to quote directly from the interviews in papers in academic journals or reports that we write.

As our research is funded by the ESRC we are required to offer our transcripts to the UK Data Archive for storage so that other researchers can study them in the future, if you agree to this. Further information about this will be available when we meet. It is completely up to you to decide whether or not you would like your transcript to be included in the data archive.

**What if there is a problem?**

If you have any concerns about any part of this research project please contact Helen Busby or the head of the research group, Professor Mary Dixon Woods. The contact details are below.

Taking part in this study involves being interviewed only and so it is unlikely that you will be harmed. In the unlikely event that anything did go wrong and you were harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against the University of Leicester but you may have to pay your legal costs.

**Further Information**

Thank you for taking the time to read this information sheet. If you have any further questions about this research please contact Helen Busby.

**Contact details**

Helen Busby, ESRC Research Fellow, Department of Health Sciences, University of Leicester, 22-28 Princess Road West, Leicester LE1 6TP. Tel: 0116 252 5453, email: [hwb1@le.ac.uk](mailto:hwb1@le.ac.uk), website: [www.le.ac.uk/people/hwb1](http://www.le.ac.uk/people/hwb1)

Mary Dixon-Woods, Professor of Medical Sociology, Department of Health Sciences, University of Leicester, 22-28 Princess Road West, Leicester LE1 6TP. Tel: 0116 252 5453, email: [md11@le.ac.uk](mailto:md11@le.ac.uk), website: [www.le.ac.uk/people/md11](http://www.le.ac.uk/people/md11)

**Interested in taking part? What to do next:**

If you would like to be interviewed for the study, please contact Helen Busby by email: [hwb1@le.ac.uk](mailto:hwb1@le.ac.uk), telephone: 0116 252 5453, or by returning the reply slip. Helen will then contact you to answer any questions that you may have, and to discuss a convenient time and place for the interview.