



The
University
Of
Sheffield.

Clinical
Trials
Research
Unit.

Participant Information Sheet

Equality, Diversity and Inclusion in Early Phase Trials

Qualitative Interviews (Professionals)

Invitation

We would like you to consider participating in an interview about your experience and perceptions of equality, diversity and inclusion (EDI) in early phase trials. Before you decide whether you want to take part, we need you to understand what the research is for and what you would be expected to do. Please read the following information carefully. If you do not understand anything or have any questions, please contact us. Please take time to decide whether you wish to take part.

What is the study about?

EDI has clear importance in late phase (phase III and IV) clinical trials. However, little attention has been paid to diversity in early phase trials (phase I or I/II). Such trials hugely influence the development and testing of treatments but pose unique challenges to incorporating diversity. In this study, we aim to explore if and how EDI has been incorporated into early phase trials (phase I or I/II), and the value and challenges of doing so.

Why have I been invited?

You have been invited as you have been involved in either designing or undertaking one or more early phase trials.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time without any negative consequences. You do not have to give a reason. However, if you decide to withdraw after having participated in the interview, we will be unable to remove your data from the study beyond this point. If you wish to withdraw from the research, please contact Robin Chatters (see contact details below).

Please note that by choosing to participate in this research, this will not create a legally binding agreement, nor is it intended to create an employment relationship between you and the University of Sheffield.

How do I give my permission to take part in the study?

If you agree to take part after reading this information sheet, and are selected for an interview, we will arrange with you a time to undertake the interview over the telephone or via a video conference. Before the interview you will be asked to sign a consent form and return this back to us. The consent form is a form you sign to say that you understand why the study is being done, that you understand what you are expected to do and what the researchers will do with the information they will collect. If you change your mind between arranging the interview and the interview itself, you are free to withdraw from the interview – just use the contact details below to inform us.

What will happen to me if I agree to take part?

If you are interested in taking part in an interview, we will ask you to complete an online survey. The survey collects details about you, including your age and gender. We are collecting this data about you as we want to represent the views of underserved groups and ethnic minorities in this research, as such, we will use this information to select a diverse group of people to interview.

If you complete the survey and provide your contact details to enable us to contact you, we may invite you to undertake an interview via video conference (via Google Meet), or in-person at a convenient location, to discuss your experiences and views of EDI of early phase trials,

If you agree to take part in the study, you will be invited to undertake the interview via video conference (via Google Meet), or in-person at a convenient location. Prior to the interview the researcher will remind you about what will be involved and confirm that you are happy to participate. The interview itself will last approximately 45 to 60 minutes. The researcher will ask you questions about your experience and perceptions of EDI in early phase trials. The interview will be audio recorded. We will also ask for your permission to record the video if Google Meet is being used to undertake the interview.

Are there any expenses or payments involved?

No, you will receive no expenses or payments for participating in this qualitative interview.

Will my taking part in the study be kept confidential?

Yes. All information about you will be handled in confidence. The information you give us will be 'anonymised'; this means that we won't use any recognisable information such as your name or any other personal information in reports or publications. Identifiable data collected for the study will only be looked at by authorised persons from the research team. Anonymised quotes from your interview may be used in reports (see below, *what will happen to the data collected, and the results of the research project?*)

What are the possible risks and benefits of taking part?

There are no risks to taking part in this extra component of the study.

What are the possible benefits of taking part?

There is unlikely to be any direct benefit to you. However, this research has the potential to benefit future trials by recommending adaptations that can be made in order to improve efficiency.

Who is organising and funding the study?

The study is organised by Sheffield Clinical Trials Research Unit at the University of Sheffield. The study has been funded by Research England Participatory Research Funding scheme.

Who has reviewed the study?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the School of Health and Related Research

What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>

What will happen to the data collected, and the results of the research project?

The identifiable data you provide will only be accessible by certain individuals based at The University of Sheffield who are directly involved in this study. Identifiable data collected about you (e.g. your name, email address, ethnicity, age and original versions of the interview transcript) will be until the end of the project.

A pseudo-anonymised transcript of the interview will be created and retained for 5 years after the end of the project, but will only be accessible to those based at The University of Sheffield who are directly involved in the study.

Quotes from your interview may be published in academic journals or other printed materials (for example, reports), but we will ensure that you cannot be identified in any way.

You will be able to access the results of the study on the University of Sheffield website.

Who is the Data Controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

What if something goes wrong and I wish to complain about the research?

If you have any cause to complain about how you have been approached or treated during this study you can contact the Principal Investigator *Robin Chatters*, in Sheffield on (0114) 222 2969 or r.chatters@sheffield.ac.uk. If you feel your complaint has not been handled satisfactorily, you can contact the Dean of the School of Health and Related Research (SchARR), John Brazier, by emailing j.e.brazier@sheffield.ac.uk.

If the complaint relates to how your personal data has been handled, you can contact The University of Sheffield Data Protection Officer, Luke Thompson – luke.thompson@sheffield.ac.uk. Further information about how to raise a complaint can be found in the University's Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

If you feel your complaint has not been handled to your satisfaction, you can contact the Information Commissioner's Office.

Contacts for further information:

You can contact the research team using any of the following methods:

-  Tel: 01142222969. Calls and answerphone messages will be monitored between 9am and 5pm
-  R.chatters@sheffield.ac.uk. Emails will be monitored between 9am and 5pm.
-  Robin Chatters, Clinical Trials Unit, c/o SchARR, The University of Sheffield, Regent Street, Sheffield, S1 4DA

***This information sheet is for you to keep.
Thank you for your time and help.***