

PARTICIPANT INFORMATION SHEET

**Shining a spotlight on the inclusion of disabled participants in clinical trials (SHINE)**

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**ICREC no:** 22IC7687

**Introduction and invitation to take part**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

**Why we are doing this study?**

We know that certain groups of people are less likely to take part in clinical trials. One of these groups is people with disabilities (both hidden and visible). It’s important that disabled people take part in clinical trials so that we know that the results from trials and new treatments can be applied to people with disabilities. We would like to understand why people with disabilities are less likely to take part in clinical trials and what might help to make clinical trials more accessible to disabled people.

**Why have you been invited?**

You have been invited to take part in this study because you have responded to an advert and you either have a disability, are a carer or close family member of a person with a disability, or a member of staff working in clinical 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 can choose whether you want print this information sheet to keep. You will be asked to tick the consent box at the beginning of the survey. If you decide you do not want to take part while you are completing the survey do not submit your answers (last button at the end of the survey). No data will be saved or answers submitted and until you click the submit button.

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

You will be asked to answer the survey questions. The surveys for people with disabilities and carers should take 15-20 minutes to complete. The survey for clinical trial staff should take 12-15 minutes to complete.

The surveys can be completed immediately by clicking the link in the advert. If you would prefer to complete a survey on paper or by phone please contact the study team on ictuedi@imperial.ac.uk or leave a message on 0207 594 9357. The surveys will be anonymous. If you complete a paper copy of the survey or do the survey by phone, the answers you provide will be entered onto the survey system and not linked to your name or contact details.

At the end of the survey you will be given contact details in case you are interested in taking part in the next part of the study which will be focus (discussion) groups.

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

We don’t think that any of the questions in the surveys will cause you distress. For the surveys for disabled people and carers of disabled people, almost all of the questions are optional. If you don’t feel comfortable answering a question you can move on to the next question. The only question that you must answer is the question about which disability/ies you or the person you care for have because we need the answer to this question for our research.

For the survey for clinical trial staff, all questions are optional to answer.

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

We cannot promise the study will help you but the information we get might help to make it easier for people with disabilities to take part in clinical trials in future.

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

The results from the survey will help us to plan two focus groups and some interviews to look at this research topic in more detail. When all the activities have finished we will publish these on our website <https://www.imperial.ac.uk/clinical-trials-unit/ictu-news-and-events/> and possibly in journals. We will share the results with clinical trials staff at other units and perhaps at conferences. As the surveys are anonymous you will not be identified in any report/publication.

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

The research survey is being conducted by Imperial College London. It is being funded by an Imperial College London Equality, Diversity and Inclusion Seed Fund.

**Who has reviewed the study?**

This study was given favourable opinion by Imperial College Research Ethics Committee (ICREC) and approval by Prof Neil Poulter, Director of the Imperial Clinical Trials Unit.

**Contact for Further Information**

If you would like further information on this research please contact Marie Miller m.miller@imperial.ac.uk or 020 7594 9357.

Thank you for taking part in this study.

**What are your choices about how your information is used?**

You can stop being part of the survey, without giving a reason, up until the point at which your answers are submitted. You can stop being part of a focus group or interview at any time, without giving a reason, but we will keep information about you that we already have.