Participant Information Sheet

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ERGO project ID: 80233

Study Title:

Widening participation in patient and public involvement (PPI) for trials being conducted at Southampton Clinical Trials Unit.

Researcher: Liz Allaway (Project Lead)
ERGO number: 80233

You are invited to take part in our research study.

- This information sheet will help you understand why the study is being done and what it will involve for you if you decided to take part.
- Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part.
- It is entirely your decision whether to take part or not. If you agree to take part, you are free to withdraw at any time without giving a reason. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

The Southampton Clinical Trials Unit (SCTU) runs academic clinical trials to test new medicines, health technologies and interventions to improve healthcare and treatments for patients.

Clinical trials rely on patients, carers or even healthy volunteers agreeing to take part in research and it is therefore vital that we make sure the patients have a say in how this research is done. For this reason, patient and public involvement (PPI) is heavily embedded into research conducted at the SCTU, with public members involved in the design, conduct and oversight of all our trials.

We know that certain groups and communities are under-represented in clinical research. To aid inclusion, we need to ensure that PPI in the design and conduct of our trials is reflective of the whole population to help make sure our trials are suitable and accessible for all.

We want to better understand whether barriers exist that prevent or dissuade some people from taking part in Patient and Public Involvement (PPI) for clinical trials and learn how we can overcome these.

Why have I been asked to participate?

You have been invited to take part in our study to help give us a wide range of views from different people and communities about participating in PPI for clinical research.
This may be because:

- You may be interested in helping research be more inclusive and accessible to everyone.
- You are interested in widening participation in PPI by making it more inclusive
- You are part of a community organisation or local group interested in promoting representation and inclusivity.

What will taking part involve?

Stage One
If you decide to take part in our study, you will be invited to either come to a discussion group, or to fill in an anonymous online survey.

Discussion Group: We are looking to speak to around 30-40 people at discussion groups, either held over the online platform Microsoft Teams or in-person at a community location. We will organise groups of up to 10 people to take part in a discussion around Patient and Public Involvement (PPI) in clinical research. The discussions will be recorded and transcribed with any reference to names or other identifying information removed. The recordings from these groups will be destroyed at the end of the study. We will ask you to discuss:

- Whether barriers exist which mean certain groups of people are excluded from taking part in PPI.
- How researchers and teams at SCTU can removed these barriers to widen participation.
- What resources could be created for future researchers to help them implement ideas from these discussions into their research projects.
- Whether you would be happy to be involved in co-producing the resources we create.

Prior to the discussion group we may give you some information to help facilitate the discussions. We do not expect this to take longer than 20minutes to read. We approximate a discussion group will last around 1hour 30 minutes. As a thank you for your time we can offer you a £25 online shopping voucher.

Online Survey: We are looking for around 30-40 people to fill in an anonymous online survey. The survey will include some multiple-choice questions about your previous knowledge of PPI and some short open-ended questions where you can write as much or as little as you wish about your thoughts on barriers to inclusion in PPI. The survey should take no more than 20 minutes to complete.

We will also ask if you would like to potentially be involved in co-producing resources to help future researchers who are conducting PPI. In this case, you will be asked to provide your contact details. We will not ask for your name and contact details if you do not wish to be involved in this.

Participants who complete the survey have the opportunity to be entered into a prize draw to receive one of two £25 online shopping vouchers.

Stage Two
We are looking to involve around 10 people in the co-production of future resources for researchers. If you indicated during a focus group or on your online survey that you would like to take part in this, we will get in touch to discuss the project further.

Depending on the outcome of the discussion groups and online survey, this resource could be in a variety of different forms: a video, an animation, a checklist for researchers, etc.

If you do decide to take part in stage two, you may be asked to sign an image/audio recording release form if you agree to take part in any filming or audio recordings which are used as part of the resources created. Images and audio will not be used without the form being signed.

Are there any benefits in my taking part?

We cannot guarantee that there will be a direct benefit to you from taking part in our study. However, your contribution will help us to improve how we include public members in PPI for clinical research, and hopefully will widen participation and inclusion in future PPI projects.

Participants in focus groups will receive a £25 shopping voucher, while those who fill in the online survey will have the opportunity to be entered into a prize draw to receive one of two £25 online shopping vouchers.

Are there any risks in my taking part?

We do not anticipate there being any risk to you from taking part in our study. However, we may be discussing potentially sensitive topics, such as why people from certain communities may feel excluded from clinical research and PPI. If there is any indication or signs that a participant has become distressed, then the focus group will be paused and/or stopped as deemed necessary by the participant/s. The participant will be asked if they want to take a break and be offered support. If the facilitator or participant is distressed, then they will be directed to an appropriate support outlet depending on their personal issue (e.g. Samaritans, faith group, etc).

All discussion group participants will be required to maintain confidentiality of the discussions.

What information about me will be collected and used?

Information you disclose or opinions you give during group discussions will be recorded and transcribed and used by the study team to inform the resources created at the end of the project, including potentially using anonymised quotes . Names and other identifiable information will be removed. Transcriptions from the discussion groups will be kept for up to 15 years on a secure University server and then destroyed.

Information disclosed or opinions given in the online survey will be used by the study team to inform the resources created at the end of the project, including potentially using anonymised quotes in these resources.

If you decide to take part in stage two of the project (co-production of future resources) your contact details will be taken by the research team so we can contact you. These contact details will be stored on a secure server and destroyed at the end of the study. You may be asked to sign an image/audio release form if you agree to participate in recordings of video/audio resources. These resources will be publicly available.

Online surveys are anonymous, unless you give us permission to contact you about helping to co-produce future resources, in which case you will be asked to provide a contact email address. If you enter the prize draw to receive one of two £25 online shopping vouchers you will need to provide a contact email address which will be destroyed once the draw has been made. Responses to the survey questions will be kept for up to 15 years on a secure University server and then destroyed.

Will my participation be confidential?

Your participation and any personal information we collect about you during the course of the project will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason.

If you withdraw during or after a discussion group, or once you have submitted an online survey, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

The information provided through discussion groups and online surveys will be used to create a resource for future researchers to use when conducting PPI as part of their research projects. This could take the form of a video, animation, checklist, or other resource, and will be decided and co-produced through the groups and surveys. Information and examples used in these resources will be anonymous and not contain any identifiable information, but anonymised quotes may be used.

A report on this study will be written up for the funder and CTU staff. Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Recordings from discussion groups will be destroyed at the end of the study. Transcripts of the recordings will have any identifiable data removed and, along with information from the anonymous online surveys, will be stored on a secure University server and kept for the University of Southampton's standard data retention period of 15 years.

Names and contact details of people who enter the draw for shopping vouchers as part of the online survey will be kept until the draw is made at the end of the active survey period and will then be destroyed.

Names and contact details of people who agree to take part in the co-production of future resources will be kept in a password protected document on the University's secure server. Only members of the study team will have access to this document. These details will be destroyed at the end of the study, unless participants opt to join the SCTU PPI mailing list.

To find out more, see the Data Protection Privacy Notice at the bottom of this information sheet.

Where can I get more information?

If you have any further questions after reading this information sheet, or to find out more about how your information will be used, please contact the project lead, Liz Allaway via email – L.Allaway@soton.ac.uk.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the project lead (Liz Allaway, L.Allaway@soton.ac.uk) who will do their best to answer your questions.
If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Thank you for reading this participant information sheet and considering taking part in our study.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 1 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).