

### Research Study:

## Facilitators and barriers to clinical trial recruitment and retention of older people: A mixed-methods study

### PARTICIPANT INFORMATION STATEMENT: Experienced clinical trial participants

- Dr Justin McNab (Responsible Researcher), Senior Lecturer, Discipline of Behavioural and Social Sciences in Health, Faculty of Medicine and Health  
Email: justin.mcnab@sydney.edu.au; telephone +61 2 9036 7432
- Ms Sue Markham, MSc (PhD Candidate)  
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#### 1. What is this study about?

We are conducting a research study about the participation of older people (aged 65 years and older) in Australian clinical trials. Clinical trials are a type of research that investigate new treatments, tests or interventions. Examples include trials that test new medicines, vaccines, psychological therapies, devices and lifestyle interventions like exercise.

Studies have shown that older people are under-represented in these types of trials compared with younger people. This can limit the relevance of the trial and means that there is less evidence to guide the management of older people.

This study aims to examine the factors that affect the recruitment of older people into clinical trials. In particular, the project aims to examine the barriers and facilitators that contribute to older people's participation – what are the issues facing the researchers, the ethics committees who review the trials, older people who have taken part in trials and older people who have not yet been involved in clinical trials?

Gaining a greater understanding of these issues is an important step towards building a more equal evidence base to guide medical care.

Taking part in this study is voluntary.

Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

## 2. Who is running the study?

The study is being carried out by the following researchers:

- Dr Justin McNab (Responsible Researcher), Senior Lecturer, Discipline of Behavioural and Social Sciences in Health, Faculty of Medicine and Health
- Ms Sue Markham, MSc (PhD candidate), Student affiliate of the ARC-funded Centre of Excellence in Population Ageing Research (CEPAR), Sydney School of Health Sciences, Faculty of Medicine and Health
- Associate Professor Kate O'Loughlin (Co-Supervisor), Associate Investigator CEPAR, Sydney School of Health Sciences, Faculty of Medicine and Health
- Professor Lindy Clemson (Co-Supervisor), Team leader of Ageing, Participation & Safety Research team, Associate Investigator CEPAR, Sydney School of Health Sciences, Faculty of Medicine and Health.

Sue Markham is conducting this study as the basis for the degree of Doctor of Philosophy at The University of Sydney.

## 3. Who can take part in the study?

We are seeking people aged 65 or older who have previously taken part in a clinical trial. Ideally, we are looking for people who have or had a common medical condition that affects older people. Some examples include:

- Heart disease
- Chronic obstructive airways disease (COPD): e.g. emphysema, chronic bronchitis
- Stroke
- Lung cancer
- Dementia
- Arthritis
- Breast cancer
- Bowel cancer
- Type 2 diabetes
- Prostate cancer
- Kidney disease
- Falls

You have been invited to take part in this study because you are aged 65 or older and have previously been in a clinical trial.

## 4. What will the study involve for me?

The study will involve a face-to-face interview or an interview via Zoom, depending on your preference.

The interview would explore your thoughts regarding older trial participants and the issue of under-representation in clinical trials, the challenges and concerns you may have had about taking part in a trial, and the things that made it easier for you to join and stay in the trial.

Those who decide to take part in an interview will have the option to select a venue, date and time that is most convenient for them.

It is anticipated that the interviews will take 30-45 minutes. These will be recorded and transcribed. No participant will be identifiable. Further information will be provided to those who register interest.

You will have the opportunity to receive a summary of the findings of the study.

### **5. Can I withdraw once I've started?**

Being in this study is completely voluntary and you do not have to take part.

Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

During the interview you may refuse to answer any questions that you do not wish to answer.

You are free to withdraw from this study at any time. If you withdraw, we will not collect any further information from you. You can choose to withdraw any information you have already provided, unless the data has already been de-identified or published.

### **6. Are there any risks or costs?**

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

### **7. Are there any benefits?**

You will not receive any direct benefits from being in the study.

### **8. What will happen to information that is collected?**

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study.

Any information you provide us will be stored securely and we will only disclose it with your permission, unless we are required by law to release information. We are planning for the study findings to be published in the form of the student's PhD thesis, published papers and conference presentations. You will not be individually identifiable in any of these publications.

No names will be on any of the interview transcripts; each participant will be assigned a number and will not be identifiable. If you take part in an interview, this will occur between yourself, any nominated significant other person and the researcher only. No-one outside the research team will have access to the recordings. Information provided in the interview will not be able to be identified as yours.

The interviews will be recorded on a hand-held device, recordings will be uploaded and stored on an encrypted, password protected computer server and transcriptions of the recordings will be deidentified. Any handwritten notes the researcher may take during the interview will be uploaded and stored in the same manner.

All study materials will be stored on the University's licensed database Research Data Store (RDS) during the project. The RDS is a secure device located within NSW. Upon completion of the project, study materials will be stored RDS.

All study materials will be retained for 5 years as required by law. Project materials will then be deleted from all hard drives on secured sites within the University of Sydney by the Chief Investigator.

## 9. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form or asking the researchers in person. A brief lay summary of the findings will be made available through email contact with the student researcher.

## 10. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

- Dr Justin McNab (Responsible Researcher), Senior Lecturer, Discipline of Behavioural and Social Sciences in Health, Faculty of Medicine and Health

Email: [justin.mcnab@sydney.edu.au](mailto:justin.mcnab@sydney.edu.au); telephone +61 2 9036 7432

- Ms Sue Markham, MSc (PhD Candidate)

Email: [smar8309@uni.sydney.edu.au](mailto:smar8309@uni.sydney.edu.au)

## 11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney (HREC Approval No. 2022/422) according to the *National Statement on Ethical Conduct in Human Research (Updated 2018)*.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager  
[human.ethics@sydney.edu.au](mailto:human.ethics@sydney.edu.au)  
+61 2 8627 8176

*This information sheet is for you to keep*