Patient Participant Information Sheet

PPhoCUs: Polypharmacy, Pharmacists and Clinical Uncertainty
Large font version available if required.

Invitation and brief summary
You are being invited to take part in a research study. You do not have to take part but before you decide, it is important for you to understand why the research study 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. My name is Tom Kallis, I am a Clinical Pharmacist undertaking a PhD at the University of Exeter. I am doing this research study as part of my degree. Ask me (t.j.kallis@exeter.ac.uk) if there is anything that is not clear or if you would like more information.

It is the purpose of this study to understand the experience of patients who have many medicines prescribed when they have a review with a clinical pharmacist. This study will also seek to understand how pharmacists make decisions when reviewing patients with multiple medicines and potential clinical uncertainty. This will be done through audio recording of medication review appointments and interviews with both patients and pharmacists.

What would taking part involve?

i. Medication Review Recording: If you decide to take part, you will be invited to have your medication review appointment audio recorded by your practice pharmacist. They will ask you to sign a consent form or gather consent from you over the phone. You will have the opportunity to ask any questions about the research. Your medication review will proceed as normal and will be recorded. You will also be asked if you would like to participate in a follow-up interview.

ii. Interviews: The follow-up interview will be arranged at a time of your convenience and will be with me (Tom Kallis). This can be done over the phone or online via Microsoft Teams. The interview will last approximately one hour and you will be asked about your experience of having a medication review with a pharmacists. You can stop the interview or a break at any time and you do not have to answer any questions you do not want to.

What are the possible benefits of taking part?
You will be paid £25 for participating in a follow up interview. There are no other direct benefits to participating. An indirect benefit may be

improved quality of medication reviews and pharmacist training which this study seeks to support.

What are the possible disadvantages and risks of taking part?
You may feel uncomfortable having your appointment recorded. We are not aware of any disadvantages or risks to you in taking part in the study.

What happens if something goes wrong?
You can contact me (Tom Kallis) if you wish to complain or have any concerns about any aspect about any way you have been approached or treated during the course of this study. I will consider such reports promptly and take appropriate action immediately. If you feel that your complaint has not been handled to your satisfaction you can contact Prof Rupert Payne r.a.payne@exeter.ac.uk. You may also complain via your local Patient Advice and Liaison Service, which can be found at https://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals.

Who has reviewed the study?
The research study has been approved by a HRA Research Ethics Committee. The study has been peer reviewed by external academics.

Who is organising and funding the research?
The study is being organised by Tom Kallis at the University of Exeter and funded by the NIHR School for Primary Care Research.

How have patients and the public been involved in this study?
Patients and members of the public have been involved in this study from the point of applying for funding. Plain English summaries and the research programme structure have been reviewed by members of the public and patients. A dedicated Patient Advisory Group will inform the research throughout the study.

How will we use information about you?
We will need to use information from you and your medical records for this research project. This information will include your name, age, ethnicity, medication and list of medical conditions. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. The recordings will be anonymised and transcribed. Third party transcription services may be used to transcribe recordings taken. Confidentiality agreements will be in place with these services if

they are used to protect your identity and personal information. Once we have finished the study, we will keep some of the data so we can check the results. Anonymised information collected (including transcriptions) about you may be used to support other research in the future. This data will be retained for up to 10 years following recording. We will write our reports in a way that no-one can work out that you took part in the study.

Do you have to take part?
It is up to you to decide whether or not to take part. If you choose to take part you will first be asked to confirm your consent and you can still withdraw at any time prior to audio recording. You do not have to give a reason. If you choose not to participate in the study, your medical care will not be affected. If you participate in an interview, you can withdraw at any point up until 7 days afterwards by contacting the researcher. After this, your data will be anonymised and you will not be able to withdraw.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

How will my information be kept confidential?
All of the personally identifiable information that we collect about you during the course of the research will be kept strictly confidential and no one outside the University of Exeter will be allowed access to it. Electronic data containing personally identifiable information about you will only be stored on a password-protected, encrypted computer location that only I and my supervisory group have access to. Paper copies of data and other documentation containing personally identifiable information about you will be kept secure in a locked cupboard that only I have access to. The recorded audio of your medication review will be retained for 10 years following data collection, at which point it will be destroyed by Prof Rupert Payne. If you participate in a recorded follow-up interview, the recording will be destroyed after 90 days from the date of the interview. You will not be able to be identified in any reports or publications.

Where can you find out more about how your information is used?
You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/, via the University of Exeter Data Protection officer informationgovernance@exeter.ac.uk or by sending an email to the researcher t.j.kallis@exeter.ac.uk