## Appendix: Participant Information Sheet for Patient/carer Interview Participants (V2)

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| ***Study Title***  **Perspectives of health professionals and patients on undertaking high quality structured medication reviews, barriers and facilitators to effectiveness and efficiency: A qualitative study**  ***Introduction***  We would like to invite you to take part in the above research project to explore your views on how healthcare professionals (doctors, nurses, pharmacists and others involved in the care of patients) manage your medicines. This includes how they check for safety and decide if any changes are needed. This process is called a structured medication review (SMR). 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 this information leaflet carefully and talk it over with others if you wish. Be sure to 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 taking the time to read this.  ***What is the purpose of the study?***  The purpose of this study is to ask your views about your experiences of taking part in medication reviews with your healthcare professional. We wish to understand what your experiences are, both the good and the bad. We also wish to understand what information you require to be able to make safe choices with your healthcare professional and what kind of tools you think might be most helpful to both of you during the consultation. We also want to know what you consider to be the top priority medication challenges you face, and what you consider to be the most challenging aspects (barriers) to being able to ensure you get an effective outcome from your medication review.  The answers that you provide will be used in the development of a digital tool to support healthcare practitioners to deliver efficient and effective medication reviews. At the moment, there is no easy way of predicting which patients are most likely to benefit from a medication review and prioritising them. The review team is then faced with gathering and making sense of information from records held in different places, and piecing the information together to see how the patient’s conditions and treatments changed over time. The tool that we are developing will use artificial intelligence (AI) to bring together information from multiple records and guidelines and calculate risks of hospital admissions and other adverse outcomes for high-risk patients. To ensure this information is easily understandable we will develop visual summaries of patients’ journeys, showing how health conditions, treatments and risks of future adverse outcomes are changing over time. These visual summaries will be tested in general practices across northern England and improved based on feedback from clinicians and patients.  ***Why have I been chosen?***  We are inviting you to take part because you are a patient with experience of living with multiple long-term conditions and/or taking multiple medications every day.  ***What will I have to do?***  If you are interested in taking part please return a completed Expression of Interest form, using the enclosed pre-paid envelope. The researcher will then contact you to arrange a convenient time for you to take part in a one-to-one interview, either over the telephone or via video conference (your preference).  If you agree to take part in the study, we will ask you some questions about your experiences and views on the topics mentioned above. The interview will be digitally recorded for later analysis. The interview will last between 30 minutes and 1 hour.  ***Do I have to take part?***  No. It is up to you to decide whether or not to take part. Taking part in this study is entirely voluntary and you are free to withdraw from the study at any time without having to give a reason. Refusing to take part in the study, or a decision to withdraw at any time, will not affect your care.  You do not have to tell us why you do not want to take part. Just tell the researcher right away if you wish to withdraw from the interview.  If you do take part you will be given a consent form to sign before the start of the interview. You are free to answer or not answer some questions.  ***What are the possible disadvantages and risks of taking part?***  We do not believe that there are risks involved in taking part in this study and your participation will be confidential.  ***What if something goes wrong?***  If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Lauren Walker, tel. 0151 795 5407 or Frances Mair, tel. 0141 330 8317]. If you remain unhappy and wish to complain formally, you can do this by calling and making a complaint [NHS complaints 0131 314 5326]. Complaints should normally be made within 12 months of an incident or of the matter coming to your attention. This time limit can be extended provided you have good reasons for not making the complaint sooner and it's possible to complete a fair investigation.  ***How will the information I tell you be kept private?***  The University of Liverpool is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly in accordance with General Data Protection Regulation (GDPR.) The information that we collect will include your name, year of your birth and your contact details. We will keep all information about you safe and secure. 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.  All your information will be treated as confidential by the study personnel. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. No personal identification information (such as names) will be used in any reports and publications arising out of this research. Only anonymised identification numbers of participants will be used. The interview will be carried out in a private and safe environment and the data collected will be kept securely in locked filing cabinets and password-protected computers. Individuals who are not directly involved in conducting the study will not be allowed access to your personal information. Personal information will be kept separately from the interview data. No samples from any part of your body will be taken. We will keep the information from the interviews for up to 5 years after the project has come to an end. During this time, we may go back to the data to look at different things that were discussed. After this five-year period, all identifiable data will be deleted or destroyed. 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.  All audio recordings will be held on secure servers at either/both the University of Liverpool or Leeds until they have been transcribed. Once they have been transcribed the audio recording will be deleted and only the transcript will be stored. Audio recordings will be transcribed either by a software programme or by a professional transcriber at the University of Liverpool. A confidentiality agreement will be in place with the professional transcriber team. These transcripts may be shared with our collaborators on the project at the University of Leeds using the University of Liverpool’s secure file transfer system. Researchers at Leeds will then anonymize and depersonalize the transcripts and when we use the information provided by you, from the interview no names or identifiable data will be mentioned if we quote something that you say in future reports or publications.  Your anonymised data (interview transcripts) will be stored for a period of ten years after the end of the study on secure University servers and secure University premises. It may be used for additional future ethically approved research performed by approved researchers – who will only be given access with the permission of the research team.  Regulatory authorities and the study sponsor may be given access to personal and research data collected as part of the study where it is required for monitoring and auditing the conduct of the study.  Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.  **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/](https://www.hra.nhs.uk/information-about-patients/) * by sending an email to [daniel.howarth@liverpool.ac.uk](mailto:daniel.howarth@liverpool.ac.uk) (Data Protection Officer at University of Liverpool) * More information can be found here: [Data Protection & Research - Legal & Governance Intranet - University of Liverpool](https://www.liverpool.ac.uk/intranet/legal/data-protection-foi-staff/dataprotectiongdpr/dp-and-research/)   ***Will you pay my expenses?***  We will pay you £25 for the hour that it takes to do the interview. Alternatively, if you prefer, we will offer a £25 retail gift voucher for appreciation of your time and assistance for taking part in the telephone or video interview.  ***What will the evidence from this study be used for?***  We would like the information you give us to improve the way in which SMRs are prioritized and undertaken. We wish to better utilise existing data on patients in order to make the process of SMRs more efficient for those undertaking them. To create the best system, we need to work with the end users and patients to ensure all their requirements are captured in the system.  The evidence from this study will be brought together in a report. We will also publish the findings in scientific journals.  **Who is organising and funding the research?**  The University of Liverpool is the Sponsor of the study. It is fully funded by the National Institute for Health Research (NIHR).  An independent ethics committee has reviewed and approved this study.  ***Are there benefits to taking part in the study?***  There will be no direct benefit to you from taking part in this study. However, the information that you provide will help us understand how best to improve SMRs for better patient care.  ***What are the costs of taking part in this study?***  There are no direct costs to you for taking part in this study.  ***What will I do if I have questions about the study?***  You can talk to the researchers about any questions or concerns you have about the study. The contact details are as follows:  Dr Lauren Walker, tel. 0151 795 5407 or Professor Frances Mair, tel. 0141 330 8317  ***Giving consent to participate in the study***  You may keep this information sheet if you wish. There is a separate form that we keep where you sign to say you agree to take part in the study.  Thank you very much for considering taking part in our study. |