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## **Participant Information Sheet & Consent Form – Dialyse@Home: A Mixed Methods Pilot Study of Home Haemodialysis (Patient)**

You are being invited to take part in a research project. 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.

### **1. What is the purpose of the study?**

This study aims to explore the impact of home haemodialysis on patient and carer experience, and wider support needs. It will also explore which factors influence the interest that patients might have in dialyzing at home, and the best ways to help people to feel supported when they are dialyzing at home.

### **2. Why have I been chosen?**

You have been invited to take part because you are treated with home haemodialysis. All home haemodialysis patients at your dialysis centre are being asked whether they would like to participate.

### **3. Do I have to take part?**

No. It is up to you whether or not you take part. You can stop at any time without giving a reason. A decision not to take part or to stop will not affect your care. If you wish to withdraw consent please speak to your local study investigator (details at the bottom of this information sheet).

### **4. What do I have to do?**

This is a study that only involves the completion of a number of questionnaires, and if you agree, interviews.

If you agree, you will be given this sheet to keep and asked to sign a copy of a consent form. Your treatment will continue as normal. You will not have any extra hospital visits or medical tests. We will only study your usual care.

The study will last for 6 months. We will complete a form with you at the beginning of the study and we will post a form out to you at the end for you to complete and return to the research team using a stamped addressed envelope. This will be so that we can document your experience of treatment with home haemodialysis and its impact on your carer if you have one.

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This will take about 15 minutes and can be completed at your clinic visit.

As part of the study, a deeper investigation into home haemodialysis treatment will be carried out using interviews with a small number of patients and carers. You will be sent information about how to participate in this part of the study should you wish to separately.

#### **5. What are the possible benefits of taking part?**

There will be no direct benefit to you from taking part. However, the study will give information that will help us to better understand and possibly improve treatment for kidney patients.

#### **6. What are the possible risks of taking part?**

The study does not involve any changes to your treatment so there are no risks to you by taking part in this study.

#### **7. What if something goes wrong?**

We do not expect anything to go wrong as this study is only collecting information.

If you have any concerns about any aspect of this study, in the first instance you should speak to the local study investigator at your site, who will do their best to answer your questions. You can also contact the Chief Investigator for the whole study (Prof. Martin Wilkie, Sheffield Teaching Hospitals NHS Foundation Trust). Contact details are at the end of this information sheet. If you feel that your concern has not been adequately dealt with, then please contact the Patient Advice and Liaison Service at your hospital.

#### **8. Will my part in this study be kept secret?**

All information collected about you as a result of your participation in the study will be kept strictly confidential, and will be used for the purposes of this research only.

Your personal information will be kept in a highly secure server within the Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield, and will be handled securely in accordance with the data protection law(s) to ensure that all information about you is handled in the strictest confidence. As part of this study your data will be shared with the UK Renal Registry but not with any third parties not directly involved with this research. You may ask to see your personal information at any time and correct any errors if necessary.

Once you have agreed to participate in this study you will be allocated a unique study number which will be used on all your study documentation. This number will be linked to your personal information; however you will only be identified by this unique number in the final study data. Authorised staff who

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work for or with the sponsor of the study and the hospital Research Department may require access to your personal information and/or medical records to verify the data for this study and ensure that it is being conducted in accordance with UK law. All information will be treated in the strictest confidence during the review process. Your data will be retained for 3 years after which it will be destroyed.

General Data Protection Regulation (GDPR) statement.

Sheffield Teaching Hospital NHS Foundation Trust is the sponsor for this study based in 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. Sheffield Teaching Hospital NHS Foundation Trust will keep identifiable information about you for 3 years after the study has finished.

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 and any samples that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsor uses your information at <https://www.sheffieldclinicalresearch.org/> or by contacting the study team.

The Sponsor Data Protection Officer is Peter Wilson and you can contact them by phone 0114 2265153 or email [Peter.Wilson@sth.nhs.uk](mailto:Peter.Wilson@sth.nhs.uk).

*The local contact is (delete depending on Site requirements)*

Your Hospital Trust [insert name] will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Sheffield Teaching Hospitals NHS Foundation Trust and regulatory organisations may look at your research records to check the accuracy of the research study. [NHS site] will pass these details to the Sponsor along with the information collected from you. The only people in Your Hospital Trust [insert name] who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyze the information will not be able to identify you and will not be able to find out your name, hospital number or contact details.

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Sheffield Teaching Hospital NHS Foundation Trust will collect information about you for this research study from the questionnaires that you complete. This information will include name, NHS Number, date of birth, post code and health information, which is regarded as a special category of information. We will use this information to answer the research question.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

#### **9. What will happen to the results of the research study?**

Study results are published about large groups of patients. Your individual information will not be shared with the public. The results of the study will be published in journals and at conferences and will contribute to the development or further research studies. If you would like to be informed of the results of the study, please complete your details at the bottom of this sheet.

#### **10. Who is organizing and funding the research?**

This study is funded by grant from the Sheffield Hospitals Charity and the Health Foundation.

#### **11. Who has reviewed the study?**

The study has been reviewed by the Yorkshire and Humber – South Yorkshire Research Ethics Committee (Ref: 18/YH/0137).

#### **12. What if I am worried?**

If you have any questions or want to report any problems with this study, please contact:

#### **Study local investigator**

Name: \_\_\_\_\_ Telephone: \_\_\_\_\_

If you want independent advice, please contact the Patient Advice and Liaison Service (PALS):

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Name: \_\_\_\_\_

Telephone: \_\_\_\_\_

**Study Chief Investigator**

Professor Martin Wilkie, Sheffield Teaching Hospitals NHS Foundation Trust. Tel 01142715326

Centre Number:

Subject Initials:

Sequential patient number:

