PARTICIPANT INFORMATION SHEET

A Real-World, In-Situ, Evaluation of the Introduction and Scale-Up of Robot-Assisted Surgical Services in the NHS: Evaluating its Impact on Clinical and Service Delivery, Effectiveness and Cost

We'd like to invite you to take part in our study. Before you decide, it is important that you understand the reason for the study and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask your local REINFORCE team. Their contact details can be found at the end of this information sheet.

What is the purpose of the study?

REINFORCE aims to evaluate surgical services within the NHS, in order to determine the best ways to perform surgery. We will be collecting data on all specified surgeries at participating hospitals for the duration of the study (2 years). We will look at outcomes from patients, surgeons, theatre staff, and the wider organisation (NHS). We hope that when completed, we can advise the NHS on how best to provide their surgical services.

Why have I been invited?

The hospital where you are being treated has chosen to take part in this study. We would like to contact patients who are having surgery to compare their health before and after the procedure. We will also be asking surgeons and theatre staff about their experiences with surgery.

Do I have to take part?

No, taking part is optional. If you do not take part, this will not affect the care that you receive. You are free to withdraw from the study at any point without giving a reason and, again, this will not affect your care.

What is involved if I decide to take part?

If you decide to take part in the study, you will be asked to sign a consent form to document your agreement to participate. We will then ask you to fill out a questionnaire about your health prior to your surgery. 3 months after your surgery date we will send

you another similar questionnaire to compare how you feel after surgery. You can choose to receive and complete this questionnaire online (by email) or on paper (by post). You will not need to return to hospital to complete your questionnaires as they can be done at home.

Each questionnaire will take around 10-15 minutes to complete. If we do not receive your questionnaire back within 14 days, we will contact you again using other methods of communication, including by telephone, to remind you.

As part of the study, we will link the information from your questionnaires with your routinely collected health data (e.g. information about hospital visits related to the surgery). Any identifiable information will be removed to ensure that no one will be able to identify you from the file.

Are there any possible disadvantages or risks from taking part?

Outside of the usual risks associated with surgery and anaesthetic, there are no anticipated risks or disadvantages to participating in the REINFORCE study. Taking part in the study will not change the standard of care you receive.

The questionnaire we give you will contain some general health questions and some questions specific to your type of surgery. If any questions cause you distress, leave them blank and contact your local REINFORCE team if needed.

What are the possible benefits of taking part?

There is no direct benefit to participants. The results of the REINFORCE study are likely to benefit future NHS patients undergoing surgery, and the information you provide which may help to improve treatment in the future.

Will my taking part in the study be kept confidential?

Yes, you will be allocated a study number and all patient information will be stored securely on the University of Aberdeen computer server in accordance with data protection rules. Access to this information will be monitored and restricted to staff who require it to undertake their role. At the end of the study, data will be de-identified so people who have taken part will not be identified.

Responsible members of the University of Oxford, University of Aberdeen or your NHS trust may be given access to data for monitoring and/or audit purposes of the study to ensure the research is complying with applicable regulations.

Will I be reimbursed for taking part?

There is no payment to people taking part in the REINFORCE study. If you receive your study questionnaires in paper format, a free post return envelope will be provided.

What will happen to my data?

We will be using information from you and your medical records in order to undertake this study. The central REINFORCE team will use your name, home address and contact details, to contact you about the research study, including sending questionnaires for you to complete We will keep identifiable information about you for

up to 12 months after the study has finished. Your medical data will be held separately from your personal details and will be linked to you through your study ID number. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for at least 5 years after the end of the study. The University of Oxford is the study sponsor and will jointly act as the data controller with the University of Aberdeen. This means that both institutions are responsible for looking after your information and using it properly.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting REINFORCE@ndorms.ox.ac.uk or going to w3.abdn.ac.uk/hsru/REINFORCE

What will happen if I don't want to carry on with the study?

Taking part in REINFORCE is voluntary; if you decide to withdraw from the study, you can do so at any time. You do not need to give a reason for your decision, and it will not affect your hospital care. You can request that any information that you have provided up to the point you withdraw is not used in the final study analysis. If you change your mind and wish to leave the study, please contact your local study team (details at the end of this leaflet).

What will happen to the results of this study?

The results of the study will be published in a medical journal and on the study website. You will be given the opportunity to receive the results by email or post if you are interested in finding out how the study went. You will not be identified from any report or publication placed in the public domain.

What if there is a problem?

If you have a concern or wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact your local Principal Investigator or you may contact the University of Oxford (details below).

If you are concerned about your clinical care, the Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. If you wish to contact the PALS team, please contact the details listed on your local NHS trust website. Please note PALS is unable to provide information about this research study.

How have patients and the public been involved in this study?

In designing this study, we have considered patient opinions on aspects such as the content of the questionnaires. They have also provided review and comment of this information sheet and other study documents. Patients will continue to be involved in

the delivery and oversight throughout this study. For general information about taking part in research visit: www.nihr.ac.uk/ patients-carers-and-the-public/I-want-to-take-part-in-a-study/

Who is organising and funding the study?

The Surgical Intervention Trials Unit (SITU) at Oxford will manage the study with the Centre for Healthcare Randomised Trials (CHaRT) in Aberdeen. The National Institute for Health Research, Health Services and Delivery Research (NIHR HS&DR) has funded the study.

Further information and contact details:

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Thank you for considering taking part