 **Participant Information Sheet**

 **Patient reported Outcomes, Postoperative pain and
Pain relief after daY case surgery**

We are inviting everyone who is having day case surgery today to take part in a research study called the POPPY study. Please take a moment to read the information and someone from the research team will ask you if you are willing to take part and answer any questions you might have.

**What is the purpose of the study?**

This is a national study, meaning most hospitals across the UK are taking part. It is being run by Anaesthetists. It aims to find out how well people recover from their surgery at home. Some people experience pain for a long time after their operation, and some people continue to take strong painkillers. This study aims to find out how often this happens and what makes this more or less likely.

In addition, you *may* receive a phone call after this to ask if you agree to be interviewed in more depth about your experience after surgery. Only a *very* small number of people will be contacted for this interview. If you wish, you can opt out of this interview and still take part in the main study.

**What will I have to do?**

You will need to sign a consent form today to take part. A researcher will ask you several questions before your surgery today.

You will then receive a text message (or email) one day, three days, and seven days after your surgery with a link to a short questionnaire. The message will look similar to this: *“The POPPY study. Please click this link to complete your survey.”*

You will receive a final text message three months after your surgery. There will be a reminder message sent before this, so you know to expect it.

The questions will ask you about your pain, any painkillers you are taking, quality of life, your emotions and your recovery from surgery. **It is really important you complete the questionnaires as soon as you receive them to make your answers as accurate as possible**.

**Do I have to take part? If I take part will anything change about my care in hospital?**

No. Taking part is voluntary. Nothing will change about your care today or in the future if you chose not to take part.

**Are there any disadvantages to taking part?**

There are questionnaires during the first week and at three months after your operation. We expect the questionnaires to take 5-10 minutes to complete.

Some of the questions you answer may identify a problem with your health. They may suggest you may be trying to manage difficult feelings and thoughts. You may receive an automatically generated supportive message in responses to answers you have given to offer you general advice (for example a suggestion to contact your GP). If the answers to questions suggest you have severe feelings of depression and/or anxiety, we will send a standardised letter to your GP informing them of this. The letter will not contain any specific information about your answers and aims to keep you safe. By participating in this study you agree for us to contact your GP.

**Are there any benefits to taking part?**

There are no direct benefits for you, but the information will be used to improve the care of patients in the future.

**How will my information be kept confidential?**

We will collect some information from you or your medical notes about your surgery, anaesthetic and medical history. We will collect the following identifiers: name, age, mobile telephone number, full postcode, local hospital number. This is stored securely, and you will be given a study number (an anonymous number not linked to your actual name), meaning the data can be analysed without identifying you. Your GP information may be required (see above) but this will not be stored and saved by the research team. The consent form that you sign today will include your name. This is stored in your medical records. A copy of your consent form may be sent to the Research Sponsor during the study.

The information that we collect about you today, and from the questionnaires that you will receive by text (or email), will be held in a secure database. Your data will initially be collected and stored confidentially by NewcastlePROMS, before being transferred to the research team at University Hospitals Plymouth NHS Trust and the University of Plymouth. The NewcastlePROMS database is used by several NHS Trusts already and stores your information in an encrypted format and is guaranteed by the ‘Cyber Essentials’ government backed system. In line with Trust policy, at the end of the study, your data will be securely archived for a minimum of 5 years. After this, the data will then be securely destroyed.

**Who has access to my data?**

Only members of the research team will have access to your data. This data will not include your name. No member outside the research team will have access to your information collected in this study. The research team includes responsible members from University Hospitals Plymouth NHS Trust, University of Plymouth, regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* at <https://www.hra.nhs.uk/information-about-patients/>
* by asking one of the research team
* by visiting <https://www.plymouthhospitals.nhs.uk/privacy-notice-for-patients->
* by sending an email to informationgovernancepht@nhs.net
* by ringing us on 01752 437284 (Data Protection Officer).

**Who can I talk to if I have a problem (relating to the study)?**

Any complaint about the way you have been dealt with during the study will be addressed. If you have concerns about any aspect of this study, you should contact the researcher overseeing the study at your hospital in the first instance:
*<Insert name of site principal investigator> <email>*

After this, if you still have concerns you can contact the Patient Advice and Liaison Service (PALS) at your hospital:

*<Insert PALS details for local site (address, phone number & email)>*

**What happens if I do not want to carry on with the study?**

You can decide to stop taking part in the study at any time. Please be aware if you chose to do this, we will still use the information we have *already* collected about you. There will be a simple opt out option in the messages we send you.

**What happens to the results of the study?**

The results will produce reports, presentations, and publications. It will not be possible to identify you in any of these. Results will be available on our study website (see below). You will receive a text message to inform you of this.

**Who is organising the study?**

Chief Investigator: Dr Mark Rockett, University Hospitals Plymouth NHS Trust.

Research and Audit Federation of Trainees (RAFT).

**Who is funding the study?**

The National Institute of Academic Anaesthesia (NIAA).
The University Hospitals Plymouth (UHP) NHS Trust Charitable Funds.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by Cornwall and Plymouth Research Ethics Committee.

**For further information and contact details:**

[www.raftrainees.org/raft-4-poppy](http://www.raftrainees.org/raft-4-poppy) plh-tr.poppystudy.raft@nhs.net