Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
The POPPY Study

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England

- [x] Scotland
- [x] Wales
- [x] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] HM Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (•) No

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

( ) Yes (•) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(•) Yes ( ) No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The POPPY Study

Please complete these details after you have booked the REC application for review.

REC Name:
PR Committee

REC Reference Number:
23/PR/0310

Submission date:
13/03/2023

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Patient reported outcomes, postoperative pain and pain relief after day case surgery

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Mark	Rockett
Post	Consultant Anaesthetist		
Qualifications	MBChB, MRCP, FRCA, BSc, PhD, FFPMANZCA, FFPMRCA		
ORCID ID	0000 0001 8907 4396		
Employer	University Hospitals Plymouth		
Work Address	Derriford Road Plymouth		
Post Code	PL6 8DH		
Work E-mail	mark.rockett@nhs.net		
* Personal E-mail	mark.rockett@nhs.net		
Work Telephone	01752 439207		

* Personal Telephone/Mobile 01752 439207

Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Christopher	Rollinson
Address	Research Office, Level 2		
	MSCP, Bircham Park Offices, 1 Roscoff Rise,		
	Derriford, Plymouth		
Post Code	PL6 5FP		
E-mail	crollinson@nhs.net		
Telephone	01752431045		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	23/SED/793
Protocol Version:	v1.2
Protocol Date:	09/03/2023
Funder's reference number (enter the reference number or state not applicable):	NIAA22R203
Project website:	https://www.raftrainees.org/raft-4-poppy

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language*

easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.

Around 3 out of 4 operations in the UK are performed as day-case, meaning the patient goes home on the same day of their operation. Hospitals usually do not follow up patients after day-case operations so we do not know very much about their short or long-term recovery. Some patients, even those who have had small operations, can develop persistent pain afterwards that continues for a long time (months to years). These patients may end up taking strong painkillers for a long time and this risks serious side effects and long-term health problems.

The POPPY study aims to find out what recovery from day-case operations is like from the patient's point of view. We will look at the first week after patients' operations and then at day 97 to see if they are in pain, and if so what pain relief they are taking.

All adults over the 5-day study period having day-case operations in the UK, with an anaesthetist, will be eligible if they have access to a smartphone. Patients will be recruited on the day of their operation from over 100 NHS hospitals. Some relevant information about the patient's current health, operation and anaesthetic will be recorded from their notes. Afterwards participants will get a text message at days 1, 3 and 7 and then at 3 months. These will connect to a data secure online questionnaire about pain, recovery, and what medications they are taking. A small number of participants with ongoing pain at day 97 will be invited to take part in a structured interview to understand their experience in more depth.

This study will provide important information that may be used to improve care of patients having day-case operations and plan future research studies aimed to prevent persistent pain and long-term use of strong painkillers.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

The main study is an observational study, and therefore carries low ethical risks. However, we have identified potential ethical, legal and management issues below:

1) Study management issues: The main study is a large, multi-centre study. It aims to recruit approximately 6,000 patients on their day of surgery from over 100 NHS sites. This poses logistical challenges, however, the data collection will be performed and facilitated by the use of Trainee Research Network (TRN) groups in Anaesthesia (under the RAFT [Research and Audit Federation of Anaesthetic Trainees] organisation). The TRN groups consist of research interested Anaesthetic trainee doctors, they are present in almost every hospital within the UK. They are united by RAFT who will be coordinating their work. In order for them to take part in POPPY we will stipulate they will need to have up to date GCP (Good Clinical Practice) certification. Similar observational snap-shot studies have been successfully conducted by RAFT previously, with a similar methodology. RAFT studies successfully operate due to trainee doctors, assisted by research nurses and senior doctors including consultants. Participant follow up, after the day of recruitment, is all electronic via SMS text messages and therefore will be automated. This will not require individual input from research teams. The exception to this will be the qualitative interviews that will be conducted with a small number of patients (n=30). This portion of the study will be managed by the University of Plymouth research team.

2) Identifying patients who are depressed, anxious or suicidal: Due to the nature of this study, we may identify participants with these conditions using the SMS questionaries and/or during the qualitative interviews. Given the observational nature of this study the occurrence of an adverse event because of participation within this study is not expected. We will consent participants at the time of recruitment, explaining these conditions maybe identified.

Participants may report high scores on the GAD-7 and/or PHQ-8 scores at day 97 postoperatively. Those with undiagnosed mental health disorders may come to harm. Anxiety and depression are common in the general population with a prevalence of 6% and 3% respectively. One quarter of the UK population will suffer from a mental health problem at some point each year (https://mind.org.uk accessed 27/4/23). At baseline, we record whether participants already have a diagnosis of anxiety or depression. These participants will have a treatment plan in place for these disorders.

For participants potentially developing anxiety or depression during the study, research sites will contact the participant's GP with a standardised letter, either via email or paper, alerting them that their patient has elevated

results on a screening test for anxiety or depression. There will also be a supportive text message sent to the participant with details of sources of help with mental illness. These participants will be identified as answering the GAD-7 or PHQ-8 with scores >= 10 representing moderate or severe anxiety or depression without pre-existing mental health diagnosis.

The more in-depth questioning nature of the qualitative part of the study may lead to identification of a patient who reports self-harm or suicidal intent. We have designed a safety pathway for participants exhibiting symptoms of suicide or self-harm. This includes pausing the interview, undertaking a risk assessment by a registered healthcare professional and categorising participants into a risk category which will determine the interventions to be performed (ranging from self help suggestions to calling a 999 ambulance).

3) Data governance: Data will be entered into an electronic database on the day of surgery by researchers, and then by participants, via SMS, at follow up. Data will be stored on the NewcastlePROMs database. The NewcastlePROMS service is well established and has been employed by several NHS trusts to follow up patients remotely as part of a variety of initiatives. The security of the system is guaranteed by the 'Cyber Essentials' government backed scheme.

The advantages of employing the NewcastlePROMS service include:
• Sensitive information encrypted using bank grade technology
• Specifically designed to be patient facing
• Inbuilt complex conditional logic to ensure participants only view relevant questions
• Integrated with an SMS provider to enable data collection
• Data available to download into suitable statistical software

Data will be stored securely with NewcastlePROMS for twelve months from the beginning of the recruitment period. Following this, the anonymised data will be downloaded to a secure password protected folder based on a computer at the University of Plymouth.

The joint controllers of the data will be the sponsor, University Hospitals Plymouth NHS Trust, and Dr Adnaan Qureshi (Consultant Anaesthetist and owner of Newcastle PROMs). The processor of the data will be NewcastlePROMS.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [ ] Case series/ case note review
- [ ] Case control
- [x] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [x] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To measure short and long-term patient reported outcomes in UK day-case surgery patients.

Short-term outcomes include quality of recovery, severity of pain and analgesia use.

Long-term outcomes include incidence of persistent post-surgical pain (PPSP), and persistent postoperative opioid use (PPOU).

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

To identify patient, medication, anaesthetic, and surgical characteristics that are associated with poor quality of recovery, development of persistent post-surgical pain (PPSP) and persistent postoperative opioid use (PPOU).

To describe acute pain and analgesia use of patients during the first postoperative week.

To estimate the demand of these patients for further healthcare support in the first postoperative week.

To determine the patient reported acceptability of SMS prompted follow-up.

To determine the difference in quality of life between those with and without persistent post-surgical pain (PPSP).

Qualitative interview objectives; To explore patient experience of:
• Preparation for day case surgery and pre-operative expectations
• Acute recovery in the first postoperative week
• Longer-term recovery and post-operative pain after 3 months
• Opioids intake, type and duration and experience

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Around 75% of all surgical procedures in the UK are carried out as day-case, with six million day-case procedures performed annually. Whilst some hospitals successfully employ next day follow-up, meaningful longer-term assessment does not currently exist in many settings despite recognition that full functional recovery may take several months. There is therefore currently no comprehensive UK data on how patients recover following day-case surgery and limited understanding of longer-term outcomes.

Patient-reported outcome measures (PROMs), such as ability to return to carrying out usual activities and a good quality of life following surgery, are increasingly recognised as important and valuable outcomes to patients over more traditional clinician-centred outcomes such as morbidity and mortality. PROMS can provide a more thorough understanding of the impact interventions may have upon patients and lead to improved service delivery.

The prevention of chronic pain was identified as a top priority for anaesthetic research by the National Institute for Academic Anaesthesia and James Lind Alliance in 2015. There is growing evidence outside the UK that day-case patients commonly develop longer term health problems following surgery including Persistent Post-surgical Pain (PPSP). PPSP, pain continuing beyond 3-months post-operatively, is common with up to 18.3% of surgical patients suffering long term moderate to severe pain. Inappropriate long term opioid use after surgery is a major public health concern, with 6% of patients in the USA who had not used opiates prior to surgery using opioids for more than 3 months postoperatively. Here opioid prescriptions given to patients on discharge from hospital were found to frequently not be patient or procedure-specific, and over-prescription of opiates is a serious concern. Information in the UK population on PPSP, opiate prescribing and Persistent Postoperative Opioid Use (PPOU) is lacking.

A conservative extrapolation of North American results suggest more than 18,000 British day-case patients are at risk of developing PPOU annually. As more complex day-case procedures are performed on patients with increasingly complex existing health problems, the incidence of PPSP and PPOU are likely to rise.

Although there may be merit in understanding the prevalence of our outcomes information only really has value if:
a) it adds more to what is currently known
b) it enhances the quality of information provided to patients as they make choices regarding treatment options
c) it changes how we provide perioperative care

The POPPY study will do a lot to address the knowledge gap that exists in the UK regarding patients' experience of recovery after day-case operations and the rate of PPSP and PPOU. It will explore the impacts that PPSP and PPOU has on a large number of patients and the effect these have on patient centred outcomes such as quality of life. This will add more to what is currently known which may enhance the quality of information provided to patients prior to surgery and may change how we provide perioperative care.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person.*

Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

The POPPY Study will be a prospective, multi-centre, observational cohort study with an initial internal pilot study prior to wider national implementation, with a qualitative subgroup analysis.

A purpose built online platform will be employed to collect and manage anonymised patient data at each participating centre throughout the study. This service, run by NewcastlePROMS, enables the input of anonymised patient data at baseline on the day of surgery by investigators. Subsequent follow up of participants will be done using automated SMS, or email contact for those without access to a smartphone. Participants are requested to select a link within the SMS (or email) which directs them to a data secure online questionnaire. Data entered will automatically be linked to any baseline information collected about the participant by the research team.

The main study will run in two phases. An initial recruitment phase, largely delivered by RAFT (Research and Audit Federation of Trainees) anaesthetic trainees with consent and electronic data collection performed on the day of surgery. Data collection on day of surgery will will be undertaken by local investigators using an electronic proforma. Data collected will be linked to an anonymised participant identifier, and then subsequently linked to any submissions using the SMS prompted system. This will all be stored securely on the NewcastlePROMS centralised database. Data collection will be completed using a combination of medical notes review, and participant involvement where necessary. On the day of recruitment the participant is likely to be recruited to the study (10 minutes) and then answer questions about themselves, their pain and medication use (5 minutes). Local researchers will need enter more data after the surgery but this will not involve further time from study participants.

The second phase will be follow-up focussed on patient reported outcomes using specifically designed and validated tools. Follow-up will occur at days 1, 3, 7 and 97 post-surgery using the SMS prompted online system. Participants will be sent an SMS that will include a series of questions (5 minutes) that they will be asked to complete. These questions assess their pain and medication use and recovery from surgery.

A small number of participants (n=30) will be recruited through the main study to the qualitative portion of the POPPY study. They will be eligible for recruitment if they report opioid drug use post-surgery at 97 days. Interviews will be conducted online, or over the phone, using a semi-structured interview guide. The interviews will last up to one hour and will be recorded and then transcribed fully.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [x] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
We engaged with local PPIE (patient and public involvement and engagement) groups at the inception of our study. A meeting with the Peninsula Patient Experience Group ('PenPEG') in November 2021 was attended by 5 patients all with a variety of experience of research involvement.

PPIE has been embedded since this initial meeting. Topic selection, study aims, proposed methodology and development of funding application was conducted in consultation the PenPEG Peninsula Patient Experience group who have been broadly supportive of the study aims and objectives.

A schedule of ongoing PPIE has been costed into the study budget, and a group of three to four members with relevant lived experience and research experience has been formed.

The schedule of PPIE is as follows:
Session 1: introductory meeting, familiarisation with research questions, aims and broad methods (undertaken July 22).
Session 2: development of patient-facing aspects, PIS, consent form and questionnaires (undertaken February 23).
Session 3: consultation regarding ethics application, consent process (ongoing throughout Nov 22 - Feb 23).
Session 4: consultation with results of embedded pilot prior to national rollout
Session 5: discussion of results and dissemination

We do not expect members of our PPIE group to be involved in undertaking the study itself (i.e. recruitment/consent/data collection/ analysis), however one of the PPIE members is on the SSC (study steering committee). We will also ask the group to be involved with the discussion of results, conclusions, co-authorship, and invited to present and disseminate research findings.

In addition to these formal meetings we have contacted the PPIE members for further feedback on participant information sheets and our website, for example. We have also tested our electronic SMS system on our PPIE members to assess usability and functionality. A PPIE member has also reviewed our protocol and is present on our Study Steering Committee (SSC).

The interview for the qualitative aspect of the study have been trialled on PPIE members (February 2023).

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 110	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

- Aged 18 years or older on day of surgery
- Day-case surgery as defined by National Day Surgery Delivery Pack
- An anaesthetist must be present for case.
- The procedure must involve one or more of: sedation, regional anaesthesia, central neuraxial anaesthesia or general anaesthesia
- Able to read and understand English

Eligibility for qualitative component:

As above, plus reporting PPSP and PPOU at day 97 post operative.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

- Less than 18 years of age on day of surgery
- No access to a smartphone
- No anaesthetist involved with the procedure (such as local anaesthesia provided by a surgeon)
- Overnight stay (admission to hospital)
- Participant lacking capacity for consent
- Diagnostic and/or minimally invasive procedures (e.g., radiology, endoscopy, or cardiology procedures)
- Pregnancy or obstetric related procedures (being pregnant is not an exclusion criterion if surgery is unrelated to pregnancy)
- Currently breast feeding
- Ophthalmic procedures
- No access to Smartphone and email
- Prisoners

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Day 0 - Recruitment and Consent	1	0	10 min	Data entry by local research team onto database, in hospital
Day 0 - Baseline data collection pre-operative	1	0	10 min	Questionnaire and data entry by local research team onto database, in hospital
Day 0 - Baseline data collection post-operative	1	0	5 min	Questionnaire and data entry by local research team onto database, in hospital
Day 1 - Early postoperative recovery outcomes, acute pain scores, analgesia use	1	0	5 min	Patient, at home/elsewhere, entering data onto online database
Day 3 - Early postoperative recovery outcomes, acute pain scores, analgesia use	1	0	5 min	Patient, at home/elsewhere, entering data onto online database
Day 7 - Early postoperative recovery outcomes, acute pain scores, analgesia use and acceptability to participants of NewcastlePROMS system	1	0	5 min	Patient, at home/elsewhere, entering data onto online database
Day 97 – Persistent pain assessments, analgesia	1	0	10	Patient, at home/elsewhere, entering data onto

use and quality of life assessment			min	online database
Beyond Day 97 - perform an in-depth qualitative analysis on a purposive sample of patients that report PPOU and PPSP after 3 months of surgery	1	0	45-60 min	Patient, at home/elsewhere, via videoconferencing software
Beyond Day 97 - participants will be identified as answering the GAD-7 or PHQ-8 with scores >= 10 representing moderate or severe anxiety or depression without pre-existing mental health diagnosis	1	0	10	Local research team will contact the selected participant's GP with a standardised letter alerting them that their patient has elevated results on a screening test for anxiety or depression. No participant involvement in this stage.

A21. How long do you expect each participant to be in the study in total?

The vast majority of participants involvement in the study will end at 3 months after recruitment.

A small number (n=30) will be invited to the qualitative portion of the study and their involvement will end after the interview which will take place within 4 months of recruitment.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

This is an observational study. There is minimal risk to the participants.

The burdens are mainly in the form of time commitments over an extended period of time (3 months). Each questionnaire is fairly rapid to complete (<10 minutes). Although we will encourage completion of the follow up questionnaires as soon as they are prompted by SMS, participants will do this online so this can be completed at a time convenient to them. Participants are able to withdraw from the study at any point - there will be an option on the SMS link to withdraw from the study at any point. We will limit two reminder SMS messages maximum per questionnaire to avoid excessive intrusion.

The qualitative interviews will be more time consuming (up to 60 minutes) but will be performed online to increase the convenience for participants.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

Given the observational nature of this study the occurrence of an adverse event because of participation within this study is not expected.

Participants may report high scores on the GAD-7 and/or PHQ-8 scores at day 97 postoperatively. Those with undiagnosed mental health disorders may come to harm. Anxiety and depression are common in the general population with a prevalence of 6% and 3% respectively. One quarter of the UK population will suffer from a mental health problem at some point each year (https://mind.org.uk accessed 27/4/23). At baseline, we record whether participants already have a diagnosis of anxiety or depression. These participants will have a treatment plan in place for these disorders.

For participants potentially developing anxiety or depression during the study, research sites will contact the participant's GP with a standardised letter, either via email or paper alerting them that their patient has elevated results on a screening test for anxiety or depression. There will also be a supportive text message sent to the participant with details of sources of help with mental illness. These participants will be identified as answering the GAD-7 or PHQ-8 with scores >= 10 representing moderate or severe anxiety or depression without pre-existing mental health diagnosis.

Safety pathway for adverse events during qualitative study:
The more in-depth questioning nature of the qualitative part of the study may lead to identification of a patient who reports self-harm or suicidal intent. The safety pathway will follow the steps below:

• All patients will be informed of this, in the consent process, at the beginning of the interview.
• In patients exhibiting symptoms of self-harm or suicide to the interviewer, the interview will be paused.
• The interviewer will immediately seek attendance of a registered professional to complete a risk assessment (see appendix E).
• After the risk assessment, the registered professional will need to allocate the participant into an outcome category (see appendix E).
• The registered professional will use and signpost the interviewee to appropriate resources (see appendix E)

We will include the possibility of these actions in the consent process at the beginning of the interview by stating:

"The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself. In the event that you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having thoughts about suicide, the research staff will ask you further questions about these thoughts. Depending on the intensity of your thoughts or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment, work with you to contact your GP, trusted family member or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety."

A24. What is the potential for benefit to research participants?

This is unlikely to have apparent direct benefits to the participants themselves. They may, however, gain additional understanding of pain and analgesia.

The outcomes from the study will aim to improve the recovery from surgery and our understanding of pain and use of pain killers for future patients.

At the time of recruitment the participants will be consented and will be informed that by participating in the study their care will not be affected in any way.

A26. What are the potential risks for the researchers themselves? *(if any)*

There are minimal risks. Patient interaction will be within their usual work place, a clinical hospital environment.

The qualitative study will take place over videoconferencing technology from the researcher's usual place of work.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

This is a multicentred study and there will be a local research team on each research site (i.e. hospital). Recruitment will be delivered by local research teams, coordinated nationally by TRNs (Trainee Research Networks), overseen by RAFT. These will consist of trainee anaesthetic doctors (as part of the RAFT group), senior anaesthetists (mainly consultants), and research nurses.

Potential participants will be identified by the usual care team and recruited from surgical admission areas and clinics. A local investigator or their nominee, i.e., a member of the participant's usual care team, will inform the participant of all aspects pertaining to participation in the study. Potential participants will be identified from theatre lists (electronic or paper based) on the basis of the inclusion/exclusion criteria and asked if they would be willing to discuss the study with the research team. The precise method of identifying patients for screening will vary between institutions as resources and processes differ. Identification of potential participants, referral and data collection will all occur within the same NHS hospital. No patient identifiable data will be recorded without consent.

Participants will be recruited from preoperative waiting areas on the day of surgery. The study will be advertised using posters in these areas, and the initial approach will be undertaken by a member of the participant's usual healthcare team. As mentioned above, depending on local resources and protocols, it may be possible to identify participants

prior to the day of surgery for example, at pre-assessment clinics where they could be given a patient information sheet with their appointment letter.

The qualitative subgroup interview study will include a purposive sample of thirty individual participants of the POPPY study that report PPOU and PPSP at 97 days. We will select participants who have complete data (including baseline, and all points of follow up), and gave consent to receive a phone call from the study team after completion of the 97-day follow up inviting them to take part in an interview. To ensure that that certain key characteristics are represented within our sample we will select participants to approach according to pre-defined primary and secondary criteria using a sampling matrix48 (see table 4 in the protocol.).

We have assigned demographic and baseline characteristics of our population to be primary or secondary criteria based on the perceived importance of these variables on PPSP and PPOU. Primary criteria include age, sex, whether the participant reports pre-operative opioid use, or prior pain including pre-existing pain condition/chronic pain/ attendance at pain clinic/ high pre-operative pain score at site of planned surgery. The sample selected according to primary criteria will be monitored to ensure diversity of secondary criteria, which include ethnicity, region of the UK, postcode, anaesthetic type and surgical type, poorly controlled post-operative pain and low initial quality of recovery scores. These criteria are based on known risk factors for PPSP and PPOU.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
Potential participants will be identified using theatre lists or electronic theatre management systems on the day of surgery. The precise method of identifying patients for screening will vary between institutions as local resources and procedures differ. These lists or theatre management systems usually detail the patient's name, age, unique hospital number and operation to be performed only. These lists are usually displayed on notice boards or computer screens within staff only areas of hospital operating theatres. This lists will be reviewed by the usual care team and they will approach appropriate participants for possible recruitment. A PIS will be provided by the usual care team. If the potential participants are willing to speak with the researchers, then the research team will discuss the study and ask for consent. Medical notes for individual participants will not be accessed until consent has been gained by the local research team.

Recruitment to the qualitative part of the study will be by set criteria at the day 97 point (positive for PPSU and PPOU). 30 participants will be selected from those eligible as detailed in 27-1. They will be informed by a SMS message and then phoned by a member of the research team to discuss the qualitative study, go through the consent process and answer any questions. The original consent form signed at enrolment will mention this. A cooling off period (of 1-2 weeks) will be present and a videoconference appointment will be organised at a later date to perform an in depth interview with the participant.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

All eligible patients will be approached by a member of their usual care team (most commonly a member of the theatre anaesthesia team, but could be other healthcare professionals e.g. surgeon, pre-operative nurse) and asked about their willingness to participate. Once eligible subjects agree to consider participation and supplied a PIS, the member of the research team will consent the patient to enrol on the day of surgery

If the potential participants are willing to speak with the researchers, then the research team will discuss the study and ask for consent. Medical notes or any confidential information for individual participants will not be accessed until consent has been gained by the local research team.

The study will be publicised through posters, local presentations. Posters will be present in prominent surgical admission and preoperative areas to notify patients of the study.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Participants maybe be recruited from pre-operative waiting areas on the day of surgery. The study will be advertised using posters in these areas. The initial formal approach will be undertaken by a member of the participant's usual healthcare team. Depending on local resources and protocols, it may be possible to identify participants prior to the day of surgery e.g., at pre-assessment clinics where they will be given a patient information sheet with their appointment letter.

A29. How and by whom will potential participants first be approached?

The initial formal approach will be undertaken by a member of the participant's usual healthcare team (usually the theatre anaesthetist). If they agree, they will then be then approached by a local researcher face to face to gain consent to participation in the study.

Consent for the main study and the possibility of entry into the qualitative study will occur at the same time. The qualitative study participants will then be fully consented, if identified by the eligibility criteria after day 97 of the main study.

Consent for the qualitative study will be gained over the phone and/or videoconferencing in advance of the interview. The qualitative study will have a second consent form and PIS that is specific to the qualitative part of the study.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

The initial approach will be undertaken by a member of the participant's usual healthcare team. A local investigator or their nominee, e.g., a member of the participant's usual care team, will inform the participant of all aspects pertaining to participation in the study.

The potential participant will be made aware that their entry into the study is entirely voluntary and that their care will not be affected by a decision to participate or not. It will also be explained that they can withdraw at any time, either by not replying to messages sent via SMS or email or by specifically requesting this of the study team. In the event of their withdrawal, it will be explained on the consent form and PIS that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Recruitment to the qualitative part of the study will be by set criteria at the day 97 point (i.e. positive diagnosis for PPSU and PPOU). 30 participants will be randomly selected from those eligible. They will have consented to entry into this part of this study at initial enrolment on the day of surgery. They will be informed again by a SMS message and then phoned by a member of the research team to discuss the qualitative study, go through the consent process and answer any questions. The original consent form signed at enrolment will mention this process. A cooling off period will be present and a videoconference appointment will be organised to perform an interview with the participant.

If you are not obtaining consent, please explain why not.

N/A

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

All participants must provide written informed consent to be included in the study. This will be undertaken only after the patient has been initially approached and has been given a participant information sheet (PIS) by a member of their usual care team. We will ensure that clinical teams offer the PIS prior to the introduction of the research team. This will allow time for reading and discussion if required.

All patients will be given time to discuss the study with the research team prior to consent being requested. Potential participants will be given sufficient time to consider their involvement and will also be given the opportunity to ask questions of the investigating team. There will be a period of time where the patient has time to read the PIS and consider what they have been told about the study. As the potential burden of harm involved in participating is very low, and following PPIE consultation, participants will be recruited and consented in the initial meeting rather than having a specified prolonged 'cooling off' period.

Participants will be informed of the qualitative study at time of the original consent process as described previously. They will be reminded of this at the completion of Day 97 data via SMS and informed they may be phoned to discuss the study. After Day 97 participants will be telephoned by a researcher to discuss the qualitative study. They will be sent, via email or post, the qualitative study PIS. Allowing sufficient time (likely 1-2 weeks) for the participant to receive, read and consider the PIS, they will be to recontacted using videoconferencing, at a pre-arranged time. The researcher will gain verbal consent, using the 'Remote Participant Consent Form'. When the consent form is complete, the participants will proceed onto the qualitative study at a separate time.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

This study will be conducted in English. If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the study, the participant information sheets, and consent forms, however, the data entry platform will only be in English. The consent forms and information sheets will not be available printed in other languages at this stage.

The main reason for this is the lack of validity of translating questions relating to pain into other languages. Non-English versions of the BPI and other questionnaires will not be validated or comparable. Therefore, the study will only capture data in English.

For similar reasons, the qualitative study will be conducted in spoken English.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

As detailed in question A33-1. Due to lack of validity of the research surveys (for example BPI), the study will be conducted solely in English.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

○ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be

assumed.

Further details:

There will be no mechanism within the main study to identify participants who loose capacity during the course of the study. The qualitative study will re-establish capacity for consent at the beginning of this aspect of the study, and therefore, participants without capacity will be excluded at this recruitment stage of the qualitative study.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☐ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:

Personal data that will be collected in this study includes only: mobile telephone number, age, name, local hospital number, GP contact details and post code. Data will be collected via a web browser, used on secure handheld devices. 'Secure' includes any device deemed secure enough to access NHS emails. Data-access is one-way for local investigators.

To comply with the Data Protection legislation information will be collected and used fairly, stored safely and not disclosed to any unauthorised person. This applies to both manual and electronically held data.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and ensure the EU General Data Protection Regulation (GDPR) in conjunction with the UK Data Protection Act 2018, which sets out the statutory requirements for the processing of personal data, is adhered to.

Data will be stored on the NewcastlePROMs database. Data will be stored securely with NewcastlePROMS for twelve months from the beginning of the recruitment period. Following this, the anonymised data will be downloaded to a

secure password protected folder based on a computer at the University of Plymouth.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Data will be stored on the NewcastlePROMs database. The NewcastlePROMS service is well established and has been employed by several NHS trusts to follow up patients remotely as part of a variety of initiatives. The security of the system is guaranteed by the 'Cyber Essentials' government backed scheme.

The advantages of employing the NewcastlePROMS service include:
• Sensitive information encrypted using bank grade technology
• Specifically designed to be patient facing
• Inbuilt complex conditional logic to ensure participants only view relevant questions
• Integrated with an SMS provider to enable data collection
• Data available to download into suitable statistical software

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

To comply with the Data Protection legislation information must be collected and used fairly, stored safely and not disclosed to any unauthorised person. This applies to both manual and electronically held data.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and ensure the EU General Data Protection Regulation (GDPR) in conjunction with the UK Data Protection Act 2018, which sets out the statutory requirements for the processing of personal data, is adhered to.

The data controller will be the Sponsor, University Hospitals Plymouth NHS Trust. Dr Adnaan Qureshi (of Newcastle PROMs) will be the data processor.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

All data will be collected electronically and stored against anonymised patient identifiers on a secure centralised database developed by the NewcastlePROMS team in collaboration with the project management group. This will be stored within NHS and University of Plymouth's secure storage. It will not be stored on personal computers.

The local research team who will be entering the data onto the database will have access to the data until it is submitted on the day of surgery. They will only have access to data entered at their research site which will be password protected. After submission they will no longer have access.

The qualitative research team will have access to participants identifiable data to allow them to contact them at 3 months after recruitment. This will be kept to essential data only (phone number only).

We will inform participants that their data can be accessed by these groups via the Participant Information Sheet. The consent form will include the fact that a participant's data can be accessed by these groups. The individuals within these teams are healthcare professionals including doctors, research nurses and those with research specific roles such as statisticians or data controllers.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data will be initially retrieved from Newcastle PROMS storage, and then transferred to the University Hospitals Plymouth storage for analysis. Dr Lexy Sorrell - statistician at University of Plymouth - will analyse the anonymous generated data. Other members of the project management group may also access the anonymous data.

Data will not be exported outside the EEA.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Mark	Rockett
Post	Consultant Anaesthetist		
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Work Address	University Hospitals Plymouth		
	Plymouth		
Post Code	PL6 8DH		
Work Email	mark.rockett@nhs.net		
Work Telephone	01752 439203		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ◉ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Data will be stored securely with NewcastlePROMS for twelve months from the beginning of the recruitment period i.e until data collection for the study is completed. Following this, the anonymised data will be downloaded to a secure password protected research drive based at the University Hospitals Plymouth.

Archiving will be authorised by the Sponsor following submission of the end of study declaration. Upon completion of the study, any paper documents will be scanned and then transferred to the Trust Research Archivist for archiving. Original copies of the documents will be destroyed as per the Research Archiving SOP (SC2).

Upon completion of the study, study documents will be archived for a minimum of 5 years as per the participating Trust's Research Archiving SOP. Once the archiving retention period has been reached, the Sponsor will liaise with the sites regarding destruction.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- ○ Yes
- ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
On the clinicaltrials.gov website.
Protocol ID: 23/SED/793

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study?*Tick as appropriate:*

☑ Peer reviewed scientific journals
☑ Internal report
☑ Conference presentation
☑ Publication on website
☑ Other publication
☐ Submission to regulatory authorities
☑ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable personal data will be published. This study is collecting data from participants from across the UK and will collect data on an estimated 6000 participants. Analysis and publication of data will be anonymous.

The qualitative study will involve interview transcripts of 30 patients. Direct quotes from their interview may be used. They will be anonymised with only minimal details in publication e.g. male, age within a range. We will take care not to include other details, e.g. occupation, in a manner that will identify the patient.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
On the PIS we will inform participants that the results and the outcomes of the study will be freely available from our website. We will highlight publications of the results on our study website which participants will have access to.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed?*Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The study has been reviewed at multiple stages in its development.

1) The study concept was initially presented by the research team to a national committee of Anaesthesia Research experts (including the RAFT chairperson/committee and Professor Tim Cook)

2) The study has undergone monthly Project Management Group (PMG) meetings where its progress has been discussed. Attendees at these meetings have included the CI and Research Advisors from the Sponsor's Organisation (University Hospitals Plymouth), as well as a statistician. The Research Advisors (multiple) have been involved throughout the study and have reviewed the study protocol multiple times.

3) The Study Steering Committee (SSC) have intermittently reviewed the study. They have met and had overview of the design and scientific quality. The SSC has members that are predominately independent from the PMG but have expertise in the subject matter (from Anaesthesia and/or Pain Medicine from both a clinical and research background) or in research processes, as well as PPIE membership and RAFT committee members (trainee Anaesthetic doctors with a research interest, including trainees with a clinical interest in Pain Medicine). The first SSC meeting was held in January 2023, which included setting a SSC charter and reviewing the study protocol.

4) The sponsor has been involved throughout all stages of our study design. A representative has attended each PMG and SSC meeting.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed?*Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator’s institution

☐ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Lexy	Sorrell
Department	Faculty of Health		
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Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

1) To measure short-term quality of recovery in UK day-case surgery patients

2) To measure the prevalence of persistent post-surgical pain (PPSP) and persistent postoperative opioid use (PPOU) in UK day-case surgery patients

A58. What are the secondary outcome measures?*(if any)*

To identify those patient, medication, anaesthetic, and surgical characteristics that are associated with poor quality of recovery, and development of PPSP and PPOU.

To describe the acute pain and analgesia use of these patients in the first postoperative week

To estimate the demand of these patients for further healthcare support in the first postoperative week

To determine the patient reported acceptability of SMS prompted follow-up

To determine the difference in quality of life between those with and without PPSP

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	6000
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
The main study aims to recruit approximately 6000 participants from over 100 NHS sites across the UK.

The qualitative aspect will recruit 30 participants.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

We are aiming to obtain a sample size of approximately 6,000 day-case patients, from approximately 100 sites, allowing for participant drop out, based on the recruitment numbers from comparable previous trainee-led snapshot studies which have demonstrated this to be feasible, and data on current day case surgery activity in the UK.

A sample size of 6,000 with a 95% confidence level will allow estimated prevalence of PPSP and PPOU with a marginal error of 1.3%.

A61. Will participants be allocated to groups at random?

(●) Yes ( ) No

If yes, please give details of the intended method of randomisation:
The 30 patients selected to enter the qualitative part of the study will be selected after day 97. They will have been identified as having persistent post-surgical pain (PPSP) and persistent post-operative opioid use (PPOU) (against set criteria from answers they have supplied to questionnaires). From all of these eligible participants, 30 patients will be randomly selected to enter the qualitative study and this random selection will continue until the 30 participant number is achieved.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Participant, anaesthetic, medication use and surgical characteristics will be summarised using appropriate descriptive statistics, such as frequencies and percentages for categorical data, mean and standard deviation for continuous data.

The prevalence of PPOU and PPSP at 3-months will be presented alongside corresponding 95% confidence intervals.

Separate mixed effects logistic regression models will be used to identify patient, anaesthetic, medication use, and surgical characteristics associated with PPSP and PPOU, adjusting for sites and geography as random effects. Model estimates will be presented with 95% confidence intervals with a p-value <0.05 considered statistically significant. Consideration will be given to the joint modelling of PPOU and PPSP in future work.

Short-term outcomes will be summarised descriptively and graphically, with regression models used to identify associations between variables of interest and the outcome, where appropriate.

A statistical analysis plan (SAP) detailing the planned analyses will be developed by the statistician.

The sample of participants will be recruited through the main study (n=30) and will be recruited according to criteria for opioid drug use post-surgery (97 days). Interviews will be conducted online or over the phone, using a semi-structured interview guide. The interviews will last up to one hour and will be recorded and then transcribed fully.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	William	Hare
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Title	Forename/Initials	Surname
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Mobile			
Work Email	harriet.daykin@nhs.net		

	Title	Forename/Initials	Surname
	Dr	Lexy	Sorrell
Post	Post Doctoral Research Fellow in Medical Statistics		
Qualifications	BSc, MSc, PhD		
Employer	University of Plymouth		
Work Address	Plymouth		
Post Code	PL4 8AA		
Telephone			
Fax			
Mobile			
Work Email	lexy.sorrell@plymouth.ac.uk		

	Title	Forename/Initials	Surname
	Ms	Lindsey	Pollard
Post	Nurse Consultant in Pain Management		
Qualifications	BSc Hons Adult Nursing, NMP.		
Employer	University Hospitals Plymouth NHS Trust		
Work Address	Rowan House Derriford Hospital Plymouth		
Post Code	PL6 8DH		
Telephone			
Fax			
Mobile			
Work Email	lindseypollard@nhs.net		

	Title	Forename/Initials	Surname
	Professor	Patricia	Schofield
Post	Professor in Clinical Nursing		
Qualifications	RGN, PhD, PGDipEd, DipN		
Employer	University of Plymouth		
Work Address	School of Nursing & Midwifery. Faculty of Health: Medicine, Dentistry and Human Sciences Kirkby Place		

	Drake Circus, Plymouth
Post Code	PL4 8AA
Telephone	
Fax	
Mobile	
Work Email	patricia.schofield@plymouth.ac.uk

Title	Forename/Initials	Surname
Dr	Katie	Samuel

Post	Consultant of Anaesthesia
Qualifications	
Employer	North Bristol NHS Trust
Work Address	Southmead Hospital
	Southmead Road
	Bristol
Post Code	BS10 5NB
Telephone	
Fax	
Mobile	
Work Email	katie.samuel@nhs.net

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University Hospital Plymouth NHS Trust
Given name	Christopher
Family name	Rollinson
Address	Research Office, Level 2
Town/city	MSCP, Bircham Park Offices, 1 Roscoff Rise,
Post code	PL6 5FP
Country	United Kingdom

Telephone	01752431045
Fax	
E-mail	crollinson@nhs.net

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

Please give details of funding applications.

Organisation	The National Institute of Academic Anaesthesia (NIAA)
Address	Churchill House, 35 Red Lion Square London
Post Code	WC1R 4SG

Telephone	02076311650
Fax	
Mobile	
Email	secretariat@anaesthetists.org

Funding Application Status: (•) Secured ( ) In progress

Amount: £29919

Duration
Years: 0
Months: 12

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Association of Anaesthetists/Anaesthesia research grant

Organisation	University Hospitals Plymouth
Address	Derriford Road Plymouth
Post Code	PL6 8DH
Telephone	
Fax	
Mobile	
Email	corinna.mossop@nhs.net

Funding Application Status: (•) Secured ( ) In progress

Amount: £10387

Duration
Years: 0
Months: 12

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Charitable Research Fund

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Mrs	Corinna	Mossop
Organisation	University Hospitals Plymouth NHS Trust		
Address	The Research Office, Level 2 MSCP		
	Bircham Park Offices, 1 Roscoff Rise		
	Derriford, Plymouth		
Post Code	PL6 5FP		
Work Email	corinna.mossop@nhs.net		
Telephone	01752431046		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

South West Peninsula

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 03/04/2023
Planned end date: 08/04/2024
Total duration:
Years: 1 Months: 0 Days: 0

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 100

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	78
☑ NHS organisations in Wales	10
☑ NHS organisations in Scotland	10
☑ HSC organisations in Northern Ireland	2
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	100

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study will be subject to monitoring by UHPNT under their remit as sponsor to ensure adherence to the UK Policy Framework for Health and Social Care Research (2017). All UHPNT studies will be initially monitored at 25 days (+/- 7 days) after R&D capability and capacity has been given. The subsequent level of monitoring will be determined by a risk assessment, or on a for cause basis. The study may also be audited/ inspected by regulatory bodies to ensure compliance with national regulations.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country	Harriet Daykin harriet.daykin@nhs.net BM MSc FRCA United Kingdom
	Organisation name	ROYAL DEVON UNIVERSITY HEALTHCARE NHS FOUNDATION TRUST		
	Address	ROYAL DEVON UNIVERSITY NHS FT BARRACK ROAD EXETER		
	Post Code	EX2 5DW		
	Country	ENGLAND		
IN3	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country	David Hutchins d.hutchins@nhs.net FRCA United Kingdom
	Organisation name	UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST		
	Address	DERRIFORD HOSPITAL DERRIFORD ROAD DERRIFORD PLYMOUTH		
	Post Code	PL6 8DH		
	Country	ENGLAND		
IN4	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email	Lorraine Harrington Lorraine.Harrington@nhslothian.scot.nhs.uk
	Organisation name	NHS Lothian		

	Address	Waverley Gate 2-4 Waterloo Place EDINBURGH MIDLOTHIAN	Qualification (MD...)	
			Country	United Kingdom
	Post Code	EH1 3EG		
	Country	SCOTLAND		

IN5

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	Julie
		Middle name	
		Family name	Naylor
		Email	julie.naylor6@nhs.net
Organisation name	NORTH WEST ANGLIA NHS FOUNDATION TRUST	Qualification (MD...)	MBBS, FRCA
Address	PETERBOROUGH CITY HOSPITAL BRETTON GATE BRETTON PETERBOROUGH	Country	United Kingdom
Post Code	PE3 9GZ		
Country	ENGLAND		

IN6

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	Antony
		Middle name	
		Family name	Ratnasingham
		Email	a.ratnasingham@nhs.net
Organisation name	SURREY AND SUSSEX HEALTHCARE NHS TRUST	Qualification (MD...)	MBBS
Address	TRUST HEADQUARTERS EAST SURREY HOSPITAL CANADA AVENUE REDHILL SURREY	Country	United Kingdom
Post Code	RH1 5RH		
Country	ENGLAND		

IN7

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	Helen
		Middle name	
		Family name	Helen McNamara

			Email	helen.mcnamara@lwh.nhs.uk
	Organisation name	LIVERPOOL WOMEN'S NHS FOUNDATION TRUST	Qualification (MD...)	MBChB
	Address	LIVERPOOL WOMENS HOSPITAL CROWN STREET LIVERPOOL	Country	United Kingdom
	Post Code	L8 7SS		
	Country	ENGLAND		

IN8

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Richard
		Middle name	
		Family name	Ramsaran
		Email	Richard.ramsaran@liverpoolft.nhs.uk
Organisation name	LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	
		Country	United Kingdom
Address	ROYAL LIVERPOOL UNIVERSITY HOSPITAL PRESCOT STREET LIVERPOOL		
Post Code	L7 8XP		
Country	ENGLAND		

IN10

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Anil
		Middle name	
		Family name	Hormis
		Email	anilhormis@nhs.net
Organisation name	THE ROTHERHAM NHS FOUNDATION TRUST	Qualification (MD...)	MBChB FCARCSI FRCA AFICM
Address	MOORGATE ROAD ROTHERHAM	Country	United Kingdom
Post Code	S60 2UD		
Country	ENGLAND		

IN11

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Sashin
		Middle name	
		Family name	Valap

			Email	sachin.valap1@nhs.net
	Organisation name	KETTERING GENERAL HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	ROTHWELL ROAD	Country	United Kingdom
		KETTERING		
	Post Code	NN16 8UZ		
	Country	ENGLAND		

IN12

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Johannes
		Middle name	
		Family name	Retief
		Email	jretief@nhs.net
	Organisation name	TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST	Qualification (MD...) Mb BCh
	Address	TORBAY HOSPITAL	Country United Kingdom
		NEWTON ROAD	
		TORQUAY	
	Post Code	TQ2 7AA	
	Country	ENGLAND	

IN13

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Amarjeet
		Middle name	
		Family name	Patil
		Email	Amarjeet.Patil@mft.nhs.uk
	Organisation name	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST	Qualification (MD...) MBBS MD EDAIC FCPS DA CPS DA
	Address	COBBETT HOUSE	Country United Kingdom
		OXFORD ROAD	
		MANCHESTER	
	Post Code	M13 9WL	
	Country	ENGLAND	

IN14

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Nicholas
		Middle name	
		Family name	Ireland
		Email	nicholas.ireland@nhs.net

	Organisation name	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	BHB, MB ChB (Auckland) FANZCA, PGCert (Clin. Res)
			Country	United Kingdom
	Address	FREEMAN HOSPITAL FREEMAN ROAD HIGH HEATON NEWCASTLE UPON TYNE		
	Post Code	NE7 7DN		
	Country	ENGLAND		

IN15

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename	Andrew
		Middle name	
		Family name	Clark
		Email	Andrew.clark@aapct.scot.nhs.uk
Organisation name	NHS Ayrshire and Arran	Qualification (MD...)	MBChB, MSc, FRCA
Address	PO Box 13, Boswell House 10 Arthur Street AYR	Country	United Kingdom
Post Code	KA7 1QJ		
Country	SCOTLAND		

IN16

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename	Rachel
		Middle name	
		Family name	Kearns
		Email	rachel.kearns@ggc.scot.nhs.uk
Organisation name	NHS Greater Glasgow and Clyde	Qualification (MD...)	MBChB, MD, FRCA
Address	J B Russell House Gartnavel Royal Hospital 1055 Great Western Road Glasgow GLASGOW LANARKSHIRE	Country	United Kingdom
Post Code	G12 0XH		
Country	SCOTLAND		

IN17

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NHS Lanarkshire
Address	14 Beckford Street HAMILTON LANARKSHIRE
Post Code	ML3 0TA
Country	SCOTLAND

Forename	Colum
Middle name	
Family name	Slorach
Email	colum.slorach@lanarkshire.scot.nhs.uk
Qualification (MD...)	MBChB, FRCA
Country	United Kingdom

IN18

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NHS Greater Glasgow and Clyde
Address	J B Russell House Gartnavel Royal Hospital 1055 Great Western Road Glasgow GLASGOW LANARKSHIRE
Post Code	G12 0XH
Country	SCOTLAND

Forename	Lisa
Middle name	
Family name	Gemmell
Email	lisa.gemmell2@ggc.scot.nhs.uk
Qualification (MD...)	MBChB, FRCA, FFICM
Country	United Kingdom

IN19

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
Address	LEICESTER ROYAL INFIRMARY INFIRMARY SQUARE LEICESTER
Post Code	LE1 5WW
Country	ENGLAND

Forename	Elinor
Middle name	
Family name	Wighton
Email	elinor.wighton@uhl-tr.nhs.uk
Qualification (MD...)	MBChB, FRCA
Country	United Kingdom

IN20

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST
Address	CHESTERFIELD ROAD CALOW CHESTERFIELD
Post Code	S44 5BL
Country	ENGLAND

Forename	Charles
Middle name	
Family name	Spittle
Email	n.spittle@nhs.net
Qualification (MD...)	MBBS, FRCA, FFICM
Country	United Kingdom

IN21

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	SOUTH TYNESIDE AND SUNDERLAND NHS FOUNDATION TRUST
Address	SUNDERLAND ROYAL HOSPITAL KAYLL ROAD SUNDERLAND
Post Code	SR4 7TP
Country	ENGLAND

Forename	Sean
Middle name	
Family name	Cope
Email	sean.cope@nhs.net
Qualification (MD...)	MBBS
Country	United Kingdom

IN22

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	JOHN RADCLIFFE HOSPITAL HEADLEY WAY HEADINGTON OXFORD
Post Code	OX3 9DU
Country	ENGLAND

Forename	Amelia
Middle name	
Family name	Vanmanen
Email	Amelia.vanmanen@ouh.nhs.uk
Qualification (MD...)	MA MPhil BM BCh (Oxon)
Country	United Kingdom

IN23

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	ROYAL FREE LONDON NHS FOUNDATION TRUST
Address	ROYAL FREE HOSPITAL POND STREET LONDON
Post Code	NW3 2QG
Country	ENGLAND

Forename	Rajeev
Middle name	
Family name	Jha
Email	rajeevjha@nhs.net
Qualification (MD...)	MBBS
Country	United Kingdom

IN24

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST
Address	KENT & CANTERBURY HOSPITAL ETHELBERT ROAD CANTERBURY
Post Code	CT1 3NG
Country	ENGLAND

Forename	Gayathri
Middle name	
Family name	Hewawasam
Email	g.hewawasam@nhs.net
Qualification (MD...)	MBBS
Country	United Kingdom

IN25

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	COUNTY DURHAM AND DARLINGTON NHS FOUNDATION TRUST
Address	DARLINGTON MEMORIAL HOSPITAL HOLLYHURST ROAD DARLINGTON
Post Code	DL3 6HX
Country	ENGLAND

Forename	Myra
Middle name	
Family name	Khan
Email	m.khan75@nhs.net
Qualification (MD...)	MBBS, BSc,FCPS, FRCA, MAcadME
Country	United Kingdom

IN26

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NORTH CUMBRIA INTEGRATED CARE NHS FOUNDATION TRUST
Address	PILLARS BUILDING CUMBERLAND INFIRMARY INFIRMARY STREET CARLISLE
Post Code	CA2 7HY
Country	ENGLAND

Forename	Geetanjali
Middle name	
Family name	Verma
Email	Geetanjali.verma@ncic.nhs.uk
Qualification (MD...)	MBBS, DNB (Anaesthesia), EDAIC, FCAI
Country	United Kingdom

IN27

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST
Address	KENT & CANTERBURY HOSPITAL ETHELBERT ROAD CANTERBURY
Post Code	CT1 3NG
Country	ENGLAND

Forename	Kim
Middle name	
Family name	Jemmett
Email	kim.jemmett@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN28

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	ANEURIN BEVAN UNIVERSITY LHB
Address	HEADQUARTERS - ST CADOC'S HOSPITAL LODGE ROAD CAERLEON NEWPORT GWENT

Forename	Tamas
Middle name	
Family name	Szakmany
Email	tamas.szakmany@wales.nhs.uk
Qualification (MD...)	MD, PhD, EDIC, DESA, FRCA, FFICM, FCCM
Country	United Kingdom

Post Code	NP18 3XQ
Country	WALES

IN30

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NHS National Waiting Times Centre Board
Address	Agamemnon Street CLYDEBANK DUNBARTONSHIRE
Post Code	G81 4DY
Country	SCOTLAND

Forename	Ben
Middle name	
Family name	Shelley
Email	benjamin.shelley@glasgow.ac.uk
Qualification (MD...)	FRCA
Country	United Kingdom

IN31

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	WRIGHTINGTON, WIGAN AND LEIGH NHS FOUNDATION TRUST
Address	ROYAL ALBERT EDWARD INFIRMARY WIGAN LANE WIGAN
Post Code	WN1 2NN
Country	ENGLAND

Forename	Anthony
Middle name	
Family name	Short
Email	anthony.short@wwl.nhs.uk
Qualification (MD...)	BSc, MBBS, FRCA, MRCP, Diploma in Medical Leadership
Country	United Kingdom

IN32

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST
Address	SALFORD ROYAL STOTT LANE SALFORD GREATER MANCHESTER

Forename	Manjunatha
Middle name	
Family name	Patel
Email	Manjunatha.Patel@nca.nhs.uk
Qualification (MD...)	MB, BS. MRCP part 1. FRCA. EDIC part 1. EDRA.
Country	United Kingdom

Post Code	M6 8HD
Country	ENGLAND

IN33

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	EAST SUSSEX HEALTHCARE NHS TRUST
Address	ST ANNES HOUSE 729 THE RIDGE ST. LEONARDS-ON-SEA
Post Code	TN37 7PT
Country	ENGLAND

Forename	James
Middle name	
Family name	Bennett
Email	james.bennett4@nhs.net
Qualification (MD...)	MBBS, FRCA
Country	United Kingdom

IN34

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	TAMESIDE AND GLOSSOP INTEGRATED CARE NHS FOUNDATION TRUST
Address	TAMESIDE GENERAL HOSPITAL FOUNTAIN STREET ASHTON-UNDER-LYNE
Post Code	OL6 9RW
Country	ENGLAND

Forename	Anand
Middle name	
Family name	Kulkarni
Email	Anand.kulkarni@tgh.nhs.uk
Qualification (MD...)	MBBS; MD, FRCA, FFARCSI, FFICM
Country	United Kingdom

IN35

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	MID YORKSHIRE HOSPITALS NHS TRUST
Address	PINDERFIELDS HOSPITAL

Forename	Brendan
Middle name	
Family name	Sloan
Email	Brendan.sloan1@nhs.net
Qualification (MD...)	MBChB, FRCA, FFICM
Country	United Kingdom

	ABERFORD ROAD
	WAKEFIELD
Post Code	WF1 4DG
Country	ENGLAND

IN41

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	QUEEN VICTORIA HOSPITAL NHS FOUNDATION TRUST
Address	HOLTYE ROAD
	EAST GRINSTEAD
Post Code	RH19 3DZ
Country	ENGLAND

Forename	Fiona
Middle name	
Family name	Ramsden
Email	Fionaramsden@nhs.net
Qualification (MD...)	MBChB PGcert MAcadMedEd
Country	United Kingdom

IN42

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	GATESHEAD HEALTH NHS FOUNDATION TRUST
Address	QUEEN ELIZABETH HOSPITAL
	SHERIFF HILL
	GATESHEAD
Post Code	NE9 6SX
Country	ENGLAND

Forename	Joanne
Middle name	
Family name	Knight
Email	Joanne.knight5@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN43

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	Sunil
Middle name	
Family name	Chaurasia
Email	sunil.chaurasia@nhs.net

	Organisation name	BARNSLEY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)	MBBs, DA (Diploma in Anaesthesia), DNB (Diplomate of National Boards) in Anaesthesia, India, FCARCSI (Fellow of College of Anaesthetists, RCSI, Ireland).
	Address	GAWBER ROAD		
		BARNSLEY	Country	United Kingdom
	Post Code	S75 2EP		
	Country	ENGLAND		

IN44

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Claire		
Middle name			
Family name	Preedy		
Email	c.preedy@nhs.net		
Organisation name	ROYAL CORNWALL HOSPITALS NHS TRUST	Qualification (MD...)	FRCA
Address	ROYAL CORNWALL HOSPITAL	Country	United Kingdom
	TRELISKE		
	TRURO		
Post Code	TR1 3LJ		
Country	ENGLAND		

IN45

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	William		
Middle name			
Family name	Rea		
Email	williamrea@nhs.net		
Organisation name	GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	FRCP FRCA FFPMRCA
Address	CHELTENHAM GENERAL HOSPITAL	Country	United Kingdom
	SANDFORD ROAD		
	CHELTENHAM		
Post Code	GL53 7AN		
Country	ENGLAND		

IN46

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Caroline
Middle name	
Family name	Thomas
Email	Caroline.Thomas27@nhs.net

	Organisation name	LEEDS TEACHING HOSPITALS NHS TRUST	Qualification (MD...)	MBChB, BSc, FRCA
	Address	ST. JAMES'S UNIVERSITY HOSPITAL BECKETT STREET LEEDS	Country	United Kingdom
	Post Code	LS9 7TF		
	Country	ENGLAND		

IN47

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename	Caroline		
Middle name			
Family name	Reavley		
Email	CAROLINE.REAVLEY@nnuh.nhs.uk		
Organisation name	NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	MBBS MRCP FRCA
Address	COLNEY LANE COLNEY NORWICH	Country	United Kingdom
Post Code	NR4 7UY		
Country	ENGLAND		

IN48

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename	Steven		
Middle name			
Family name	Brown		
Email	steven.brown13@nhs.net		
Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	
Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD	Country	United Kingdom
Post Code	S5 7AU		
Country	ENGLAND		

IN49

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename	Chris
Middle name	
Family name	Newell

			Email	christopher.newell@nbt.nhs.uk
	Organisation name	NORTH BRISTOL NHS TRUST	Qualification (MD...)	MBChb
	Address	SOUTHMEAD HOSPITAL SOUTHMEAD ROAD WESTBURY-ON-TRYM BRISTOL	Country	United Kingdom
	Post Code	BS10 5NB		
	Country	ENGLAND		

IN50

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Mansoor
		Middle name	
		Family name	Sange
		Email	msange@nhs.net
Organisation name	DARTFORD AND GRAVESHAM NHS TRUST	Qualification (MD...)	MD, FRCA, FFICM, EDIC.
Address	DARENT VALLEY HOSPITAL DARENTH WOOD ROAD DARTFORD	Country	United Kingdom
Post Code	DA2 8DA		
Country	ENGLAND		

IN51

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Adnan
		Middle name	
		Family name	Faraj
		Email	adnan.faraj@york.nhs.uk
Organisation name	YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	FRCS Orth.
		Country	United Kingdom
Address	YORK HOSPITAL WIGGINTON ROAD YORK		
Post Code	YO31 8HE		
Country	ENGLAND		

IN52

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	YORK HOSPITAL WIGGINTON ROAD YORK
Post Code	YO31 8HE
Country	ENGLAND

Forename	Ben
Middle name	
Family name	Chandler
Email	ben.chandler@nhs.net
Qualification (MD...)	MBChB, FRCA, FFICM, EDIC
Country	United Kingdom

IN53

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	YORK HOSPITAL WIGGINTON ROAD YORK
Post Code	YO31 8HE
Country	ENGLAND

Forename	Andrew
Middle name	
Family name	Chamberlain
Email	andrew.chamberlain@york.nhs.uk
Qualification (MD...)	MBChB, FRCA, FFICM
Country	United Kingdom

IN54

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	WALSALL HEALTHCARE NHS TRUST
Address	MANOR HOSPITAL MOAT ROAD WALSALL
Post Code	WS2 9PS
Country	ENGLAND

Forename	Aditya
Middle name	
Family name	Kuravi
Email	Aditya.kuravi@nhs.net
Qualification (MD...)	FRCA
Country	United Kingdom

IN55

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	NORTH TEES AND HARTLEPOOL NHS FOUNDATION TRUST
Address	UNIVERSITY HOSPITAL OF HARTLEPOOL HOLDFORTH ROAD HARTLEPOOL
Post Code	TS24 9AH
Country	ENGLAND

Forename	Farooq
Middle name	
Family name	Brohi
Email	Farooq.brohi@nhs.net
Qualification (MD...)	MBBS, FFARCSI, FRCA (associate) FFICM (associate)
Country	United Kingdom

IN56

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	BRADFORD ROYAL INFIRMARY DUCKWORTH LANE BRADFORD
Post Code	BD9 6RJ
Country	ENGLAND

Forename	Bret
Middle name	
Family name	Claxton
Email	bret.claxton@bthft.nhs.uk
Qualification (MD...)	FRCA
Country	United Kingdom

IN57

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	EAST SUFFOLK AND NORTH ESSEX NHS FOUNDATION TRUST
Address	COLCHESTER DIST GENERAL HOSPITAL TURNER ROAD COLCHESTER
Post Code	CO4 5JL
Country	ENGLAND

Forename	Joanna
Middle name	
Family name	Simpson
Email	Joanna.Simpson@esneft.nhs.uk
Qualification (MD...)	MA MBBS MRCP FRCA
Country	United Kingdom

IN58

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	COUNTY DURHAM AND DARLINGTON NHS FOUNDATION TRUST
Address	DARLINGTON MEMORIAL HOSPITAL HOLLYHURST ROAD DARLINGTON
Post Code	DL3 6HX
Country	ENGLAND

Forename	Iain
Middle name	
Family name	Cummings
Email	iaincummings@nhs.net
Qualification (MD...)	MBChB
Country	United Kingdom

IN59

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST
Address	JAMES COOK UNIVERSITY HOSPITAL MARTON ROAD MIDDLESBROUGH
Post Code	TS4 3BW
Country	ENGLAND

Forename	Rebecca
Middle name	
Family name	Parker
Email	rebecca.parker12@nhs.net
Qualification (MD...)	FRCA
Country	United Kingdom

IN60

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
Address	COBBETT HOUSE OXFORD ROAD MANCHESTER
Post Code	M13 9WL
Country	ENGLAND

Forename	Alistair
Middle name	
Family name	Sawyerr
Email	alistair.sawyerr2@mft.nhs.uk
Qualification (MD...)	MBCHB
Country	United Kingdom

IN61

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
Address	TRUST HEADQUARTERS QUEENS MEDICAL CENTRE DERBY ROAD NOTTINGHAM
Post Code	NG7 2UH
Country	ENGLAND

Forename	David
Middle name	
Family name	Hewson
Email	David.Hewson@nuh.nhs.uk
Qualification (MD...)	MBBS, PGCert, MRCS, FHEA, FRCA, PhD
Country	United Kingdom

IN62

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	AIREDALE NHS FOUNDATION TRUST
Address	AIREDALE GENERAL HOSPITAL SKIPTON ROAD STEETON KEIGHLEY
Post Code	BD20 6TD
Country	ENGLAND

Forename	Tamsin
Middle name	
Family name	Gregory
Email	tamsin.gregory@nhs.net
Qualification (MD...)	BSc MBBS MSc MRCP(UK) FRCA
Country	United Kingdom

IN63

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	TAMESIDE AND GLOSSOP INTEGRATED CARE NHS FOUNDATION TRUST
Address	TAMESIDE GENERAL HOSPITAL FOUNTAIN STREET ASHTON-UNDER-LYNE

Forename	Ranvir
Middle name	
Family name	Singh
Email	Ranvir.singh@tgh.nhs.uk
Qualification (MD...)	MBBS, FCARCSI
Country	United Kingdom

Post Code	OL6 9RW
Country	ENGLAND

IN64

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	GREAT WESTERN HOSPITALS NHS FOUNDATION TRUST
Address	GREAT WESTERN HOSPITAL MARLBOROUGH ROAD SWINDON
Post Code	SN3 6BB
Country	ENGLAND

Forename	Bahaael
Middle name	
Family name	El Sady
Email	bahaael.elsady@nhs.net
Qualification (MD...)	EDAIC (European Diploma of Anaesthesia and Intensive Care), Master Degree in anaesthesiology and surgical intensive care
Country	United Kingdom

IN65

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
Address	SOUTHAMPTON GENERAL HOSPITAL TREMONA ROAD SOUTHAMPTON
Post Code	SO16 6YD
Country	ENGLAND

Forename	Anna
Middle name	
Family name	Walton
Email	anna.walton@uhs.nhs.uk
Qualification (MD...)	BM
Country	United Kingdom

IN66

○ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Helen
Middle name	
Family name	Burton
Email	helen.burton@mcht.nhs.uk
Qualification (MD...)	MBChB (Hons), Masters in Public Health Education, FRCA
Country	United Kingdom

IN67

- ○ NHS/HSC Site
- ○ Non-NHS/HSC Site

Forename	Ashok
Middle name	
Family name	Elayaperumal
Email	a.elayaperumal@nhs.net
Qualification (MD...)	MBBS MD FRCA
Country	United Kingdom

IN68

- ○ NHS/HSC Site
- ○ Non-NHS/HSC Site

Forename	Pallavi
Middle name	
Family name	Marghade
Email	pallavi.marghade@nhs.net
Qualification (MD...)	MBBS, MD (Anaesthesia), PDCC (Cardiac Anaesthesia), FRCA (London)
Country	United Kingdom

IN73

- ◉ NHS/HSC Site
- ○ Non-NHS/HSC Site

Forename	Prashanth
Middle name	
Family name	Reddy
Email	Prashanth.Reddy@uhnm.nhs.uk
Qualification (MD...)	MBBS, FRCA
Country	United Kingdom

Organisation name	UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST
Address	NEWCASTLE ROAD STOKE-ON-TRENT
Post Code	ST4 6QG
Country	ENGLAND

IN75

- ◉ NHS/HSC Site
- ○ Non-NHS/HSC Site

Forename	Corinne
Middle name	
Family name	Rimmer
Email	corinne.rimmer@mbht.nhs.uk
Qualification (MD...)	FRCA
Country	United Kingdom

Organisation name	UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST
Address	WESTMORLAND GENERAL HOSPITAL BURTON ROAD KENDAL
Post Code	LA9 7RG
Country	ENGLAND

IN76

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	CARDIFF & VALE UNIVERSITY LHB
Address	WOODLAND HOUSE MAES-Y-COED ROAD CARDIFF
Post Code	CF14 4HH
Country	WALES

Forename	Danielle
Middle name	
Family name	Huckle
Email	HuckleDL@cf.ac.uk
Qualification (MD...)	MBBCh
Country	United Kingdom

IN77

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	DORSET COUNTY HOSPITAL NHS FOUNDATION TRUST
Address	DORSET COUNTY HOSPITAL WILLIAMS AVENUE DORCHESTER
Post Code	DT1 2JY
Country	ENGLAND

Forename	Duncan
Middle name	
Family name	Farquhar-Thomson
Email	Duncan.Farquhar-thomson@dchft.nhs.uk
Qualification (MD...)	MBBS FRCA FFICM
Country	United Kingdom

IN78

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	EAST LANCASHIRE HOSPITALS NHS TRUST
Address	ROYAL BLACKBURN HOSPITAL HASLINGDEN ROAD BLACKBURN
Post Code	BB2 3HH
Country	ENGLAND

Forename	Matt
Middle name	
Family name	Newport
Email	matthew.newport@elht.nhs.uk
Qualification (MD...)	MBChB MSc DTM&H PGCert MAcadMEd FIMC FRCA
Country	United Kingdom

IN79

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD
Post Code	S5 7AU
Country	ENGLAND

Forename	Sumayer
Middle name	
Family name	Sanghera
Email	sumayer.sanghera@nhs.net
Qualification (MD...)	FRCA
Country	United Kingdom

IN80

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BOLTON NHS FOUNDATION TRUST
Address	THE ROYAL BOLTON HOSPITAL MINERVA ROAD FARNWORTH BOLTON
Post Code	BL4 0JR
Country	ENGLAND

Forename	Peter
Middle name	
Family name	Sandbach
Email	peter.sandbach@boltonft.nhs.uk
Qualification (MD...)	BSc MBBS MRCP FRCA
Country	United Kingdom

IN81

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST
Address	CHELSEA & WESTMINSTER HOSPITAL 369 FULHAM ROAD LONDON
Post Code	SW10 9NH
Country	ENGLAND

Forename	Marcela
Middle name	
Family name	Vizcaychipi
Email	marcela.vizcaychipi@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN82

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	ROYAL UNITED HOSPITALS BATH NHS FOUNDATION TRUST
Address	COMBE PARK
	BATH
Post Code	BA1 3NG
Country	ENGLAND

Forename	Tim
Middle name	
Family name	Cook
Email	timcook@nhs.net
Qualification (MD...)	MBBS BA DA FRCA
Country	United Kingdom

IN83

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	JAMES PAGET UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	LOWESTOFT ROAD
	GORLESTON
	GREAT YARMOUTH
Post Code	NR31 6LA
Country	ENGLAND

Forename	Sudha
Middle name	
Family name	Garg
Email	Sudha.Garg@jpaget.nhs.uk
Qualification (MD...)	MD FRCA
Country	United Kingdom

IN84

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	BETSI CADWALADR UNIVERSITY LHB
Address	EXECUTIVE OFFICES, YSBYTY GWYNEDD
	PENRHOSGARNEDD
	BANGOR GWYNEDD
Post Code	LL57 2PW
Country	WALES

Forename	Anna
Middle name	
Family name	Williams
Email	anna.williams9@wales.nhs.uk
Qualification (MD...)	MBChB BSc (Hons), MRCP, FRCA
Country	United Kingdom

IN85

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	SALISBURY NHS FOUNDATION TRUST
Address	SALISBURY DISTRICT HOSPITAL ODSTOCK ROAD SALISBURY
Post Code	SP2 8BJ
Country	ENGLAND

Forename	Xantha
Middle name	
Family name	Holmwood
Email	
Qualification (MD...)	
Country	United Kingdom

IN87

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST
Address	WESTMORLAND GENERAL HOSPITAL BURTON ROAD KENDAL
Post Code	LA9 7RG
Country	ENGLAND

Forename	Corinne
Middle name	
Family name	Rimmer
Email	corinne.rimmer@mbht.nhs.uk
Qualification (MD...)	FRCA
Country	United Kingdom

IN88

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	DORSET COUNTY HOSPITAL NHS FOUNDATION TRUST
Address	DORSET COUNTY HOSPITAL WILLIAMS AVENUE DORCHESTER
Post Code	DT1 2JY

Forename	Duncan
Middle name	
Family name	Farquhar-Thomson
Email	Duncan.Farquhar-thomson@dchft.nhs.uk
Qualification (MD...)	MBBS FRCA FFICM
Country	United Kingdom

Country	ENGLAND

IN89

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	EAST LANCASHIRE HOSPITALS NHS TRUST
Address	ROYAL BLACKBURN HOSPITAL HASLINGDEN ROAD BLACKBURN
Post Code	BB2 3HH
Country	ENGLAND

Forename	Matthew
Middle name	
Family name	Newport
Email	matthew.newport@elht.nhs.uk
Qualification (MD...)	MBChB MSc DTM&H PGCert MAcadMEd FIMC FRCA
Country	United Kingdom

IN90

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD
Post Code	S5 7AU
Country	ENGLAND

Forename	Sumayer
Middle name	
Family name	Sanghera
Email	sumayer.sanghera@nhs.net
Qualification (MD...)	MBChB FRCA
Country	United Kingdom

IN91

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BOLTON NHS FOUNDATION TRUST
Address	THE ROYAL BOLTON HOSPITAL MINERVA ROAD FARNWORTH BOLTON
Post Code	BL4 0JR

Forename	Peter
Middle name	
Family name	Sandbach
Email	peter.sandbach@boltonft.nhs.uk
Qualification (MD...)	BSc MBBS MRCP FRCA
Country	United Kingdom

Country	ENGLAND

IN92

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST
Address	CHELSEA & WESTMINSTER HOSPITAL 369 FULHAM ROAD LONDON
Post Code	SW10 9NH
Country	ENGLAND

Forename	Marcela
Middle name	
Family name	Vizcaychipi
Email	marcela.vizcaychipi@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN93

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	ROYAL UNITED HOSPITALS BATH NHS FOUNDATION TRUST
Address	COMBE PARK BATH
Post Code	BA1 3NG
Country	ENGLAND

Forename	Tim
Middle name	
Family name	Cook
Email	timcook@nhs.net
Qualification (MD...)	MBBS BA DA FRCA
Country	United Kingdom

IN94

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	HULL UNIVERSITY TEACHING HOSPITALS NHS TRUST
Address	HULL ROYAL INFIRMARY ANLABY ROAD

Forename	Pawan
Middle name	
Family name	Pernu
Email	pawan.pernu@nhs.net
Qualification (MD...)	MBBS, FRCA
Country	United Kingdom

	HULL
Post Code	HU3 2JZ
Country	ENGLAND

IN95

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	JAMES PAGET UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	LOWESTOFT ROAD GORLESTON GREAT YARMOUTH
Post Code	NR31 6LA
Country	ENGLAND

Forename	Sudha
Middle name	
Family name	Garg
Email	Sudha.Garg@jpaget.nhs.uk
Qualification (MD...)	MD FRCA
Country	United Kingdom

IN96

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	BETSI CADWALADR UNIVERSITY LHB
Address	EXECUTIVE OFFICES, YSBYTY GWYNEDD PENRHOSGARNEDD BANGOR GWYNEDD
Post Code	LL57 2PW
Country	WALES

Forename	Anna
Middle name	
Family name	Williams
Email	anna.williams9@wales.nhs.uk
Qualification (MD...)	MBChB BSc (Hons), MRCP, FRCA
Country	United Kingdom

IN97

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	SALISBURY NHS FOUNDATION TRUST
Address	SALISBURY DISTRICT HOSPITAL ODSTOCK ROAD

Forename	Xantha
Middle name	
Family name	Holmwood
Email	xantha.holmwood@nhs.net
Qualification (MD...)	MBBS FRCA
Country	United Kingdom

	SALISBURY
Post Code	SP2 8BJ
Country	ENGLAND

IN98

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	HAMPSHIRE HOSPITALS NHS FOUNDATION TRUST
Address	BASINGSTOKE AND NORTH HAMPSHIRE HOS ALDERMASTON ROAD BASINGSTOKE HAMPSHIRE
Post Code	RG24 9NA
Country	ENGLAND

Forename	Kathleen
Middle name	
Family name	Hempenstall
Email	kathleen.hempenstall@hhft.nhs.uk
Qualification (MD...)	MBBS, FRCA, FFPMRCA
Country	United Kingdom

IN99

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	WEST SUFFOLK NHS FOUNDATION TRUST
Address	WEST SUFFOLK HOSPITAL HARDWICK LANE BURY ST. EDMUNDS
Post Code	IP33 2QZ
Country	ENGLAND

Forename	Mayank
Middle name	
Family name	Kulshrestha
Email	Mayank.Kulshrestha@wsh.nhs.uk
Qualification (MD...)	MBBS, MD(Anaesthetics), FRCA
Country	United Kingdom

IN100

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	HYWEL DDA UNIVERSITY LHB
Address	CORPORATE OFFICES, YSTWYTH BUILDING

Forename	Alun
Middle name	
Family name	Thomas
Email	Alun.w.Thomas@wales.nhs.uk
Qualification (MD...)	MBBCh
Country	United Kingdom

	HAFAN DERWEN ST DAVIDS PARK, JOBSWELL ROAD CARMARTHEN DYFED	
Post Code	SA31 3BB	
Country	WALES	

IN101

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	John
		Middle name	
		Family name	Schutzer-weissmann
		Email	john.schutzer-weissmann@rmh.nhs.uk
Organisation name	THE ROYAL MARSDEN NHS FOUNDATION TRUST	Qualification (MD...)	MBBS FRCA FFPMRCA
Address	FULHAM ROAD	Country	United Kingdom
	LONDON GREATER LONDON		
Post Code	SW3 6JJ		
Country	ENGLAND		

IN102

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	John
		Middle name	
		Family name	O'Donoghue
		Email	john.o'donoghue@lanarkshire.scot.nhs.uk
Organisation name	LANARKSHIRE	Qualification (MD...)	MBChB, FRCA
Address	KIRKLANDS	Country	United Kingdom
	FALLSIDE ROAD		
	BOTHWELL GLASGOW		
Post Code	G71 8BB		
Country	SCOTLAND		

IN103

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	Laura
		Middle name	
		Family name	Perry
		Email	Laura.perry@esneft.nhs.uk

	Organisation name	EAST SUFFOLK AND NORTH ESSEX NHS FOUNDATION TRUST	Qualification (MD...)	MBBS FRCA
	Address	COLCHESTER DIST GENERAL HOSPITAL TURNER ROAD COLCHESTER	Country	United Kingdom
	Post Code	CO4 5JL		
	Country	ENGLAND		

IN104

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename	Guy		
Middle name			
Family name	Rousseau		
Email	guy.rousseau@nhs.net		
Organisation name	ROYAL DEVON UNIVERSITY HEALTHCARE NHS FOUNDATION TRUST	Qualification (MD...)	MB ChB
Address	ROYAL DEVON UNIVERSITY NHS FT BARRACK ROAD EXETER	Country	United Kingdom
Post Code	EX2 5DW		
Country	ENGLAND		

IN105

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename	Nagendra		
Middle name			
Family name	Prasada		
Email	nagendra.prasad@nhs.net		
Organisation name	UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST	Qualification (MD...)	MBBS
Address	ROYAL DERBY HOSPITAL UTTOXETER ROAD DERBY	Country	United Kingdom
Post Code	DE22 3NE		
Country	ENGLAND		

IN106

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	LANARKSHIRE
Address	KIRKLANDS FALLSIDE ROAD BOTHWELL GLASGOW
Post Code	G71 8BB
Country	SCOTLAND

Forename	Jim
Middle name	
Family name	Ruddy
Email	jim.ruddy@lanarkshire.scot.nhs.uk
Qualification (MD...)	MBChB, FRCA, FFICM
Country	United Kingdom

IN107

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST
Address	NORTH TYNESIDE GENERAL HOSPITAL RAKE LANE NORTH SHIELDS
Post Code	NE29 8NH
Country	ENGLAND

Forename	Michael
Middle name	
Family name	Blundell
Email	michael.blundell@northumbria-healthcare.nhs.uk
Qualification (MD...)	MBBS
Country	United Kingdom

IN108

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NORTH WEST ANGLIA NHS FOUNDATION TRUST
Address	PETERBOROUGH CITY HOSPITAL BRETTON GATE BRETTON PETERBOROUGH
Post Code	PE3 9GZ
Country	ENGLAND

Forename	Jyothi
Middle name	
Family name	Hosahalli
Email	j.hosahalli@nhs.net
Qualification (MD...)	MD (Anaesthesia), MBBS
Country	United Kingdom

IN109

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	PORTSMOUTH HOSPITALS UNIVERSITY NATIONAL HEALTH SERVICE TRUST
Address	QUEEN ALEXANDRA HOSPITAL SOUTHWICK HILL ROAD COSHAM PORTSMOUTH
Post Code	PO6 3LY
Country	ENGLAND

Forename	Aparna
Middle name	
Family name	Cockrell
Email	aparna.cockrell@porthosp.nhs.uk
Qualification (MD...)	MBBS MRCP FRCA
Country	United Kingdom

IN110

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST
Address	TRUST HEADQUARTERS MARLBOROUGH STREET BRISTOL
Post Code	BS1 3NU
Country	ENGLAND

Forename	Tony
Middle name	
Family name	Pickering
Email	Tony.Pickering@bristol.ac.uk
Qualification (MD...)	BSc, PhD, MB ChB(Birm), FRCA
Country	United Kingdom

IN111

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	TAYSIDE
Address	NINEWELLS HOSPITAL DUNDEE
Post Code	DD1 9SY
Country	SCOTLAND

Forename	Sharon
Middle name	
Family name	Hilton-Christie
Email	sharon.hilton-christie@nhs.scot
Qualification (MD...)	
Country	United Kingdom

IN112

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
Address	DENMARK HILL LONDON
Post Code	SE5 9RS
Country	ENGLAND

Forename	Marta
Middle name	
Family name	Blanco Cabana
Email	marta.blancocabana@nhs.net
Qualification (MD...)	MD, MBBS
Country	United Kingdom

IN113

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	MID AND SOUTH ESSEX NHS FOUNDATION TRUST
Address	PRITTLEWELL CHASE WESTCLIFF-ON-SEA
Post Code	SS0 0RY
Country	ENGLAND

Forename	Arun
Middle name	
Family name	Sahni
Email	arunsahni@nhs.net
Qualification (MD...)	BSc, MBBS, FRCA, MFCI
Country	United Kingdom

IN114

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS DORSET NHS FOUNDATION TRUST
Address	MANAGEMENT OFFICES POOLE HOSPITAL LONGFLEET ROAD POOLE
Post Code	BH15 2JB

Forename	Rob
Middle name	
Family name	Wiltshire
Email	
Qualification (MD...)	
Country	United Kingdom

Country ENGLAND

IN115

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email
Organisation name
Qualification (MD...)
Address
Country
Post Code
Country

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Mark Rockett on 06/05/2023 09:26.

Job Title/Post:	Consultant anaesthetist
Organisation:	Plymouth University Hospitals
Email:	mark.rockett@nhs.net

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Dr Chris Rollinson on 08/05/2023 09:39.

Job Title/Post:	Research Governance Manager
Organisation:	University Hospitals Plymouth NHS Trust
Email:	crollinson@nhs.net

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	The Poppy Study
IRAS project ID* (or REC reference if no IRAS project ID is available):	321740
Sponsor amendment reference number*:	NSA 02
Sponsor amendment date* (enter as DD/MM/YY):	06 September 2023
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	Addition of new sites, change of PI's at existing sites, and extension of study to allow for qualitative element of study to be completed.

Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	Yes		**No**	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		**No**	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	**Yes**	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	**Yes**	No

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1

Area of change (select)*:	Researchers
Specific change (select - only available when area of change is selected first)*:	PI - New PI, or temporary arrangements to cover the absence of a PI
Further information (free text - note that this field will adapt to the amount of text entered):	New PIs at Queen Elizabeth The Queen Mother Hospital - Dr Peratheepa Vimalatharmaiyah and Dr Antony Hodgetts email: p.vimalatharmaiyah@nhs.net; tony.hodgetts@nhs.net New PI at Conquest Hospital - Dr Judith Highgate email: judith.highgate@nhs.net New PI at Northern General Hospital - Sumayer Sanghera email: sumayer.sanghera@nhs.net New PI at Tameside Hospital - Ranvir Singh email: Ranvir.singh@tgh.nhs.uk New PI at University Hospitals Llandough - Dr. Sunil Dasari email: sunil.dasari@wales.nhs.uk New PI at University Hospital of Wales - Dr. Sunil Dasari email: sunil.dasari@wales.nhs.uk New PI at Dorset County Hospital - Dr Russell Goodall email: russell.goodall@dchft.nhs.uk New PI at Royal Blackburn Hospital - Dr Anuradha Kurvey email: anuradha.kurvey@elht.nhs.uk

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	All		**Some**	

Remove all changes below

Change 2	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will not have any additional resource implications for participating organisations - Please specify in the free text below
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Change to planned end date of study to 01/02/2025. To reflect data collection period starting 15/1/2024 and then to allow for qualitative study to be completed after main study ends.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	

Remove all changes below

Change 3	
Area of change (select)*:	Participating Organisations
Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites
Further information (free text - note that this field will adapt to the amount of text entered):	Please see file titled New_Sites_ID321740_RefNSA02.docx

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	All		**Some**	

Add another change

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Victoria Carrington Yates
Email address:*	victoriayates@nhs.net

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)				N					B
Change 2:						(Y)				(Y)				(Y)					C
Change 3:						Y				(Y)				Y					New site
Overall reviews for the amendment:																			
Full review:						Y				N				Y					
Notification only:						N				Y				N					
Overall amendment type:	Non-substantial																		
Overall Category:	B/C																		

For national coordinating function office use:	
New nation(s):	This amendment adds new participating nation(s) for the first time: Scotland. Ensure that HARP is updated.

A new site registered, address: Dewsbury Hospital, Mid yorks NHS Trust, Halifax Rd, Dewsbury WF13 4HS. Principal investigator: Dr Brendan Sloan, email: Brendan.sloan1@nhs.net

A new site registered, address: Pontefract Hospital, Mid yorks NHS Trust, Friarwood Ln, Pontefract WF8 1PL. Principal investigator: Dr Brendan Sloan, email: Brendan.sloan1@nhs.net

A new site registered, address: Pinderfields Hospital, Mid yorks NHS Trust, Aberford Road, Wakefield, Wf1 4dg. Principal investigator: Dr Brendan Sloan, email: Brendan.sloan1@nhs.net

A new site registered, address: Poole Hospital, Longfleet Rd, Poole BH15 2JB. Principal investigator: Dr Rob Wiltshire, email: Robert.Wiltshire@uhd.nhs.uk

A new site registered, address: Frimley Park Hospital, Frimley Park Hospital, Portsmouth Road, Frimley, GU16 7UJ. Principal investigator: Dr Sioned Phillips, email: sioned.phillips@nhs.net

A new site registered, address: Basingstoke/Winchester, Basingstoke and North Hampshire Hospital, Aldemanston Road, Basingstoke, Hampshire, RG24 9NA. Principal investigator: George Evetts, email: George.Evetts@hhft.nhs.uk

A new site registered, address: Royal Preston Hospital and Chorley District Hospital, Royal Preston Hospital, Sharoe Green Lane, Fulwood, Preston, Lancashire, England, UK, PR2 9HT. Principal investigator: Dr Laura Talbot, email: Laura.talbot@lthtr.nhs.uk

A new site registered, address: Princess Alexandra Hospital, Hamstel Road, Harlow. Essex. CM20 1QX. Principal investigator: Dr Dagmar Holmquist, email: Dagmar.holmquist@nhs.net

A new site registered, address: St Mary's Hospital, The Bays Praed Street London W2 1NY. Principal investigator: Dr Harriet Gardiner, email: harrietgardiner@nhs.net

A new site registered, address: Weston General Hospital, Grange Road, Uphill, Weston Super Mare, North Somerset. BS23 4TQ. Principal investigator: Dr Chetan Pataki, email: Chetan.Pataki@uhbw.nhs.uk

A new site registered, address: West Hertfordshire Teaching Hospitals, vicarage Rd, Watford WD18 0HB. Principal investigator: Dr. Nidhi Gautam, email: nidhi.gautam@nhs.net

A new site registered, address: Warwick Hospital, Lakin Road, Warwick, England, CV34 5BW. Principal investigator: Ben Wooldridge, email: ben.wooldridge@swft.nhs.uk

A new site registered, address: Princess of Wales Hospital, Coity Road, Bridgend, Mid Glamorgan, CF31 1RQ, Wales. Principal investigator: Rhidian Jones, email: rhidian.jones@wales.nhs.uk

A new site registered, address: Doncaster and Bassetlaw Teaching Hospitals NHS Trust, Armthorpe Road, Doncaster, DN25LT, UK. Principal investigator: Dr Raj McNab, email: r.mcnab@nhs.net

A new site registered, address: Stepping Hill Hospital, Poplar Grove, Stockport, SK2 7JE. Principal investigator: Dr Hywel Garrard, email: Hywel.Garrard@stockport.nhs.uk

A new site registered, address: Kings Mill Hospital, Mansfield Road, Sutton In Ashfield, Nottinghamshire NG17 4JL. Principal investigator: Dr Srinivas Magham, email: s.magham@nhs.net

A new site registered, address: Queens Hospital Burton, Belvedere Road, Burton-on Trent, DE130RB. Principal investigator: Dr Manabendra Haldar, email: Manabendra.haldar@nhs.net

A new site registered, address: Musgrove Park Hospital, Parkfield drive, Taunton, TA1 5DA. Principal investigator: Dr Kath Stenlake, email: Kath.stenlake@somersetFT.nhs.uk

A new site registered, address: Burnley General Hospital, Casterton Avenue, Burnley, BB10 2PQ. Principal investigator: Dr Anuradha Kurvey, email: anuradha.kurvey@elht.nhs.uk

A new site registered, address: Russells Hall Hospital, Dudley, West Midlands. DY1 2HQ. UK. Principal investigator: Dr Nomonde Laxa, email: nomonde.laxa@nhs.net

A new site registered, address: Queens Hospital, Rom Valley Way, Romford, Essex, United Kingdom RM7 0AG. Principal investigator: Dr. Vikas V Tripurneni, email: vikasvijay.tripurneni@nhs.net

A new site registered, address: Borders General Hospital, Chiefswood Road, Melrose, Roxburghshire, Scotland TD6 9BS. Principal investigator: Dr Shona Smith, email: shona.smith@borders.scot.nhs.uk

A new site registered, address: Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR, Scotland, United Kingdom. Principal investigator: Dr Ian Edmond, email: fv.randd-depart@nhs.scot

A new site registered, address: Lincoln County Hospital (LCH), Greetwell Road Lincoln LN2 5QY. Principal investigator: Dr Teodora Orasanu, email: Teodora.Orasanu@ULH.nhs.uk

A new site registered, address: Pilgrim Hospital Boston (PHB), Sibsey Road, Boston PE21 9QS. Principal investigator: Dr Teodora Orasanu, email: Teodora.Orasanu@ULH.nhs.uk

A new site registered, address: Grantham & District Hospital (GDH), 101 Manthorpe Road, Grantham, NG31 8DG. Principal investigator: Dr Teodora Orasanu, email: Teodora.Orasanu@ULH.nhs.uk

A new site registered, address: York Hospital, Wigginton Road, Clifton, York, YO31 8HE. Principal investigator: Mo Williams, email: mrw526@york.ac.uk

A new site registered, address: Robert Jones & Agnes Hunt Orthopaedic Hospital, Oswestry, SY10 7AG. Principal investigator: Dr Melanie Bloor; Dr Daniel Redfern, email: melanie.bloor@nhs.net; d.redfern1@nhs.net

A new site registered, address: Eastbourne DGH, Kings Dr, Eastbourne BN21 2UD. Principal investigator: Dr Judith Highgate, email: judith.highgate@nhs.net

A new site registered, address: Royal Orthopaedic Hospital Birmingham, Bristol Road South, Northfield, Birmingham. B31 2AP. Principal investigator: Dr William Rea, email: williamrea@nhs.net

A new site registered, address: Hereford County Hospital, Hereford County Hospital, Union Walk, Hereford, HR1 2ER, England. Principal investigator: Dr Ryan O'Leary, email: Ryan.OLeary@wvt.nhs.uk

A new site registered, address: University College London Hospital , 3rd Floor Main Tower, University College London Hospital, 235 Euston Road, London. NW12bU . Principal investigator: Dr Sam Bampoe, email: Sohail.bampoe@nhs.net

A new site registered, address: Worcestershire Royal Hospital, Charles Hastings Way, Worcester, WR5 1DD. Principal investigator: Dr Emily Johnson, email: emily.johnson9@nhs.net

A new site registered, address: Yeovil hospital, Higher Kingston, Yeovil. BA21 4AT. Principal investigator: Dr Agnieszka KUBISZ-PUDELKO, email: Agnieszka.Kubisz-Pudelko@SomersetFT.nhs.uk

A new site registered, address: Royal Glamorgan Hospital, Cwm Taf Morgannwg University Health Board Ynysmeurig House, Navigation Park, ABERCYNON, Rhondda Cynon Taf CF45 4SN. Principal investigator: Dr Ceri Lynch, email: Ceri.Lynch5@wales.nhs.uk

A new site registered, address: Medway Maritime Hospital, Windmill Road, Gillingham, Kent,ME7 5NY.. Principal investigator: Dr Samantha Black, email: samantha.black1@nhs.net

A new site registered, address: UHCW, Prince Charles Hospital. Principal investigator: Ms Davina Hewitt, email: Davina.hewitt@uhcw.nhs.uk

A new site registered, address: Warrington site, Warrington site Lovely Lane Warrington Cheshire WA5 1QG United Kingdom. Principal investigator: Dr Seema Charters , email: seema.charters@nhs.net

A new site registered, address: Halton site, Halton site Nightingale building Hospital way Runcorn WA7 2DA United Kingdom. Principal investigator: Dr Seema Charters , email: seema.charters@nhs.net

A new site registered, address: Captain sir tom moore site, The Captain Sir Tom Moore Building Earls Way WA7 2HH United Kingdom. Principal investigator: Dr Seema Charters , email: seema.charters@nhs.net

A new site registered, address: Blackpool Victoria Hospital, Blackpool Victoria Hospital, Blackpool Teaching Hospitals NHS Foundation Trust, Whinney Heys Road, Blackpool, Lancashire, UK, FY3 8NR. Principal investigator: Dr Stephen Davies, email: stephen.davies22@nhs.net

A new site registered, address: Northampton General Hospital , Research and Innovations area J . Northampton General Hospital NHS Trust Cliftonville . Northampton NN1 5BD. Principal investigator: A, email: Sadasivan.chinniah@nhs.net

A new site registered, address: Wythenshawe Hospital, Southmoor Rd, Wythenshawe, Greater Manchester, M23 9LT. Principal investigator: Dr Clifford Shelton, email: clifford.shelton@mft.nhs.uk

A new site registered, address: QEH Kings Lynn, Gayton Road, King's Lynn, PE30 4ET, Norfolk, England. Principal investigator: Dr Daniel Gareth Stolady, email: DanielGareth.Stolady@qehkl.nhs.uk

A new site registered, address: Addenbrooke's Hospital, Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ. Principal investigator: Lisa Grimes and Garry Davenport , email: lisa.grimes1@nhs.net; garry.davenport@nhs.net

A new site registered, address: University Hospital of Wales, Heath Park Way, Cardiff, CF14 4XW, Wales. Principal investigator: Dr. Sunil Dasari, email: sunil.dasari@wales.nhs.uk

A new site registered, address: University Hospital LLandough, Penlan Rd, Llandough, Penarth CF64 2XX. Principal investigator: Dr. Sunil Dasari, email: sunil.dasari@wales.nhs.uk

A new site registered, address: Perth Royal Infirmary, James Arrott Dr, Dundee DD2 1SG. Principal investigator: Dr Sharon Hilton-Christie, email: sharon.hilton-christie@nhs.scot

A new site registered, address: Stracathro Hospital, Brechin DD9 7QA. Principal investigator: Dr Sharon Hilton-Christie, email: sharon.hilton-christie@nhs.scot

POPPYSTUDY.RAFT (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST)

From: Cornwall and Plymouth <cornwallandplymouth.rec@hra.nhs.uk>
Sent: 14 September 2023 15:45
To: ROCKETT, Mark (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST); ROLLINSON, Christopher (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST); ROLLINSON, Christopher (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST); ROLLINSON, Christopher (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST)
Cc: BRAYNE, Adam (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST)
Subject: Amendment 23/SW/0039/AM02, IRAS Project ID 321740. HRA and HCRW Approval for the Amendment

Dear Dr Rockett,

IRAS Project ID:	321740
Short Study Title:	The POPPY Study
Amendment No./Sponsor Ref:	NSA 02
Amendment Date:	06 September 2023
Amendment Type:	Non Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

Please contact amendments@hra.nhs.uk for any queries relating to the assessment of this amendment.

Kind regards

Miss Charlotte Miller
Health Research Authority
Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
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