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)
SNAP3: Frailty & delirium

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational 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)*

☑ 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)
- [ ] Her Majesty's 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

Please describe briefly the involvement of the student(s):
Claire Swarbrick is the PhD student. She will be supervised by Professor Iain Moppett and Dr Judith Partridge. Claire will be responsible for the day to day running of the project including work setting up the sites, organising data collection, data analysis and write up. The project will be part of her thesis.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ 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)
SNAP3: Frailty & delirium

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

REC Name:
Wales REC 7

REC Reference Number:
21/WA/0203

Submission date:
08/06/2021

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Sprint National Anaesthesia Project 3: an observational study of frailty, multimorbidity and delirium in older people in the perioperative period

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Dr	Claire	Swarbrick
Address	6 Madison Avenue		
	Exeter		
Post Code	EX1 3AH		
E-mail	cswarbrick1@gmail.com		
Telephone	07502225186		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Anaesthesia PhD

Name of educational establishment:
School of Medicine, Univeristy of Nottingham

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Iain	Moppett
Address	Anaesthesia and Critical Care		
	Queen's Medical Centre		
	Nottingham		
Post Code	NG7 2UH		
E-mail	iain.moppett@nottingham.ac.uk		
Telephone	01158230959		
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Judith	Partridge
Address	Guys and St Thomas Hospital		
	Westminster Bridge Road		
	London		
Post Code	SE1 7EH		
E-mail	judith.partridge@gstt.nhs.uk		
Telephone	02071887188		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Dr Claire Swarbrick	☑ Professor Iain Moppett ☑ Dr Judith Partridge

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Iain	Moppett

Post	Professor of Anaesthesia and Perioperative Medicine /Honorary Consultant
Qualifications	MB BChir MA MRCP FRCA DM
ORCID ID	0000 0003 3750 6067
Employer	University of Nottingham and Nottingham University Hospitals NHS trust
Work Address	Anaesthesia and Critical Care Queen's Medical Centre Nottingham
Post Code	NG7 2UH
Work E-mail	iain.moppett@nottingham.ac.uk
* Personal E-mail	iain.moppett@nottingham.ac.uk
Work Telephone	01158230959
* Personal Telephone/Mobile	07903337617
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
	Mrs	Angela	Shone

Address	East Atrium Jubilee Conference Centre, Triumph Road Nottingham
Post Code	NG8 1DH
E-mail	sponsor@nottingham.ac.uk
Telephone	0115 8467906
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):	N/A
Sponsor's/protocol number:	21002
Protocol Version:	1.0
Protocol Date:	28/05/2021
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	https://www.niaa-hsrc.org.uk/SNAP3-Commissioning-Brief

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.*

BACKGROUND
More older people are undergoing surgery as the population ages and surgical care improves. Frailty is an age-related syndrome that increases an individual's vulnerability to adverse outcomes in response to illness, injury and surgery. Delirium is a period of temporarily altered, fluctuating consciousness, triggered by illness, surgery or environment. There is evidence that surgical outcomes are worse in patients with these conditions.

AIMS
The purpose of SNAP3 is to investigate which patients are frail and which are at risk of delirium. It will investigate current perioperative care and its outcomes.

METHODOLOGY
Our research includes three parallel studies which will run in NHS hospitals within the UK. S2 and S3 are service evaluation surveys for clinicians and are included for completeness:

S1 Prospective, observational study of approximately 12,000 surgical patients who are at least 60 years old
S2 Organisational survey of preoperative and postoperative care
S3 Survey of acute referrals and interventions to medical doctors and geriatricians

S1 participants recruited will have the following information collected:
-Notes review and data linkage with government agencies, for demographic, medical and socioeconomic details
-Frailty assessments: 2 requiring active participant involvement, 2 using electronic medical records
-Assessments for delirium and perioperative complications
-Quality of life telephone survey 4 months postoperatively.

OUTCOMES
We will report the proportion of patients with frailty, multiple medical problems and delirium. We will identify relationships between management and outcomes. We will investigate how to predict who will develop delirium and how we can manage this.

IMPACT
Our dataset will hopefully provide evidence to direct resources to manage frailty and delirium in the best way possible. We hope to understand what constitutes excellent care for frail patients, those with multiple medical problems and those at risk of delirium. We will develop a tool that to alert clinicians to those at risk of delirium early in the surgical pathway, so that they can be actively managed.

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.

ELECTRONIC CONSENT AND DATA ENTRY
This study will pose minimal inconvenience, and no risk for participants. We will use validated scoring systems that require short surveys to be administered to the participants. We will use data linkage to gain personal health data from public health authorities and government agencies. There is no alteration to their clinical treatment.

In order to simplify interactions with participants, we plan to implement electronically enhanced consent and data collection. This will minimise the time and inconvenience for patients wishing to take part, whilst providing specific safeguards to ensure that investigators explicitly gain patient consent before proceeding on to the surveys. All sites will also have access to traditional paper consent, patient information sheets and data collection forms. The choice of electronic or traditional paper consent and data collection will be determined by the individual sites.

All precautions will be taken to safeguard patient data and ensure confidentiality. No data will be stored on individual electronic devices. The online portal (REDCap)is a secure internet-based platform that is controlled by the University of Nottingham. Any data entered into the portal (via secure web browser) is stored in a password protected, secure database at the University of Nottingham. Data held here will be treated in accordance with Information Governance Policies at the university.

Individual sites will have an executive summary provided to them at the end of the study. This will not include individual patient identifiable information, only a broad summary of their local data.

CONSENT AND LACK OF CAPACITY
Due to the study's population, it is expected that some patients will not have capacity to give informed consent. The three options for obtaining consent are summarised below. A Consultee can be used in England, Wales and Northern Ireland. A Personal Legal Representative (PLR) is used in Scotland:
1) If the patient is judged by the Clinician to have mental capacity, we will approach them directly to seek informed consent for participation.
2) If the patient lacks mental capacity, we will seek advice from a relative or friend (Consultee or Personal Legal Representative). If the patient regains capacity, their consent to continue in the study will be obtained. Separate information sheets and a consultee/ Personal Legal Representative advice/consent form have been produced for this situation.
3) If it is not reasonably practicable to seek advice/consent from a Consultee/ Personal Legal Representative within a suitable time frame, a Professional Consultee will be approached for advice. As soon as possible after this, the patient or their representative will be approached for consent.

The inclusion of participants unable to consent are essential to the scientific success of this study, to improve care for those with and at risk of frailty and delirium. To exclude them would be viewed as discriminatory and unethical. Their inclusion will add knowledge and improve care for surgical patients with frailty and delirium in the future.

Previous PPI work and previous research studies by our team and others, have shown that our target population generally prefer a single approach and consent process without a ‘reflection’ time. This is a largely non-interventional study where consent for further participation (e.g., frailty and delirium assessments will be sought verbally).

DETECTION OF DELIRIUM
Delirium is notoriously difficult to capture in research studies due to its fluctuating nature. Classically patients are most likely to develop delirium outside of normal working hours. The study will use two methods to maximise the chance of capturing delirium. The 4AT will be carried out by researchers on days one and three postoperatively (CAM-ICU if participants are admitted to critical care). The 4AT has good sensitivity and specificity. It does not require formal training and takes less than two minutes to complete. Secondly a notes review of the medical and nursing documentation will be carried out manually. The notes review will aim to capture those patients who are transiently delirious but do not trigger a positive 4AT.

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
- ☑ Cohort observation

- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☑ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☐ 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 characterise the epidemiology of frailty, multi-morbidity and postoperative delirium in approximately 12 000 older people undergoing surgery in the UK.

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

-Examine the relationship between frailty and perioperative outcomes separately by surgery types
-Examine the relationship between multimorbidity and perioperative outcomes separately by surgery types
-Examine the relationship between frailty and multimorbidity in the older person undergoing surgery
-Describe the variation in hospital-level and patient-level frailty-related interventions
-Identify associations between hospital-level and patient-level frailty-related interventions and outcome -Develop and internally validate a risk-prediction tool for postoperative delirium.

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

The number of older people undergoing surgery globally is increasing due to demographic changes and improvements in surgical and perioperative care. Frailty is an age-related syndrome that increases an individual's vulnerability to adverse outcomes in response to stressors such as illness, injury and surgery.

There is reasonable evidence that surgical outcomes are worse in the presence of frailty. The largest study of frailty and surgical outcomes using administrative data and a binary frail/non-frail categorisation for elective major noncardiac surgery found that the impact of frailty was dependent on surgery type, age (the independent impact of frailty is less as age increases) and greatest in the early perioperative period. Whilst the link between socioeconomic status, frailty and health outcomes is well-described in the community setting, less is known about these factors in the surgical setting. Furthermore, little is known about the importance of particular domains of frailty and the relationship with surgical outcome. Screening for frailty is increasingly advocated but there is a lack of consensus on which tool to use for screening and/or diagnosis in the perioperative setting. Recent systematic reviews have highlighted the heterogeneity of frailty measurement tools. This may be one contributor to a lack of standardised approach to modifying the frailty syndrome in the perioperative setting with the aim of improving surgical outcomes. This is further complicated by the acknowledged limitation of many 'frailty' tools which are instead counts of multimorbidity as opposed to multi domain assessment tools. Distinguishing between multimorbidity and frailty is important given the recognition that seven out of ten frail individuals also display multimorbidity, but, only two of ten patients with multimorbidity are also frail.

Delirium is a distinct clinical syndrome associated with adverse outcomes following surgery. Less is known about the influence of severity, timing or form (hyperactive or hypoactive) of delirium on postoperative outcomes. To date, there is no effective pharmacological treatment to prevent delirium, with evidence instead supporting non-pharmacological multicomponent interventions aiming to reduce the incidence of delirium through targeting the triggers for the syndrome, in addition to reducing severity.

Whilst evidence supports commonality in the aetiology and pathogenesis of frailty and delirium, less is known about the interface of these distinct syndromes in the perioperative setting. The initial suggestion from the data is that these two conditions confer cumulative negative effect on postoperative outcomes, but this requires further exploration at

scale.

A key question for researchers, clinicians, those responsible for planning perioperative operative services, and most importantly, patients and their families, is therefore, how to identify frailty and risk of delirium in routine clinical settings. If frailty and delirium can be identified then we can move on to answer; what should clinicians do with frailty, multimorbidity and delirium risk in the time before surgery and how these conditions should be managed during and after surgery. This study will generate a large, high-quality dataset on a cohort of older people undergoing a range of surgical procedures to help address these questions.

Although there may be epidemiological merit in understanding the prevalence and associated outcomes, this information only really has value if:

a) it adds more than we currently know
b) it changes how we provide perioperative care, either currently or in the future
c) it enhances the quality of information provided to patients as they make choices regarding treatment options.

It is not possible for this study to answer every question about surgery, frailty, multimorbidity and delirium. This study's main focus is on the impact and management of frailty but will attempt to answer key questions about postoperative delirium

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.*

STUDY DESIGN
This study is a multi-centre prospective observational cohort study.

The project will involve three parallel studies:
-S1 Prospective observational patient participant cohort study
-S2 Organisational clinician survey of current preoperative and postoperative care
-S3 Clinician survey of acute referrals and interventions to general and geriatric medicine teams

S2 and S3 are clinician surveys and do not involve patients or their health data. They are included to demonstrate the full scope of the survey and are included for completeness. Data will be collected from a variety of sources:

-Direct patient report and observation
-Routinely collected hospital data from paper and electronic health records
-Reported hospital level data from perioperative medicine leads
-Reported (anonymised) activity from general medical and geriatrician medicine teams

S1: Observational patient participant study
All patients who are 60 years or older, attending for surgery (day-case, elective and emergency) during up to two periods, of up to seven days, will be considered for inclusion. Patients will be given a participant information sheet (PIS) whilst waiting in the preoperative areas.

1. Patients will be identified from operating lists by clinical teams, given a PIS and referred to the research team if they are willing. They will be approached by the research team to discuss the study and consent.

2. Consent will be taken either on an electronic device using electronic signatures with declarations and tick boxes or a traditional paper consent form.

3. Pre-operative data collection
Primarily through a review of the medical notes, with participant confirmation if necessary. Medical data, admission information, demographic and socioeconomic data will be sought.

4. Frailty assessments
Four tools will be used to assess presence and severity of frailty. Two tools require participant involvement and two are passive.

4a. The Clinical Frailty Scale (CFS) provides a word and pictorial representation of the frailty syndrome and is recommended in the UK as a national screening tool for frailty, with prior use in surgical populations. The use of the

CFS requires observation of the patient and a brief discussion of their activities of daily living. This will be completed by researchers before other frailty tools are seen to avoid confirmation bias.

4b. The Reported Edmonton Frailty Scale is brief, feasible and has also been used in surgical populations. It involves answering 10 short questions and participating in drawing a clock face.

4c. The electronic Frailty Index (eFI) uses the deficit accumulation model of frailty. It isn't available in all areas of the UK, it will be collected wherever it is currently recorded.

4d. The Hospital Frailty Risk Score can be calculated from HES data at discharge. We will report this, as it may be a useful automated method to highlight frailty to primary care colleagues.

5. Process of care data
Primarily a notes review with participant confirmation if necessary. This will assess the process of preoperative assessment, modes of anaesthesia, use of a catheter and level of postoperative care.

6. Delirium
The presence or absence of delirium will be assessed on days one and three if the participant remains in hospital. The 4AT (delirium assessment tool) or CAM ICU (Confusion Assessment Method Intensive Care Unit) and a review of nursing and medical notes of delirium trigger words will be used. The 4AT is a brief assessment tool requiring patients to answer six questions. CAM ICU is a brief 4 stage assessment tool for delirium that is validated for use in ICU. Notes review will be done manually by local researchers. These processes together will optimise our chances of detecting delirium.

7. Postoperative morbidity
Postoperative Morbidity Survey (POMS) (with appropriate speciality specific modifications for cardiac and hip fracture patients) will be used on days three and seven if the participant remains in hospital. POMS is a tool used to assess postoperative morbidity. This is mainly a notes review but may require brief face to face interaction with the participant.

8. Quality of life (QoL)
QoL will be assessed using the EQ-5D-5L questionnaire and a patient/carer estimate of days alive at home (DAH) via telephone interview or electronic email questionnaire. The EQ-5D-5L is a six question tool suitable for use over the telephone or electronic device. DAH is a patient preferred QoL outcome. We will cross check reported DAH with data linked by Hospital Episode Statistics/ Office for National Statistics/ Health and Social Care Wales/ Electronic Data Research and Innovation Services/ NHS Services Scotland (collected for DAOH). This will account for hospital length of stay and readmissions but not residence out of hospital but not at home (this specifically relies on patient/carer reports).

Initial data linkage will be approximately four months after final enrolment, then one year mortality data will be linked at 12 months. Last participant contact will be four months after recruitment. The final data linkage will occur at 10 years when we will look for mortality.

Data linkage will be carried out with NHS Digital, Health and Social Care Wales, NHS National Services Scotland and individual trusts as appropriate. The following will be collected:

1. Length of stay: Acute hospital stay and days alive and out of hospital (DAOH) within 30 and 90 days will be recorded.
2. Mortality: in hospital death, mortality at one year, two, five and ten years
3. Readmission: Readmission of participants within 30 days will be recorded
4. Discharge destination
5. Socio-economic status: post code will be linked with indices of deprivation

Length of acute hospital stay (days) will be the primary outcome as it is expected to be affected by both medical complications and discharge planning issues. The other outcomes are important either as mechanistic explanations or as complementary patient-relevant metrics.

S2 Organisational survey of current preoperative and postoperative care (for interest)

A survey link will be emailed to Principal Investigators. The survey will ask for details of existing services in perioperative care. For example, nurse-led and anaesthetist-led preoperative assessment clinics, geriatrician led perioperative medicine services and specialist nurse services. Reminders will be sent via email to the leads to improve completion rates.

S3 Survey of acute referrals and interventions to general medical and geriatric medicine teams (for interest)

A survey will be conducted with on call medical and geriatrician registrars (if applicable). The purpose of the survey is to gain an understanding of the workload that older surgical patients contribute to the on call medical teams. This will also offer a brief insight into the training medical doctors get in perioperative medicine. Researchers will approach the on-call doctors at the end of their on-call shifts (day and night) for seven consecutive days. No patient identifiable information will be collected.

ANALYSIS
The primary analysis will be performed by the national trainee lead as part of a higher degree, in conjunction with the study statistician and the Study Management Group.

To address the primary objective, the proportion of frail patients, proportion of multimorbid patients and the proportion of patients experiencing post-operative delirium will be recorded. Multimorbidity is when a person has two or more chronic diseases. Delirium is a worsening or change in a person's mental state, that is often related to a stressor.

To investigate the relationship between frailty, multimorbidity, delirium and other factors we will use statistical models to find associations and their effects.

A risk prediction model for delirium will be developed and internally validated using our dataset whilst adhering to national guidance (TRIPOD).

SAMPLE SIZE AND JUSTIFICATION
The estimated sample size is around 12,000 participants based on national data and previous SNAP projects recruitment. We verified that this is a sufficient sample size to achieve the primary and secondary objectives of this study.

To estimate the proportion of frail patients, and the proportion of patients who develop delirium, we have calculated that a sample size of 7,203 is needed. Strict quality criteria suggests that a sample size of 11,000 patients is sufficient to estimate a high-quality clinical prediction model for delirium.

NOTE
Sites who have expressed interest in our study so far have been added to this form.
Additional sites will be added by amendment when confirmed.

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
- [x] Undertaking the research
- [ ] 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 have two PPI/E members on our study steering committee and study management group. Their input, alongside the comprehensive review of our study by Patient, Carer and Public Involvement and Engagement (PCPIE), have guided our study design, advising us on what is acceptable to our target population. PCPIE is a Health Services Research Council (HSRC) group that offers lay representative advice to studies. PCPIE and our own PPI/E members have been very positive and supportive of the project and its aims.

We have adapted our recruitment and data collection processes after the PPI/E members guidance. They have specifically commented that they study is of low patient burden and so time to reflect prior to consent is not necessary or desirable to patients. PPI/E members have been supportive of the use of electronic devices for consent and data collection. They have been essential to the production of clear, understandable and accessible patient/public facing documentation. PPI members and the wider PCPIE group have specifically recommended that Participant Information Sheets are available in a fully comprehensive and shortened version. They are keen that the shortened version exists to increase accessibility whilst not greatly reducing information for potential participants. Both forms of the PIS will be available to potential participants.

The results will be produced into a document which will be reviewed by our PPI/E members for distribution amongst

interested participants. Our PPI/E members will be involved in dissemination of our findings, including to relevant national and local patient groups (eg Age UK). They are keen for social media to be used alongside more traditional routes of dissemination. We anticipate that our PPI/E members will help us to understand which pieces of data are of most significance to patients.

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
- [x] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [x] 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
- [x] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 60	Years
Upper age limit:	No upper age limit

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

People aged 60 years or older undergoing any surgery in NHS hospitals over two periods of up to seven days:
• Day-case, emergency, and elective surgery
• General, neuraxial and regional anaesthesia
• Able to give informed consent or consultee/Personal Legal Representative available to provide advice/consent

• Include repeated theatre procedures (will be clearly documented)

Planned day-case surgery: patients admitted for surgery with the expectation of same-day discharge (unplanned admission would be included within the day-case cohort)
Emergency: using the same definitions as used by Hospital Episode Statistics
Elective: Planned / booked admissions for in-patient surgery

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

- Cataract surgery
- Endoscopy performed without general anaesthesia
- Superficial surgery or minimally invasive procedures performed solely under topical/infiltration local anaesthesia (awake craniotomy for instance would be included)
-ASA VI

A detailed list of procedures for inclusion and exclusion in this study will be provided to local research teams as an appendix to the protocol.

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
Consent	1	0	10 minutes	Local PI or delegated to appropriately trained member of research team. On the day of surgery.
Frailty assessments (Clinical Frailty Scale and Reported Edmonton Frail Scale)	1	0	10 minutes	Local PI or delegated to appropriately trained member of research team. On the day of surgery prior to anaesthesia (unless not possible), face to face.
Confirmation of preoperative care and process of care data	1	0	5 minutes	Local PI or delegated to appropriately trained member of research team. Perioperative period. This will be face to face only if notes don't give adequate information.
4AT/CAM-ICU Delirium Assessment Tool	0-2	0	5 minutes	Local PI or delegated to appropriately trained member of research team. On postoperative days 1 and 3 (if remains inpatient), face to face.
Delirium trigger words notes review	0-2	0	5 minutes	Local PI or delegated to appropriately trained member of research team. On postoperative days 3 and 7 (if remains inpatient), notes review only.
Postoperative Morbidity Survey (POMS)	0-2	0	5 minutes	Local PI or delegated to appropriately trained member of research team. On postoperative days 3 and 7 (if remains inpatient), mainly notes review, may require confirmation from participant.
EQ-5D-5L, EQ-VAS (quality of life surveys) and days alive at home estimate (DAH)	1	0	8 minutes	Local PI or delegated to appropriately trained member of research team. Via email or telephone 4 months postoperatively.

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

Study participants will be participating in the study for four months (last contact will be by telephone or email). Their personal health data will be followed up via data linkage for ten years.

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.

There are very limited participant risks associated with this study as it is observational. The burden is limited to inconvenience from confirming data, participation in scoring systems and collection of confidential data.

Participants will be asked questions about medical history, social history, activities of daily living and undergo some basic bedside tests. We will minimise the burden to patients by obtaining as much information from the notes and medical staff as possible, only requiring patient participation when necessary. We have deliberately chosen assessment tools that are brief and simple for participants to answer. Most of our interventions will take place whilst the participant is an inpatient, they are spread over days and will not require extended periods of concentration. It is hoped that this will minimise the burden to our participants.

A brief telephone call or emailed questionnaire four months postoperatively will be the only intervention that occurs after discharge. From PPI with people over 59 years old, we have found that a telephone call or email is generally not considered intrusive and is quite acceptable. Our PPI has shown that three emailed reminders sent with a week's interval are acceptable to participants. It has also shown that up to three telephone calls are acceptable for follow up.

In order to minimise the burden to participants whilst also ensuring a robust consent process, we have chosen to implement an electronically enhanced consent. Specific checks and safeguards are in place to ensure that a named investigator must explicitly gain patient consent to proceed to data entry. We believe that this is a proportionate, pragmatic approach for data collection in this study. An electronic signature with checkboxes for each declaration will be used. This will not be cumbersome for patient and investigator and is in line with current HRA guidance. We will ensure that individual devices are cleaned in line with hospital infection control guidance, when passing between investigator and participant.

We have minimised the risk of a breach of confidentiality through robust data management systems. We will collect confidential data via a secure web-based portal onto the study database. The research database and website will be run through 'REDCap' (an internationally recognised standard for study database management) which will be hosted on servers managed by the University of Nottingham. Communication with NHS Digital will be carried out with the minimum patient identifiable data and will be password protected.

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:

The questionnaires include questions about medical history, discussion of activities of daily living and brief cognitive testing. It is possible that a few participants may find these questions upsetting as they may reveal a degree of vulnerability from a health/social care perspective. The questionnaires will be conducted face to face by researchers who are anaesthetists or research nurses. These medical professionals are experienced in discussing these topics and this patient group during their day-to-day work. They will reassure the participants and discuss any clinical concerns with the clinical team responsible for their care. If there are any participants that need further reassurance or assistance, then the Principal Investigator at each site will be able to help and direct participants to appropriate support.

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

There is no direct benefit from taking part in this study.

Patients may have a sense of wellbeing from making a contribution to research that may benefit their peers in the future. Participants may benefit from increased observation during their clinical course through detection of delirium or other comorbidities. If these are found through our research assessments, we will inform the usual care team so they can be appropriately managed.

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

There are no risks for the researchers themselves.

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).*

Potential participants will be identified by the usual care team and recruited from surgical admission areas and clinics. Potential participants will be identified from theatre lists on the basis of the inclusion/exclusion criteria and asked if they would be willing to discuss the study with the research team. 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.

It is anticipated that recruitment will take place during up to two periods, of up to seven days. Estimated recruitment rates have been calculated using operational data from before the Covid-19 pandemic. As there is uncertainty about future waves of infection and reduced theatre operating, the actual number of patients undergoing operations may be less. If this study is not able to recruit it's targeted 12,000 participants initially, then a further round of recruitment may be necessary. If this were to be required, then this would be within a fortnight of the first round.

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 by the usual care team from the published theatre lists on the basis of our inclusion/exclusion criteria. 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.

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.*

The study will be publicised through posters, local presentations and discussions to surgical staff including nursing and medical staff members. Posters in prominent surgical admission and preoperative areas will notify patients of the study.

During data collection, the criteria for recruitment will be discussed with the usual care team, usually the anaesthetist. They will review their theatre lists and identify those who are suitable for the study. The usual care team will then approach the potential participant and will inform the researcher if the patient is willing to be approached by the research team. No identifiable information will be reviewed by the researcher until consent has been given.

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).

Posters will be displayed in preoperative areas and wards to inform surgical patients about the study during the period of data collection. The poster is designed to give some details to interested parties prior to them being approached by their usual care team (if they meet inclusion/exclusion criteria).

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

The study will take place in acute secondary care hospitals in all four nations of the UK. Participants will be recruited from wards and surgical admission areas and clinics. The initial approach will be either from the usual clinical team. Information about the study will be on display and available as patient information sheets (PIS) in the relevant clinical areas. Only after a potential participant has agreed to speak with the research team, will they be approached by the research team.

The principal investigator or their nominee, will inform the participant or their nominated representative (other individual or other body with appropriate jurisdiction), of all aspects pertaining to participation in the study including a PIS.

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 process for obtaining participant informed consent or assent will be in accordance with the REC guidance, Good Clinical Practice (GCP), Health Research Authority (HRA) and any other regulatory requirements that might be introduced.

All potential participants will receive a Participant Information Sheet (PIS) from the introducing clinical team member. They will be encouraged to read and/or discuss the PIS. All participants will be given the opportunity to ask questions and discuss the study before consent is requested.

Different versions of the PIS are available for countries with differing legislation/terminology. At the request of our PPI members and on the advice of PCPIE (a PPI group associated with the Health Services Research Centre) there is a shortened version of the PIS, which can be requested if participants prefer. The full PIS will always be available too. There is also a PIS for those without capacity, but who wish to read a simpler document. PIS have also been produced for consultees/Personal Legal Representatives to receive via email or telephone if a face-to-face conversation is not possible. We will provide participants and their representatives with accessible and detailed information in order to obtain informed consent.

The investigator or their nominee, and the participant or other legally authorised representative, shall both sign and date the Consent/Advice Form before the person can participate in the study. It is anticipated that most sites will carry out electronic consent, but traditional paper forms will be available if required.

The participant will receive a copy of the signed and dated forms (via email or paper) and the original will be retained in the Study records. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the study.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or

affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

The investigator will inform the participant/consultee/legal representative of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms. If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

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

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?

Previous PPI work and research studies by our team and others, have shown that participants prefer a single approach and consent process without a 'reflection' time. This is a largely non-interventional study where consent for continued participation (e.g., previously discussed frailty and delirium assessments will be sought verbally). Therefore, 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. There will be posters and PIS available for patients in the preoperative areas to increase awareness of the study.

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)*

If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial, the participant information sheets, and consent forms and the consent forms and information sheets will be available printed in other languages.

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?

Participants in Wales can request a copy of the consent form and PIS in Welsh. If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial.

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:

Our interventions are of low burden and do not pose risk to participants who lack capacity. Participants will be made aware (via the information sheet and consent form) that should they withdraw/lose capacity, the data collected to date cannot be erased and may still be used in the final analysis. In England and Wales, the opinion of a consultee will be sought for the ongoing involvement of participants if they lose capacity. In Scotland and Northern Ireland, the original statement of consent still stands unless it is withdrawn after a participant loses capacity.

It is anticipated that a proportion of our participants will lose capacity during the study. Participants who lose capacity will provide us with important information that will help to answer our research objectives and hopefully benefit society. It would bias our results to exclude this patient group, reducing the quality of the study results.

Please complete Part B, Section 6, giving further information about arrangements for including adults unable to consent for themselves.

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)*

- [x] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [x] Electronic transfer by magnetic or optical media, email or computer networks
- [x] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] 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
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [ ] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
All data will be collected via a web browser, used on secure handheld devices. 'Secure' includes any device deemed secure enough to access NHS emails. Access is via encrypted webpages with no information stored on the device in question, but rather going directly to a secure server based at the University of Nottingham. Data-access is one-way for local investigators.

Personal email addresses and phone numbers will be recorded for follow up at four months and dissemination of results with consent. These personal contact details will be entered directly into the REDCap system. Personal contact details will be stored separately to the pseudonymised collected data. The REDCap system has the ability to send email follow up surveys direct to participants. This reduces the number of people who will access a participant's contact details. If a participant doesn't respond to the email reminders, then a local site researcher will

be provided with details to contact them by telephone. Contact details of participants will not be shared with any other organisations or used for any other purposes. Personal email addresses will be securely stored for dissemination of results for up to three years with consent.

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

Data will either be entered directly to the secure web-based portal onto the study database or onto a paper Case Report Form (CRF), with later transcription to the database.

The website and database will run through the encrypted research database platform, 'REDCap', an internationally recognised standard for study database management. This will be hosted on servers managed by the University of Nottingham. The database will be password protected and auditable. The servers are protected both physically and electronically. Analysis of the data will also be carried out on University of Nottingham servers.

If paper is used for data collection or consent, CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number or NHS number, and Participant Study Number, to permit identification of all participants enrolled in the study, in case additional follow-up is required. CRFs shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

Where data is directly entered onto REDCap at time of collection, no information is stored on the device with which it was originally collected. Front-line data collectors have no access to the master data set.

The minimum amount of patient identifiable data will be extracted from the study database by the central investigation team, onto a password protected Excel spreadsheet, and emailed securely to NHS Digital and NHS National Services Scotland, to facilitate linkage to central held personal health data. In Wales, data linkage information will be exchanged via Digital Health and Care Wales secure platform. Mortality will be tracked for all patients with a final censure date of ten years after participant recruitment.

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.*

All Principal Investigators will have completed their Good Clinical Practice training.

Each participant will be assigned a study identity code number, for use on CRFs, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy).

Four patient identifiers will be used: patient name, date of birth, NHS number and postcode. These identifiers will also be used to link the SNAP3 dataset to NHS Digital personal health data. The NHS number is not completely populated in the NHS Digital system and the other patient identifiers are used when the NHS number is absent. In addition, by using these four identifiers in combination, possible erroneous record linkages are flagged. Exact details of this linkage will be dependent upon the current regulations and requirement of NHSD at the time of linkage.

Among the patient identifiers, only sex will used for analysis. A pseudonymised dataset will be used by the central SNAP3 study team for analysis. In this pseudonymised dataset:

-The NHS number will be replaced by a unique study patient identifier.
-Date of Birth will be converted to Age on date of surgery, and trimmed to year of birth
-Postcode will be converted to Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation (IMD) and the Income Deprivation Affecting Older People Index (IDAOPI).

The data items will be retained in their original format in the identifiable dataset which is retained within the University of Nottingham servers. No one outside of the study team will access personal health data except when sending information for data linkage.

The minimum amount of patient identifiable data will be extracted from the study database by the central investigation team, onto a password protected Excel spreadsheet, and emailed securely to NHS Digital and NHS National Services Scotland, to facilitate linkage to central held personal health data. In Wales, this information will be exchaged via Digital Health and Care Wales secure portal.
Mortality will be tracked for all patients with a final censure date of 10 years after participant recruitment.

Personal health data will be retained for seven years following the end of data collection, 17 years after recruitment. Contact details of participants, consultees and Personal Legal Representatives will be retained for three years after

recruitment. These items of data will be securely destroyed in line with University of Nottingham data policy.

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.*

Participants' personal health data can be accessed by their hospitals research team, the central SNAP 3 team. The sponsor and regulatory bodies may require access for audit or monitoring purposes.

Hospital level local data collectors will only be able to access data that they have entered. This would be for the purpose of checking or updating an individual participants information. Once submitted, the data collectors are not able to access participants' personal data.

Analysis will be carried out by the SNAP 3 research team who are based at the University of Nottingham, Health Services Research Centre and the Royal College of Anaesthetists. The central SNAP 3 team will use a pseudonymised dataset for analysis. The identifiable data set will be held separately on University servers.

The minimum amount of patient identifiable data will be extracted from the study database by the central investigation team, onto a password protected Excel spreadsheet, and emailed securely to NHS Digital and NHS National Services Scotland, to facilitate linkage to central held personal health data.

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?

Pseudonymised data generated by the study will be analysed by the core study team based at the University of Nottingham, Health Services Research Centre and the Royal College of Anaesthetists.

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

	Title	Forename/Initials	Surname
	Professor	Iain	Moppett
Post	Professor of Perioperative Medicine and Anaesthetics		
Qualifications	MB BChir MA MRCP FRCA DM		
Work Address	Anaesthesia & Critical Care Section, Division of Clinical Neuroscience		
	Queen's Medical Centre, University of Nottingham		
	Nottingham		
Post Code	NG7 2UH		
Work Email	iain.moppett@nottingham.ac.uk		
Work Telephone	0115 823 0959		
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: 7
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.*

In compliance with the International Conference on Harmonisation (ICH)/Good Clinical Practice (GCP) guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for 10.5 years or for longer if required, at the University of Nottingham in secure archive facilities. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

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.
We will submit to peer review scientific journal. Due to the observational nature of the study we do not intend to register on a public database.

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 patient will be identifiable from the published results. Date of birth will be converted into age on date of surgery and trimmed to year of birth. Sex is the only patient identifier that will be used for analysis directly. This is an epidemiological cohort study where individual participants will not be identified.

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.
Participants can opt into study result updates by providing an email address for this purpose. We will collect email addresses to disseminate results direct to participants or a nominee. Relevant patient groups/charities will be informed of the results for publication in newsletters or websites. We will also publish details on our Twitter account and other social media channels. We plan to offer limited results regarding recruitment to interested participants at the four months follow up email/telephone call.

5. Scientific and Statistical Review

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

- ☑ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ 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 original proposal for SNAP 3 has been reviewed by members of the Health Services Research Centre. Draft versions of the protocol have been reviewed by British Geriatric Society specialist interest group chairs for delirium/dementia and frailty. Draft proposals have been reviewed by the networks who will perform data collection.

Our Study Steering Committee includes nursing, surgical, geriatrician and primary care representatives. The committee will have regular meetings and are consulted about the scientific quality of research and practical considerations.

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

☐ 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	Peter	Martin
Department			
Institution	NIAA Health Services Research Centre		
Work Address	Churchill House		
	35 Red Lion Square		
	London		
Post Code	WC1R 4SG		
Telephone	+44 (0) 20 7092 1677		
Fax			
Mobile			
E-mail	peter.martin@ucl.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

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

Length of acute hospital stay (days) will be the primary outcome as it is expected to be affected by both medical complications and discharge planning issues.

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

1. Postoperative Morbidity Survey (POMS): Days three and seven postoperatively if participant remains an inpatient (binary). Using specialty specific adaptations where appropriate (cardiac, hip fracture)
2. Delirium:
   - -Presence or absence of delirium postoperatively
   - -Patients should not be discharged if they are suffering delirium
   - -4AT scored on days one & three (if participant remains an inpatient)
   - -Review of nursing and medical notes for standard 'delirium' trigger words, to be done manually (if participant remains an inpatient)
   - -Total 4AT score from both days (Total 0- 24)
3. Death:
   - -In-hospital mortality (local data and Hospital Episode Statistics (HES)) (binary)
   - -One, two, five and ten year mortality (Office of National Statistics (ONS)) (survival analysis)
4. Length of stay
   - -Acute hospital stay (days)
   - -Days alive and out of hospital (DAOH) within first 30 and 90 days (HES / ONS data combined)
5. Readmission within 30 days: Routine data available from HES (binary)
6. Quality of life:
   - -Discharge disposition from hospital using same definitions as for admission
   - -EQ-5D-5L (descriptive system as a health profile) at four months telephone follow up
   - -EQ VAS (measure of overall self-rated health status) at four months telephone follow up
   - -EQ-5D-5L index value
   - -Patient / carer estimate of days alive at home (DAH) Days at home is defined as number of days in the patients' own home (i.e., not family (other than for planned holidays), rehabilitation, respite or new residential care) in the time since surgery

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: 12000

Total international sample size (including UK):

Total in European Economic Area:

Further details:

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.*

The estimated sample size is around 12,000 participants based on national data (Hospital Episode Statistics, HES) and previous SNAP projects. We verified that this is a sufficient sample size to achieve the primary and secondary objectives of this study.

To estimate the proportion of frail patients, and the proportion of patients who develop delirium, a sample size of 7,203 is needed for a margin of error of 1 percentage point (width of 95 % confidence interval: 2 percentage points). This calculation is based on an outcome proportion of 0.25, which is a plausible conservative upper bound. The true proportions are likely to be smaller, which would yield better precision of the estimation of the true proportion.

To estimate required sample sizes for the delirium risk prediction model, we followed Riley et al (2020). We made the following assumptions:

The number of candidate parameters in the risk prediction model is at most 30

The proportion of patients with delirium is at least 0.05, and at most 0.25

The Cox-Snell R-square of the prediction model is at least 0.05

These are conservative assumptions. Using the most conservative assumptions in each calculation, the required sample sizes for the following desirable quality criteria are:

Mean absolute error of predicted probabilities <= 0.01: n = 11,077

Shrinkage during model development using penalized regression methods <= 5 %: n = 5,395

Overoptimism of model performance <= 1 %: n = 8,909

These are strict quality criteria, and they suggest that a sample size of around 11,000 patients is sufficient to estimate a high-quality clinical prediction model for delirium.

To achieve the objectives relating to hospital variation in, and effects of, processes and procedures for treating frail patients, we plan to estimate multilevel multivariate models. There is no precise method for sample size calculations for these kinds of analyses. A conservative lower bound of the percentage of frail patients in our achieved sample is 10 %, which implies a minimum sample size of 1,200 frail patients. This will give these analyses meaningful precision even in the presence of many covariates.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

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.

The primary analysis will be performed by the trainee lead as part of a higher degree, in conjunction with the study statistician, Peter Martin and the Study Management Group. Analyses will be conducted using up-to-date versions of R and relevant packages.

To address the primary objective, we will report the proportion of frail patients, proportion of multimorbid patients and the proportion of patients experiencing post-operative delirium. Bootstrap confidence intervals will be calculated to allow for heterogeneity in the patient population.

To investigate the relationship between frailty and a range of outcomes, we will use multilevel regression models adjusting for other preoperative patient characteristics and type of surgery, with hospital-level random intercepts to control for potential between-hospital differences in outcomes. Appropriate models will be chosen for different outcome types: multilevel logistic regression for binary outcomes, multilevel quantile regression for length of stay, days alive out of hospital (DAOH) and days at home (DAH), and multilevel linear regression for the EQ5D utility index and visual analogue scale.

To address the objectives relating to hospital-level and patient-level interventions and procedures designed to address risks associated with patient frailty, we will study the sample of patients identified as frail pre-operatively. We will document between-hospital differences in interventions and procedures, using descriptive statistics and graphical methods. The role of these interventions in modifying the risk of adverse outcomes in patients with frailty will then be assessed using the types of multilevel models described above, as appropriate for each outcome.

Development and internal validation of a risk prediction model for delirium will involve the following steps: (1) Exploratory and graphical analysis of the shapes of the relationships between (numeric) candidate predictors and the probability of delirium. (2) Use of fractional polynomials to identify suitable transformations of numeric predictors, as appropriate. (3) Penalized logistic regression (ridge or lasso regression) will be considered for predictor selection, since these have been shown to outperform maximum likelihood estimation and backward selection procedures in the development of risk models (van Smeden et al 2019). (4) The quality of the risk model will be assessed using the C-statistic (area under the ROC curve), which is to be estimated using optimism correction via bootstrapping (Austin & Steyerberg 2017). We will follow the TRIPOD statement in reporting the development and internal validation of the risk prediction model for delirium.

For all analyses, missing variable values will be investigated and described. Likely processes of missing information will be identified, and the risk of bias due to missing values assessed. If appropriate assumptions are met, multiple imputation of missing values may be employed to reduce the risk of bias due to missing values.

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	Judith	Partridge
Post	Co-Lead Investigator, Consultant Geriatrician, Perioperative medicine for Older People undergoing Surgery (POPS)		
Qualifications	MSc, PhD, FRCP		
Employer	Guy's and St Thomas' NHS Foundation Trust		
Work Address	Perioperative medicine for Older People undergoing Surgery (POPS)		
	Guy's Hospital		
	Great Maze Pond		
Post Code	SE1 9RT		
Telephone	020 7188 2092		
Fax			
Mobile			
Work Email	Judith.Partridge@gstt.nhs.uk		

	Title	Forename/Initials	Surname
	Dr	Claire	Swarbrick
Post	Co-investigator, HSRC Research Fellow and Specialty Trainee in Anaesthesia, Trainee Lead and PhD student		
Qualifications	BM, FRCA, MRCP		
Employer	Royal Devon and Exeter Hospital NHS Trust		
Work Address	Anaesthetics Department		
	Royal Devon and Exeter Hospital (Wonford)		
	Barrack Road		
Post Code	EX2 4EQ		
Telephone	07502225186		
Fax			
Mobile			
Work Email	claire.swarbrick@nottingham.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Akshay	Shah
Post	Co-investigator, NIHR Clinical Lecturer and Specialty Trainee in Anaesthesia & Critical Care		
Qualifications	BMedSci (Hons), BM BS, MSc, DipHRes, MRCP, FRCA		
Employer	University of Oxford and Oxford University Hospitals NHS Trust		
Work Address	Anaesthetics Department		
	John Radcliffe Hospital		
	Headley Way, Headington, Oxford		
Post Code	OX3 9DU		
Telephone	0300 304 7777		
Fax			
Mobile			
Work Email	Akshay.shah@linacre.ox.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Jugdeep	Dhesi

Post	Co-investigator, Consultant Geriatrician and Lead for Perioperative medicine for Older People undergoing Surgery (POPS)
Qualifications	MBChB, BSc, PhD, MRCP
Employer	Guy's and St Thomas' NHS Foundation Trust
Work Address	Perioperative medicine for Older People undergoing Surgery (POPS) Guy's Hospital Great Maze Pond
Post Code	SE1 9RT
Telephone	020 7188 2092
Fax	
Mobile	
Work Email	jugdeep.dhesi@gstt.nhs.uk

Title	Forename/Initials	Surname
Dr	Tom	Poulton

Post	Co-investigator, Honorary Clinical Lecturer at the University of Melbourne
Qualifications	BM BS, PGCert, MSc
Employer	Sir Charles Gairdner Hospital
Work Address	Anaesthetics Department Sir Charles Gairdner Hospital Perth, Western Australia
Post Code	6009
Telephone	+61 8 6457 3333
Fax	
Mobile	
Work Email	t.e.poulton@doctors.org.uk

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 of Nottingham
Given name: Angela

Family name	Shone
Address	East Atrium, Jubilee Conference Centre, Triumph Road
Town/city	Nottingham
Post code	NG8 1DH
Country	United Kingdom
Telephone	+44 (0)115 8467906
Fax	
E-mail	sponsor@nottingham.ac.uk

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	Royal College of Anaesthetists
Address	Churchill House, 35 Red Lion Square Holborn
Post Code	WC1R 4SG
Telephone	020 7092 1500
Fax	
Mobile	
Email	info@rcoa.ac.uk

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

Amount: 164000

Duration
Years: 3
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Sprint National Anaesthesia Project

Organisation	Frances and Augustus Newman Foundation
Address	55 Victoria Street Bristol
Post Code	BS1 6AD
Telephone	0117 945 2000
Fax	
Mobile	
Email	

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

Amount: 53000

Duration
Years:
Months:

If applicable, please specify the programme/ funding stream:

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

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	Jennifer	Boston
Organisation	Nottingham University Hospitals NHS Trust		
Address	Research & Innovation Nottingham Health Science Partners		
	Queen's Medical Centre Campus		
	Derby Road, Nottingham		
Post Code	NG7 2UH		
Work Email	R&I@nuh.nhs.uk		
Telephone	0115 9249924 ext 60645		
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:

East Midlands

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: 04/10/2021
Planned end date: 03/05/2032
Total duration:
Years: 10 Months: 6 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 156

Does this trial involve countries outside the EU?

(●) Yes ( ) No

[ ] USA

[ ] Other international (please specify)

England, Scotland, Wales and Northern Ireland (now outside of the EU)

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:*

[x] NHS organisations in England	139
[x] NHS organisations in Wales	6
[x] NHS organisations in Scotland	10
[x] HSC organisations in Northern Ireland	1
[ ] 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:	156

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?

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g., inclusion/exclusion criteria, timeliness of visits) ; accountability of study materials and equipment calibration logs. The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

A Study Steering Group has been assembled. They have a chair independent of the applicant, the College and Sponsor. Members of the group include the Chief Investigator, Trainee Lead, PPI/E, Nursing, Surgical, Geriatrician

and Primary Care Representatives and a member of the Royal College of Anaesthetists Research Team. They will continue to review conduct of the research through regular meetings with the Study Management Group.

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)

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

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)

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

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)

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols

with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

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

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

Examples of pre-existing impairing conditions will include:

-Dementia e.g., Alzheimer's, vascular (most common)
-Mental health problems e.g., schizophrenia, bipolar disorder
-Stroke or brain injury
-Severe learning difficulties

Other reasons for inability to consent may be related to:

-The reason for admission/surgery e.g., cholecystitis causing sepsis, ruptured AAA causing haemorrhage -Delirium
-Medications
-Medical/surgical complications e.g., infection

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

Inclusion of people without capacity to consent is essential to the success of the study. SNAP3s primary objective is to characterise the epidemiology of frailty, multimorbidity and delirium. A proportion of participants will enter the study without capacity due to pre-existing conditions. A significant number will lose capacity during the study due to factors surrounding their admission or treatment pathway. Excluding such people from studies is viewed as discriminatory and unethical.

The purpose of the study is to improve care for those with and at risk of frailty and delirium, so excluding them, or putting barriers to their participation undermines the scientific purpose of the study. Not including those without capacity would introduce selection bias and not allow us to address our primary objective.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

Capacity will be assessed by the Principal Investigator (consultant) or a nominated representative (doctor or research nurse) in accordance with the Mental Capacity Act (MCA 2005) guidance. All have experience in capacity assessment and obtaining consent clinically and for research purposes. They will have been trained in assessment of capacity formally through medical training and research training, they also routinely assess capacity as part of clinical practice.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

○ Yes ◉ No

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

◉ Yes ○ No

If Yes, please explain how the research will achieve this:

Our study will investigate the epidemiology of frailty, multi-morbidity and delirium as its primary objective. Our secondary objectives include examining the relationships between frailty, multimorbidity and perioperative outcomes. It will also identify associations between frailty-related interventions and outcomes and develop a risk prediction tool for postoperative delirium. Fulfilling our objectives will increase our knowledge of how to best optimise care for older surgical patients, many of whom lose capacity during their surgical episode. New knowledge will be disseminated throughout the UK and drive improvements in hospital resources for frail surgical patients and those with delirium.

B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

◉ Yes ○ No

If Yes, please give an assessment below. Highlight any risk, burden or discomfort specific to these participants and say what will be done to minimise it. You may refer back to your answers to Questions A22 and A23.

There are very limited participant risks associated with this study as it is observational. The burden is limited to inconvenience from confirming data, participation in scoring systems and collection of confidential data. The burden is similar to those participants with capacity.

Participants will be asked questions about medical history, social history, activities of daily living and undergo some basic bedside tests. We will minimise the burden to patients by obtaining as much information from the notes and medical staff as possible, only requiring patient participation when necessary. We have deliberately chosen assessment tools that are brief and simple for participants to answer. Most of our interventions will take place whilst the participant is an inpatient, they are spread over days and will not require extended periods of concentration. It is hoped that this will minimise the burden to our participants.

A brief telephone call or email four months postoperatively will be the only intervention that occurs after discharge. From previous PPI with people over 59 years old, we have found that a telephone call is generally not considered intrusive and is quite acceptable.

Participants may benefit from assistance from hospital staff, carers, relatives or friends where necessary during the study.

We have minimised the risk of a breach of confidentiality through robust data management systems. We will collect confidential data via a secure web-based portal onto the study database. The research database and website will be run through 'REDCap' (an internationally recognised standard for study database management) which will be hosted on servers managed by the University of Nottingham. Communication with NHS Digital will be carried out with the minimum patient identifiable data and will be password protected.

Questions B7 and B8 apply to any participants recruited in England and Wales.

B7. What arrangements will be made to identify and consult persons able to advise on the presumed wishes and feelings of participants unable to consent for themselves and on their inclusion in the research?

Participants unable to consent for themselves will be treated according to section 30-34 of the MCA. A personal or professional consultee process will be used. The advice of a personal or nominated consultee (section 32, MCA 2005) and the presence of an advance statement will be sought.

If the next of kin, relative or friend of the patient is available and willing to act as the personal consultee, they will be approached and provided with an Information Sheet and Consultee Advice form. The role of the consultee would be to advise the research team on the participants' wishes and feelings would be if they were able to consent for themselves, and if they should take part.

This person should be:
-Engaged in caring for the participant (not professionally or for payment) or is interested in his/her welfare
-Willing to be consulted either in person or over the telephone

Consultation including a brief explanation of the study with personal consultees may be performed by telephone, in order to comply with hospital visiting requirements. A Consultee PIS can be sent by email for those giving advice over the telephone. A researcher guidance document with a scripted Telephone Consultee PIS has also been prepared, in case consultees would prefer to receive the information verbally.

If a personal consultee is not available in person or by phone before the surgical procedure is due to take place, then a professional consultee will be involved. This is because frailty assessment is thought to be most accurate when assessment of the participants' frailty is carried out prior to surgery. Professional consultees will be either ward managers or doctors of at least 4 years clinical experience (registrars and consultants) and responsible for the clinical care of the patients, but completely unrelated to the study.

If the lack of capacity is temporary or intermittent every effort will be made to inform the participant and seek their retrospective consent. All participants' general practitioners will be informed of their involvement in the study.

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

B8. Is it possible that a participant requiring urgent treatment might need to be recruited into research before it is possible to identify and consult a person under B7?

◉ Yes ○ No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants and what arrangements will be made to seek consent from the participant (if capacity has been recovered) or advice from a consultee as soon as practicable thereafter.

In order to produce generalisable, applicable research and not exclude patients undergoing emergency surgery, if necessary, we will attempt to recruit participants before it has been possible to consult a personal consultee in England and Wales. If a personal consultee is not available, then we will use a professional consultee (ward manager or doctor of at least 4 years clinical practice) who is not part of the research team. This study is of low participant burden and risk so use of a professional consultee is reasonable.

Question B7-1 applies to any participants recruited in Scotland.

B7-1. What arrangements will be made to identify and seek consent from a guardian or welfare attorney or, if there is no such person, from the participant's nearest relative?

If a potential participant is unable to consent then the research team will attempt to contact the welfare guardian, welfare attorney or, if there is no such person, the participants nearest relative. Any advance statements will be sought.

The research team and guardians/attorneys/relatives can discuss the potential involvement either face to face or over the telephone (if preferable due to visiting restrictions). Information sheets will be provided and an opportunity to ask questions be given. Written or verbal consent will be sought and documented. A Personal Legal Representative (PLR) PIS can be sent by email for those giving advice over the telephone. A researcher guidance document with a scripted Telephone PLR PIS has also been prepared in case a PLR would prefer to receive the information verbally. In Scotland it is not permitted to use a professional consultee.

Please enclose a copy of the written information to be provided and the consent form to be used. The information sheet should provide information about the research similar to that which might be given to participants able to consent for themselves.

Questions B7-2 and B8-2 apply to any participants recruited in Northern Ireland.

B7-2. What arrangements will be made to consult a close relative or close friend able to advise on the inclusion of the participant and on their likely wishes?

If a potential participant is unable to consent then the research team will attempt to contact a close relative or close friend. The presence of an advance statement will be sought. Research teams and relatives/friends can discuss the potential involvement either face to face or over the telephone (if preferable due to visiting restrictions). A Consultee PIS can be sent by email for those giving advice over the telephone. A researcher guidance document with a scripted Telephone Consultee PIS has also been prepared, in case consultees would prefer to receive the information verbally. Written or verbal advice will be sought and documented.

B8-2. Is it possible that a participant might need to be treated urgently as part of the research before it is possible to consult with a close relative or close friend?

◉ Yes ○ No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants.

In order to produce generalisable applicable research and not exclude patients undergoing emergency surgery, if

necessary we will recruit participants before it has been possible to consult a close relative/ friend as personal consultee. If a personal consultee is not available then we will use a professional consultee (ward manager or doctor of at least 4 years clinical practice) who is not part of the research team. This study is of low participant burden and risk so use of a professional consultee is reasonable in these cases.

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

Permission will be sought from personal consultees/Personal Legal Representatives (PLR) to keep their contact details for the duration of the study. The investigator will inform the personal consultee/PLR of any relevant information that becomes available during the course of the study, and will discuss with them, whether the participant would wish to continue with the study. If applicable they will be asked to sign revised advice/consent forms. If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

Participants who are unable to consent for themselves will be given time to discuss the study with the research team and given access to information sheets. Attempts will be made to communicate the most relevant pieces of information with participants. A PIS for those without capacity/with incapacity has been prepared.

The study relies on participant participation with frailty, delirium and quality of life assessment. Explanation of the study and each element of participant involvement will be explained at each active intervention. This will be done in an appropriate manner and questions will be encouraged. If a participant doesn't wish to participate with these assessments, then this will be recorded.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

Fluctuating capacity is not uncommon in our study population. Consent to continue to include participants in the study (for data linkage only in England and Wales) if they lose capacity, will be sought at the time of enrolment. If a participant were found to not have capacity when visited for an intervention, then a consultee opinion would be sought to continue any further interventions in England and Wales. In Northern Ireland, a participant's original consent would still apply to interventions unless a participant overtly objects. In Scotland, we would anticipate that the original consent would continue to stand unless the participant objects.

If a participant who has previously been enrolled via a personal/professional consultee or Personal Legal Representative, regains capacity, then the participant will be offered the opportunity to consent. If they do not wish to consent, then they will be withdrawn from the study and informed that data previously collected may still be used in analysis. A Participant Information Sheet has been prepared for this circumstance.

B12-1. What will be the criteria for withdrawal of participants?

There are no set criteria for withdrawl. Participants will be withdrawn at their request, or at the request of their personal/professional consultee (if applicable).

B12-2. Where a participant is recruited urgently, and later withholds their consent or is withdrawn or dies before consent / consultation can take place, what provisions will apply to the study data collected up to that point?

Any study data previously collected cannot be withdrawn from the study's database. In the event that a participant/consultee withdraws their consent/assent then no further data will be collected.

A patient is only considered a participant after they have been recruited and given consent or a consultee/Personal Legal Representative has given their advice/consent respectively. If a participant dies after being recruited, then their death will be recorded as part of the study data. If a patient dies before entering into the study, then they will not be included in the data.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

As this study is observational, we do not anticipate any processes to cause participants to appear to object. Their views and beliefs on participating in this research study will be sought from a consultee. When/if participants regain capacity, their permission will be sought for ongoing participation in the study.

Participants will give assent prior to continuing with the delirium and quality of life assessments. If they object to these assessments, then their responses will be recorded. If a participant appears distressed, then the research team will ensure that the participant is appropriately reassured, or their clinical team will be notified for further care.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

The consultee/Personal Legal Representative will be asked to consider advance decision or statements before providing advice on enrolling the participant. This is specifically mentioned in the consultee advice/Personal Legal Representative consent form.

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	James Pittman james.pittman@nhs.net
	Organisation name	ROYAL DEVON AND EXETER NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	ROYAL DEVON & EXETER HOSPITAL BARRACK ROAD EXETER	Country	United Kingdom
	Post Code	EX2 5DW		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Priya Nair priya.nair@thewaltoncentre.nhs.uk
	Organisation name	THE WALTON CENTRE NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	LOWER LANE LIVERPOOL	Country	United Kingdom
	Post Code	L9 7LJ		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Sarah Martindale sarah.martindale@nbt.nhs.uk
	Organisation name	NORTH BRISTOL NHS TRUST	Qualification (MD...)	
	Address	SOUTHMEAD HOSPITAL	Country	United Kingdom

	SOUTHMEAD ROAD
	WESTBURY-ON-TRYM
	BRISTOL
Post Code	BS10 5NB
Country	ENGLAND

IN4

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

Forename	Lesley
Middle name	
Family name	Jordan
Email	lesleyjordan@btinternet.com
Qualification (MD...)	
Country	United Kingdom

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

IN5

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

Forename	Jon
Middle name	
Family name	Wedgwood
Email	jonathan.wedgwood@nhslothian.scot.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	NHS Lothian
Address	Waverley Gate
	2-4 Waterloo Place
	Edinburgh Scotland
Post Code	EH1 3EG
Country	SCOTLAND

IN6

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

Forename	Satya
Middle name	
Family name	Jakkampudi
Email	satya.jakkampudi@nhs.net
Qualification (MD...)	
Country	

Organisation name	KETTERING GENERAL HOSPITAL NHS FOUNDATION TRUST
Address	ROTHWELL ROAD

	KETTERING
Post Code	NN16 8UZ
Country	ENGLAND

IN7

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Naomi
Middle name	
Family name	Goodwin
Email	Naomi.Goodwin@wales.nhs.uk
Qualification (MD...)	
Country	United Kingdom

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

IN8

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Michael
Middle name	
Family name	Bretland
Email	michael.bretland@wales.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	CWM TAF MORGANNWG UNIVERSITY LOCAL HEALTH BOARD
Address	DEWI SANT HOSPITAL ALBERT ROAD PONTYPRIDD MID GLAMORGAN
Post Code	CF37 1LB
Country	WALES

IN9

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Simon
Middle name	
Family name	Young
Email	simon.young@ggc.scot.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	NHS Greater Glasgow and Clyde
Address	J B Russell House Gartnavel Royal Hospital

	1055 Great Western Road Glasgow Glasgow Scotland	
Post Code	G12 0XH	
Country	SCOTLAND	

IN10

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

		Forename	Mark
		Middle name	
		Family name	Pulletz
		Email	mark.pulletz@dchft.nhs.uk
Organisation name	DORSET COUNTY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)	
Address	DORSET COUNTY HOSPITAL WILLIAMS AVENUE DORCHESTER	Country	United Kingdom
Post Code	DT1 2JY		
Country	ENGLAND		

IN11

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

		Forename	Abhi
		Middle name	
		Family name	Kant
		Email	abhinavkant@nhs.net
Organisation name	HARROGATE AND DISTRICT NHS FOUNDATION TRUST	Qualification (MD...)	
Address	HARROGATE DISTRICT HOSPITAL LANCASTER PARK ROAD HARROGATE	Country	United Kingdom
Post Code	HG2 7SX		
Country	ENGLAND		

IN12

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

		Forename	Caroline
		Middle name	
		Family name	Reavley
		Email	CAROLINE.REAVLEY@nnuh.nhs.uk
	NORFOLK AND	Qualification	

	Organisation name	NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	(MD...)	
			Country	United Kingdom
	Address	COLNEY LANE		
		COLNEY		
		NORWICH		
	Post Code	NR4 7UY		
	Country	ENGLAND		

IN13

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

			Forename	Dhanasekar
			Middle name	
			Family name	Boopathy
			Email	boopathy.dhanasekar@pat.nhs.uk
	Organisation name	PENNINE ACUTE HOSPITALS NHS TRUST	Qualification (MD...)	
			Country	United Kingdom
	Address	TRUST HEADQUARTERS		
		NORTH MANCHESTER GENERAL HOSPITAL		
		DELAUNAYS ROAD, CRUMPSALL MANCHESTER		
	Post Code	M8 5RB		
	Country	ENGLAND		

IN14

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

			Forename	Jason
			Middle name	
			Family name	Cupitt
			Email	dr.cupitt@nhs.net
	Organisation name	BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	
			Country	United Kingdom
	Address	VICTORIA HOSPITAL		
		WHINNEY HEYS ROAD		
		BLACKPOOL		
	Post Code	FY3 8NR		
	Country	ENGLAND		

IN15

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

Organisation name	UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST
Address	WALSGRAVE GENERAL HOSPITAL CLIFFORD BRIDGE ROAD COVENTRY
Post Code	CV2 2DX
Country	ENGLAND

Forename	Carol
Middle name	
Family name	Bradbury
Email	carolouisebrad@hotmail.com
Qualification (MD...)	
Country	United Kingdom

IN16

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

Organisation name	BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST
Address	ROYAL SUSSEX COUNTY HOSPITAL EASTERN ROAD BRIGHTON
Post Code	BN2 5BE
Country	ENGLAND

Forename	Stuart
Middle name	
Family name	White
Email	igasbest@hotmail.com
Qualification (MD...)	
Country	United Kingdom

IN17

- (●) 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	Richard
Middle name	
Family name	Pugh
Email	richard.pugh@wales.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN18

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST
Address	ST THOMAS' HOSPITAL WESTMINSTER BRIDGE ROAD LONDON
Post Code	SE1 7EH
Country	ENGLAND

Forename	Kariem
Middle name	
Family name	El-Boghdadly
Email	elboghdadly@gmail.com
Qualification (MD...)	
Country	United Kingdom

IN19

◉ 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	Kulkarni
Middle name	
Family name	Anand
Email	anand.kulkarni@tgh.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN20

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	THE ROYAL ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST
Address	THE WOODLANDS BRISTOL ROAD SOUTH

Forename	Dr Narendra
Middle name	
Family name	Siddaiah
Email	narendra.siddaiah@nhs.net
Qualification (MD...)	
Country	United Kingdom

		NORTHFIELD BIRMINGHAM
	Post Code	B31 2AP
	Country	ENGLAND

IN21

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

Forename	Eleanor
Middle name	
Family name	Carter
Email	eleanor.carter3@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
Address	250 EUSTON ROAD
	LONDON
Post Code	NW1 2PG
Country	ENGLAND

IN22

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

Forename	Mansoor
Middle name	
Family name	Sange
Email	msange@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	DARTFORD AND GRAVESHAM NHS TRUST
Address	DARENT VALLEY HOSPITAL
	DARENTH WOOD ROAD
	DARTFORD
Post Code	DA2 8DA
Country	ENGLAND

IN23

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

Forename	Thomas
Middle name	
Family name	Fitzgerald
Email	tfitzgerald@nhs.net
Qualification (MD...)	

Organisation	LONDON NORTH WEST UNIVERSITY

	name	HEALTHCARE NHS TRUST	Country	United Kingdom
	Address	NORTHWICK PARK HOSPITAL		
		WATFORD ROAD		
		HARROW		
	Post Code	HA1 3UJ		
	Country	ENGLAND		

IN24

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

		Forename	Asha
		Middle name	
		Family name	Ramkumar
		Email	asharamkumar@nhs.net
	Organisation name	THE ROYAL WOLVERHAMPTON NHS TRUST	Qualification (MD...)
	Address	NEW CROSS HOSPITAL	Country United Kingdom
		WOLVERHAMPTON ROAD	
		HEATH TOWN WOLVERHAMPTON	
	Post Code	WV10 0QP	
	Country	ENGLAND	

IN25

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

		Forename	Davina
		Middle name	
		Family name	Ross-Anderson
		Email	davina.ross-anderson@nhs.net
	Organisation name	BARTS HEALTH NHS TRUST	Qualification (MD...)
	Address	THE ROYAL LONDON HOSPITAL	Country United Kingdom
		80 NEWARK STREET	
		LONDON	
	Post Code	E1 2ES	
	Country	ENGLAND	

IN26

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

		Forename	Emert
		Middle name	
		Family name	White

			Email	emert.white@swft.nhs.uk
	Organisation name	SOUTH WARWICKSHIRE NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	WARWICK HOSPITAL LAKIN ROAD WARWICK	Country	United Kingdom
	Post Code	CV34 5BW		
	Country	ENGLAND		

IN27

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

			Forename	Pravin
			Middle name	
			Family name	Dandegaonkar
			Email	pravin.dandegaonkar@cht.nhs.uk
	Organisation name	CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	TRUST HEADQUARTERS ACRE STREET LINDLEY HUDDERSFIELD	Country	United Kingdom
	Post Code	HD3 3EA		
	Country	ENGLAND		

IN28

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

			Forename	Helen
			Middle name	
			Family name	Bromhead
			Email	hjbromhead@hotmail.com
	Organisation name	HAMPSHIRE HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	BASINGSTOKE AND NORTH HAMPSHIRE HOS ALDERMASTON ROAD BASINGSTOKE HAMPSHIRE	Country	United Kingdom
	Post Code	RG24 9NA		
	Country	ENGLAND		

IN29

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
Address	TORBAY HOSPITAL NEWTON ROAD TORQUAY
Post Code	TQ2 7AA
Country	ENGLAND

Forename	Johannes
Middle name	
Family name	Retief
Email	jretief@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN30

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	KINGSTON HOSPITAL NHS FOUNDATION TRUST
Address	GALSWORTHY ROAD KINGSTON UPON THAMES
Post Code	KT2 7QB
Country	ENGLAND

Forename	Sarang
Middle name	Puranik
Family name	
Email	sarangpuranik@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN31

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	PENNINE ACUTE HOSPITALS NHS TRUST
Address	TRUST HEADQUARTERS NORTH MANCHESTER GENERAL HOSPITAL DELAUNAYS ROAD, CRUMPSALL MANCHESTER
Post Code	M8 5RB
Country	ENGLAND

Forename	Bhaskar
Middle name	
Family name	Saha
Email	bhaskar.saha@pat.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN32

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	HYWEL DDA UNIVERSITY LHB
Address	CORPORATE OFFICES, YSTWYTH BUILDING HAFAN DERWEN ST DAVIDS PARK, JOBSWELL ROAD CARMARTHEN DYFED
Post Code	SA31 3BB
Country	WALES

Forename	Sunita
Middle name	
Family name	Agarwal
Email	sunita.agarwal@wales.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN33

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	BEDFORDSHIRE HOSPITALS NHS FOUNDATION TRUST
Address	LEWSEY ROAD LUTON
Post Code	LU4 0DZ
Country	ENGLAND

Forename	Peter
Middle name	
Family name	Knowlden
Email	peter.knowlden@bedfordhospital.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN34

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	LIVERPOOL HEART AND CHEST HOSPITAL NHS FOUNDATION TRUST
Address	THOMAS DRIVE LIVERPOOL
Post Code	L14 3PE
Country	ENGLAND

Forename	Jonathan
Middle name	
Family name	Kendall
Email	john.kendall@lhch.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN35

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	CAMBRIDGE BIOMEDICAL CAMPUS HILLS ROAD CAMBRIDGE
Post Code	CB2 0QQ
Country	ENGLAND

Forename	Svet
Middle name	
Family name	Petkov
Email	svet.petkov@addenbrookes.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN36

◉ 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	Roshmi
Middle name	
Family name	Kumar
Email	roshmi.kumar@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN37

◉ 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

Forename	Lew-Chin
Middle name	
Family name	Chee
Email	lew-chin.chee@ggc.scot.nhs.uk
Qualification (MD...)	
Country	United Kingdom

	Scotland
Post Code	G12 0XH
Country	SCOTLAND

IN38

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

Forename	Christine
Middle name	
Family name	Range
Email	christine.range@wales.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	SWANSEA BAY UNIVERSITY LOCAL HEALTH BOARD
Address	ONE TALBOT GATEWAY, SEAWAY DRIVE SEAWAY PARADE INDUSTRIAL ESTATE BAGLAN PORT TALBOT WEST GLAMORGAN
Post Code	SA12 7BR
Country	WALES

IN39

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

Forename	K
Middle name	
Family name	Katyayani
Email	kkatyayani@nhs.net
Qualification (MD...)	
Country	United Kingdom

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

IN40

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

Forename	James
Middle name	
Family name	Craig
Email	james.craig@uhd.nhs.uk
Qualification (MD...)	

Organisation	UNIVERSITY HOSPITALS DORSET

	name	NHS FOUNDATION TRUST	Country	United Kingdom
	Address	MANAGEMENT OFFICES POOLE HOSPITAL LONGFLEET ROAD POOLE		
	Post Code	BH15 2JB		
	Country	ENGLAND		

IN41

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

		Forename	Jaya
		Middle name	
		Family name	Nariani
		Email	jaya.nariani@nhs.net
	Organisation name	THE CHRISTIE NHS FOUNDATION TRUST	Qualification (MD...)
	Address	550 WILMSLOW ROAD WITHINGTON MANCHESTER	Country United Kingdom
	Post Code	M20 4BX	
	Country	ENGLAND	

IN42

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

		Forename	Jane
		Middle name	
		Family name	Pilsbury
		Email	jane.pilsbury@uhb.nhs.uk
	Organisation name	BIRMINGHAM WOMEN'S AND CHILDREN'S NHS FOUNDATION TRUST	Qualification (MD...)
			Country United Kingdom
	Address	STEELHOUSE LANE BIRMINGHAM WEST MIDLANDS	
	Post Code	B4 6NH	
	Country	ENGLAND	

IN43

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

		Forename	Patrick
		Middle name	
		Family name	Dill-Russell

	Organisation name	ROYAL BERKSHIRE NHS FOUNDATION TRUST	Email	patrick.dill-russell@royalberkshire.nhs.uk
			Qualification (MD...)	
	Address	ROYAL BERKSHIRE HOSPITAL LONDON ROAD READING	Country	United Kingdom
	Post Code	RG1 5AN		
	Country	ENGLAND		

IN44

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename	Joyce
		Middle name	
		Family name	Yeung
		Email	j.yeung.4@warwick.ac.uk
Organisation name	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST	Qualification (MD...)	
		Country	United Kingdom
Address	QUEEN ELIZABETH HOSPITAL MINDELSOHN WAY EDGBASTON BIRMINGHAM WEST MIDLANDS		
Post Code	B15 2GW		
Country	ENGLAND		

IN45

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename	Stephen
		Middle name	
		Family name	Washington
		Email	stephenwashington78@gmail.com
Organisation name	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST	Qualification (MD...)	
		Country	United Kingdom
Address	COBBETT HOUSE OXFORD ROAD MANCHESTER		
Post Code	M13 9WL		
Country	ENGLAND		

IN46

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

Organisation name	MID CHESHIRE HOSPITALS NHS FOUNDATION TRUST
Address	LEIGHTON HOSPITAL LEIGHTON CREWE
Post Code	CW1 4QJ
Country	ENGLAND

Forename	Helen
Middle name	
Family name	Burton
Email	helen.burton@mcht.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN47

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

Organisation name	LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	ROYAL PRESTON HOSPITAL SHAROE GREEN LANE FULWOOD PRESTON
Post Code	PR2 9HT
Country	ENGLAND

Forename	Sharmin
Middle name	
Family name	Shohelly
Email	sshohelly@gmail.com
Qualification (MD...)	
Country	United Kingdom

IN48

- (●) 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	Hannah
Middle name	
Family name	Greenlee
Email	hannahgreenlee@doctors.org.uk
Qualification (MD...)	
Country	United Kingdom

IN49

(●) 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	Sujesh
Middle name	
Family name	Bansal
Email	sujesh.bansal@mft.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN50

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	WYE VALLEY NHS TRUST
Address	COUNTY HOSPITAL 27 UNION WALK HEREFORD
Post Code	HR1 2ER
Country	ENGLAND

Forename	Richard
Middle name	
Family name	Hodgson
Email	Richard.Hodgson@wvt.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN51

(●) 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	Tony
Middle name	
Family name	Short
Email	Anthony.Short@wwl.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN52

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	SALFORD ROYAL NHS FOUNDATION TRUST
Address	SALFORD ROYAL STOTT LANE SALFORD GREATER MANCHESTER
Post Code	M6 8HD
Country	ENGLAND

Forename	Manjunatha
Middle name	SV
Family name	Patel
Email	Manjunatha.Patel@srft.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN53

◉ 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 Scotland
Post Code	G12 0XH
Country	SCOTLAND

Forename	Michael
Middle name	
Family name	Brett
Email	michael.brett@ggc.scot.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN54

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	STOCKPORT NHS FOUNDATION TRUST
Address	STEPPING HILL HOSPITAL POPLAR GROVE STOCKPORT
Post Code	SK2 7JE
Country	ENGLAND

Forename	Robert
Middle name	
Family name	Loveridge
Email	robert.loveridge@stockport.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN55

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BUCKINGHAMSHIRE HEALTHCARE NHS TRUST
Address	AMERSHAM HOSPITAL WHIELDEN STREET AMERSHAM
Post Code	HP7 0JD
Country	ENGLAND

Forename	Jeremy
Middle name	
Family name	Drake
Email	jeremy.drake@nhs.net
Qualification (MD...)	
Country	United Kingdom

IN56

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NHS Ayrshire and Arran
Address	PO Box 13, Boswell House 10 Arthur Street AYR Scotland
Post Code	KA7 1QJ
Country	SCOTLAND

Forename	Joellene
Middle name	
Family name	Mitchell
Email	joellene.mitchell@aapct.scot.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN57

◉ 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	Beth
Middle name	
Family name	Farr
Email	Beth.Farr@meht.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN58

◉ NHS/HSC Site
○ Non-NHS/HSC Site

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

Forename	Harriet
Middle name	
Family name	Pearson
Email	Harriet.pearson@york.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN59

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	ROYAL LIVERPOOL UNIVERSITY HOSPITAL PRESCOT STREET LIVERPOOL
Post Code	L7 8XP
Country	ENGLAND

Forename	Shiv
Middle name	
Family name	Singh
Email	SHIV.SINGH2@liverpoolft.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN60

◉ 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	Adrian
Middle name	
Family name	Taylor
Email	Adrian.Taylor@northumbria-healthcare.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN61

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Forename	Jonathan
Middle name	
Family name	Edgar
Email	Jonathan.Edgar@lanarkshire.scot.nhs.uk
Qualification (MD...)	
Country	United Kingdom

IN66

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	HOMERTON ROW
	LONDON
Post Code	E9 6SR
Country	ENGLAND

Forename	Ernst
Middle name	Christian
Family name	Schwiebert
Email	christian.schwiebert@nhs.net
Qualification (MD...)	
Country	United Kingdom

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 Iain Moppett on 08/06/2021 09:26.

Job Title/Post: CI / Professor

Organisation:

Email:

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 Ms Angela Shone on 08/06/2021 10:12.

Job Title/Post:	Head of Research Governance
Organisation:	University of Nottingham
Email:	sponsor@nottingham.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

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

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Miss Judith Partridge on 08/06/2021 11:07.

Job Title/Post:	Cons geriatrician
Organisation:	GSTT
Email:	judith.partridge@gstt.nhs.uk

Academic supervisor 2

This section was signed electronically by Iain Moppett on 08/06/2021 09:25.

Job Title/Post:	CI / Professor
Organisation:	
Email:	