FULL/LONG TITLE OF THE STUDY	The VIP-3 study: Decision-making in the older ICU patient: How are family meetings implemented across diverse European cultures?
SHORT STUDY TITLE / ACRONYM	The VIP-3 study: Family involvement in treatment decisions for ICU patients aged seventy-five years and above.
PROTOCOL VERSION NUMBER AND DATE	**Version 6.0 14/12/2025**
IRAS Number:	**337942**
JRES Reference Number	**2023. 0182**
Funder Reference Number:	**LEAVERSUSANNAH-VIP3-RESEARCH**
This protocol has regard for the HRA guidance and order of content	

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: 

Date: 13/03/24

.....

Name: Lauren Thomson

Position: Research Governance and Facilitation Officer

Chief Investigator:

Date: 12/03/24

Signature:

.....

Name: Susannah Leaver

KEY STUDY CONTACTS	
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Sponsor	St Georges, University Hospitals NS Foundation Trust Name: Subhir Bedi Position: Head of Research Governance and Delivery Email: researchgovernance@sgul.ac.uk St Georges Joint Research & Enterprise Service (JRES), Cranmer Terrace SW17 ORE
Funder(s)	European Society of Intensive Care Medicine Research Grant
Key Protocol Contributors	**Prof Bertrand GUIDET (co-chief investigator)** **National coordinator for France and member of the steering group.** **Chief of Intensive Care** Hôpital Saint Antoine (AP-HP), 184, rue du Faubourg Saint Antoine 75012 PARIS, France. Phone: +33 1 49 28 23 19 e-mail: bertrand.guidet@aphp.fr **Dr Jesper Fjoelner (co-chief investigator)** **Data base co-ordinator, national co-ordinator for Denmark and member of the steering group.**

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STUDY SUMMARY	
Study Title	Decision-making in the older ICU patient: How are family meetings implemented across diverse European cultures.
Internal ref. no. (or short title)	The VIP3 study: Family involvement in treatment decisions for ICU patients aged seventy-five years and above
Inclusion and Exclusion Criteria	Inclusion criteria: (up to 20 consecutive patients per ICU) • Patients admitted to the ICU of a participating centre • Emergency admission • Age ≥75 years • Expected LOS ≥ 3 days Exclusion criteria: • Refusal to participate. • Limitation of treatment upon ICU admission (other than Cardiopulmonary Resuscitation-CPR) Planned/elective admission
Study Design	Observational study with a central registration of defined variables
Study Participants	All patients aged 75 years and above admitted to an intensive care unit with an expected length of stay ≥ 3 days
Planned Size of Sample (if applicable)	Number of ICUs: 30-50 Number of patients: 600-1000
Follow up duration (if applicable)	N/A- completes on hospital discharge or 30 days from ICU admission (whichever is longer)
Planned Study Period	1st April 25 to 31st December 2026 Individual ICUs will have 6 months during this study period to recruit
Research Question/Aim(s)	Primary objectives: To investigate whether formal family meetings are implemented in ICUs in Europe and other regions and, if so, how they are conducted and influence patient-centred outcome measures. Secondary objectives: To determine the characteristics of family meetings (when performed). To determine whether family meetings change ICU and hospital stay characteristics.
FUNDING AND SUPPORT	
FUNDER(S)	ESICM family partnership award

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The roles of the steering group are outline below. Prof Guidet and Dr Leaver are co-chairs of the project. Dr Fjoelner is co-ordinating and running the database. Dr Boumendil is the statistician who will complete the statistical analysis.

All other members were involved in writing the protocol and the electronic CRF. All members are national co-ordinators for the trial.

Trial Steering Group	
Co chair	**Prof Bertrand Guidet**
Member	**Prof Hans Flaaten**
Chief database manager	**Dr Jesper Fjoelner**
Member	**Dr Dylan deLange**
Member	**Dr Michael Beil**
Member	**Prof Christian Jung**
Member	**Dr Sigal Sviri**
Member	**Wojciech Szczeklik**
Co chair	**Dr Susannah Leaver**
Member	**Arianne Boumendil**

PROTOCOL CONTRIBUTORS

- All the members of committee were involved in the design of the trial and writing up the manuscript. Bertrand Guidet, Jesper Fjolner and Susannah Leaver are joint chief investigators. Jesper Fjolner manages the data base. Arianne Boumendil will analyse the statistics.
- We have a grant from the European Society of Intensive care which will help fund the statistics and the running of the data base.
- As part of the grant the manuscript from the study must first be offered to Intensive Care Medicine for consideration of publication.

STUDY Schematic

Timeline:

<u>On ICU registration for trial</u>

- ICUs register nationally to trial
- Pre-ICU questions.

<u>On admission of patient to ICU</u>:

Identify patients age ≥75 with expected length of stay of 3 days or more.

On discharge / or after a FM has taken place: Meet with patient/ consultee to discuss trial and give them the patient information leaflet

Obtain consent/next of kins assents by signing consultee declaration form.

Collect baseline data:

- Demographics
- Pre ICU status (activities of daily living, frailty, co-morbidity)- the research team will have a conversation with the patient or next of kin to obtain this information or take it from the medical records.

Collect admission diagnosis and specific physiological data on the day of admission to ICU

<u>During ICU stay</u>

- If a family meeting takes place- collect data about this meeting (for details see eCRF). Data includes:
    - Who was present
    - Duration of the meeting
    - Were the patient wishes elicited?
    - Was outcome discussed?
    - Were therapy levels discussed?
    - Was a consensus reached between the family and the medical staff
    - Conclusions of the meeting
    - SOFA Score on the day of the family meeting

- If a family meeting does not take place- skip to next section of the CRF
- Collect data on physiology and interventions.

<u>On ICU discharge</u>

- Collect information on treatment received and discharge location

<u>On Hospital discharge</u>

- Collect vital status on discharge

The family will be given, via a QR code on the consultee declaration form, the opportunity to provide feedback about communication with medical and nursing staff whilst their relative was on the ICU. If a family meeting took place they will be asked questions about the family meeting. If no family meeting took place, they will be asked general question about the communication with nursing and medical staff during their relative's ICU stay. Paper copies will be provided for those unable to use a QR code.

ABBREVIATIONS	
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
FM	Family Meeting
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ICU	Intensive Care Unit
ISF	Investigator Site File
LST	Life sustaining Treatment
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SGUL	St George's, University of London
SGHFT	St George's, University Hospitals NHS Foundation Trust
JRES	(St George's) Joint Research and Enterprise Services
TLT	Time Limited Trial

STUDY PROTOCOL

The VIP-3 study: Family involvement in treatment decisions for ICU patients aged seventy-five years and above.

1 BACKGROUND

The variability of decision-making in the ICU has been documented in numerous studies. Recent research into the decision-making about life-sustaining treatment has focused on the communication between physicians, families, and patients to align the extent of intensive care with individual preferences and expectations. [Chang DW. JAMA Intern Med. 2021]. This is especially important in elderly multi-morbid patients admitted to the ICU.

In cases of life-sustaining interventions which are not aligned with the patient's values, these therapies should be withheld or withdrawn, and, in some cases, end-of-life care initiated. However, a decision about limiting life sustaining treatment should only be made after carefully balancing the benefit of the achievable outcome for the individual patient with the burden and harm of further aggressive treatment and communicating these issues with family members. Intensivists struggle to determine the best time for this decision and the communication with stakeholders varies substantially [Vink. ICM 2018].

Dealing with uncertainty is probably one of the most difficult tasks for the ICU team. We need to avoid over- but also under-treatment. Time-limited trials (TLTs) have been advocated in this context to improve predictive accuracy while minimising the patient's exposure to potentially harmful therapies [Vink ICM 2018].

Although the overall benefit of a TLT hinges on its actual length, there is little evidence to determine the optimal time [Vink. ICM 2018; Beil Chest 2022] for decisions about life-sustaining treatment to be made. We have analysed data from the VIP2 study involving very old ICU patients [Guidet. ICM 2020] and found an association between the severity of chronic and acute conditions with the optimal duration of a TLT based on variations of uncertainty [Beil et al. J Crit Care 2022]. Regardless of these data, the key element factors required for decision-making during a TLT are family meetings enabling discussions about the appropriate level of care by considering new information gathered since ICU admission including response to treatment.

The importance of the above considerations is underlined by the fact that admissions of very old patients to ICU are likely to continue to increase in all European countries. In two large prospective studies in this patient group, the VIP1 and VIP2 studies, we found the short-term mortality was very high (around 40% after 30 days). This was later confirmed by a systematic review [Vallet 2021]. Health-related quality of life is also poor 6 months after ICU discharge [Guidet 2017]. Many of these patients will receive treatment limitations while in the ICU [Guidet 2018]. However, very little is known about the process that occurs in the ICU which leads to the decision to limit or withhold treatment, especially in the context of TLT. Some ICUs have a formalised approach, with structured meetings with family members, caregivers and health care workers from the ICU and other departments, to discuss prognosis and the benefit / burden of ongoing care. Whereas others may have a less structured approach.

It is essential to involve all major stakeholders in this process, notably caregivers as they are often the closest relatives and are best informed about the patient's wishes and expectations. It is important to build trust between the ICU team and the patient and caregivers. This setup can enable a more personalised approach to decision-making based on the expertise of the ICU team, but also sometimes of other professionals such as geriatrician, psychologist as well as the patient's relatives. On admission to ICU, caregivers (and patients if appropriate) would be informed about the uncertainties of intensive care with respect to its benefit and burden. A Time limited Trial (TLT) would then be a suitable approach to balance these issues with the individual preferences of the patient.

However, before implementing such a programme in ICU information about the current practice of communication between ICU staff, patients and their relatives needs to be established.

We expect to find a substantial variation in approaches, similar to that observed for ICU admission decision making [Bassford 2019]. This information may then help design targeted interventions enabling shared decision-making focused on patient-centred outcome measures.

We wish to perform this prospective observational study in Europe and other countries. The study is coordinated by the HSRO section in the European Society of Intensive Care Medicine (ESICM) through the VIP study research group.

2 RATIONALE

The demographics of the global population is changing with increasing numbers of elderly and co-morbid patients. As a result, more elderly patients will be admitted to ICU, which will bring several ethical challenges. It is for this reason we have chosen to focus on this historically neglected and important patient population.

Little is known about how family meetings are implemented in ICUs in Europe and other parts of the world. However, these meetings contribute to building trust between the family and the ICU team. They are a crucial component for planning and conducting a TLT as they provide the opportunity for shared decision making with the ICU team and with other stakeholders.

We plan to determine the current practice of communication between ICU staff and patients and their relatives.

Therefore, our research aim is to to investigate whether Family meetings are used in ICUs across Europe and other regions and, if so, how they are conducted and the influence on patient-centred outcome measures.

3 THEORETICAL FRAMEWORK

Please see background information

With increasing life expectancy, the admission of very old patients to ICU is rising. We showed in two large prospective studies in this patient group (the VIP1 and VIP2 studies) that the short-term mortality was very high (around 40% after 30 days). This was later confirmed by a systematic review [Vallet 2021]. Health-related quality of life is also poor 6 months after ICU discharge [Guidet 2017]. Although an ICU admission can be beneficial for some patients it can be inappropriate for others when there is no realistic chance of survival. However, it is not always clear on admission who will and won't benefit

from an ICU admission. As a result, some patients receive 'a time limited trial (TLT) of ICU' and many of these patients will receive treatment limitations while in the ICU [Guidet 2018].

Very little is known about the process that occurs in the ICU which leads to the decision to limit or withhold treatment, especially in the context of a TLT. Some ICUs have a formalised approach, with structured meetings with caregivers and health care workers from the ICU and other departments, to discuss prognosis and the benefit / burden of ongoing care. Whereas others may have a less structured approach. We expect to find a substantial variation in approaches both within and between countries. This information may help to design targeted interventions enabling shared decision-making focused on patient-centred outcome measures.

Before implementing such a program in ICUs, we need information about the current practice of communication between ICU staff and patients and their relatives. Hence, we wish to perform this prospective observational study in Europe and other countries.

4 RESEARCH QUESTION/AIM(S)

To investigate whether Family meetings are conducted in ICUs in Europe and other regions and, if so, how they are conducted and influence patient-centred outcome measures. In those units that use family meetings we hope to gain a better understanding of who is involved, what is discussed, whether the patients' previous wishes were expressed and whether there were discussions about escalation of therapy or ceilings of care. We also wish to explore whether there was a consensus between family members but also between family members and medical staff.

4.1 Objectives

Objectives:

- To determine whether family meetings (FM) are conducted in acutely admitted ICU patients aged 75 years and older.
- To determine the characteristics of the FM when performed.
- To determine whether FMs alter ICU and hospital stay characteristics.

4.2 Outcome

Primary outcome:

- Number of patients with a structured/planned family meeting out of all patients with an expected LOS (Length of Stay) $\geq$ 3 days

Secondary outcomes:

- Median day since ICU admission when the family meeting took place
- People present (number and function)
- Conclusions from the meeting: continuation of care, therapy reduced due to improvement, therapy withheld (WH), therapy withdrawn (WD)
- Delta SOFA score: FM day - Admission Day
- ICU survival, ICU LOS
- Hospital survival, hospital LOS
- Discharge location: geriatric unit, non-geriatric unit
- Decision to limit Life Sustaining Treatment (LST), yes/no
- If yes:
    - Time from FM to Withholding LST

    - Time from FM to Withdrawing LST
- Time between WH/WD of LST and death or discharge

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This is an observational cohort study in patients aged 75 years old and above admitted as an emergency to the ICU and expected to have a length of stay of 3 days or more.

When an ICU registers for the trial they will be asked on the CRF to answer the following questions:

1. Do you have national recommendations or guidelines for shared decision-making meetings and/or family meetings.
2. Do you have national recommendations or guidelines for palliative care in ICU
3. In your country, is it forbidden by law to withdraw life sustaining treatment (LST).
4. Do you organise formal family meetings (FMs) in your unit

A Family Meeting is defined with all the following criteria:

- People sitting in a private quiet room, ideally at least 2 members of the ICU team (physician and nurse if possible).
- At least one relative or caregiver.

We plan to collect informed consent from the patients or consultee declaration from the next of kin either when the patient is discharged from ICU (in those where no FM takes place) or following the first FM (information will only be collected from this meeting). This will help to avoid bias caused by consenting patients on admission. If they are consented prior to a FM they may expect and ask for a FM and thus skew the results.

On discharge or after the first FM has taken place:

1. Information about the study will be given to the patient/consultee and around 24 hours will be allowed for them to have a think about participating or ask the research team any questions.

2. If consent has been gained, the research team will record basic demographics of the patient and specific physiological data from the day of admission to the ICU.

3. The research nurse will have a conversation with the patient or next of kin regarding how they were prior to admission. From this information, they can determine the frailty score, Katz activities of daily living and the comorbidity polypharmacy score. Other baseline information taken will be activities of daily living and co-morbidities.

4. The research nurse will document whether a FM takes place, if it does, they will document information about the family meeting in the CRF. The information will be sought from the patient notes and the doctor or nurse who was in the meeting. If a FM does not take place this will be recorded.

5. The outcome of the FM and the patient will be documented.

6. When the relative signs the consultee declaration they will have the opportunity to feedback on the communication they received from the medical team whilst their relative was on the ICU via a QR code. Paper copies will also be available.

7. Survival at 30 days and date of hospital discharge will be recorded by looking at the hospital notes.

8. Where patients have died prior to consent/assent being sought (see section 7), data provided will be based on the clinical data available from the medical records.

5.1 Procedure for data collection

Individual ICUs will start data collection after regulatory and ethical clearance. A web site will be set up to facilitate information about the study and to allow for data entry using an electronic CRF on https://vipstudy.org/

As for the VIP and COVIP studies, the case record form and database will run on a secure server composed and stored in Aarhus University, Denmark. The servers are managed in co-operation between the Information Technology Department and the Department of Clinical Medicine at the University.

5.2 Data Collection

Each participating ICU will be responsible for collecting data on the e-CRF.
The data manager (located in Aarhus University, Denmark) will issue queries in cases of missing, incomplete or incoherent data.
The country coordinator will check for completeness and accuracy of collected data for their own country. The week-to-week recruitment of patients at country level will be displayed on the web-page.
The data base will be closed after final checks of the quality of the data.
The data will be analysed by a dedicated statistician.

5.3 Data Analysis:

The study was planned as a prospective study, as data available from retrospective studies may be partial or of poor quality, they may not have been collected systematically or with the same rigor as in prospective studies. Furthermore, specific data describing family meeting organisation may not be available from charts, hence the need for a prospective study. In the UK, consent will be collected retrospectively as soon as possible after the family meeting to ensure these data can be collected as soon as possible, to ensure it is of good quality.

The protocol has been reviewed by a statistician who will analyse the data. Characteristics of family meetings will be described and outcomes according to the duration of the trial will be evaluated. Patient, organisational and hospital stay characteristics and outcomes will be compared between centres that did and did not implement family meetings. Binary outcomes will be analysed using logistic regression models. Crude overall survival estimated by the Kaplan-Meier method and compared using a log-rank test.

SPSS (IBM SPSS statistics, version 24) and using R (R Foundation for Statistical Computing, Vienna, Austria) will be used for analysis.

5.4 Right to access participant data and source documents.

Data access:

In accordance with GCPs:

- the sponsor is responsible for ensuring all parties involved in the study agree to guarantee direct access to all locations where the study will be carried out, the source data, the source documents, and the reports, for the purposes of the sponsor's quality control and audit procedures.

- the investigators will ensure the persons in charge of monitoring and auditing the research and of quality control have access to the documents and personal data strictly necessary for these tasks, in accordance with statutory and regulatory provisions in force.

- The data entry forms and database run on a secured server using the REDCap-software (www.project-redcap.org).
This software is used worldwide and is composed of a MySQL database and PHP web-application. Secure Socket Layer (SSL) encryption is used. The servers are located on the campus of Aarhus University, Aarhus C, Denmark in a professional server environment with physical access control and logging of personnel access. Other security measures include hardware and software firewalls. For technical inquiries please contact the data-manager: Jesper Fjølner, MD. email: contact@vipstudy.org.

Source document

Source documents are defined as any original document or item that can prove the existence or accuracy of a data or a fact recorded during the study. These documents will be kept by the investigator, or by the hospital in the case of a hospital medical file, for 5 years.

Data and document storage
All data and documents for the study will be kept for 5 years after publication.

Confidentiality
All data will be handled in accordance with the Data Protection Act 1998.

The Case Report Forms (CRFs) will not bear the participant's name or other directly identifiable data. The participant's trial Identification Number (ID) only, will be used for identification. The sponsor Subject ID log JREOLOG0002 can be used to cross reference participant's identifiable information.

Data collection tool
Case Report Forms have been designed by the VIP team. All data will be entered electronically on a secure CRF. This will be kept on a secure server running the REDCap-software (www.redcap-project.org) hosted at Aarhus University, Aarhus, Denmark. It is the Investigator's responsibility to ensure the accuracy of all data entered and recorded in the CRFs. The Staff Delegation of Responsibilities Log JREOLOG0004 will identify all trial personnel responsible for data collection, entry, handling and managing the database.

Data will be recorded directly onto the e-CRF which will be completely anonymised. No data relating to the study will be kept in the notes. Data recorded for each patient includes basic demographic non-identifiable data and reason for admission to ICU. Specific information relating to frailty will be collected using the Clinical Frailty Score. Information regarding activities of daily living will be collected using the KATZ INDEX for activity of daily living.

Comorbidity will be documented using the Comorbid and Polypharmacy score (CPS). All of these are standardised and well-known validated scoring systems. Once data has been collected on the e-CRF, these data are submitted electronically to the secure database based in Denmark. Only anonymised and un-identifiable data will be submitted. Data will then be downloaded from the database in Denmark and analysed.

Archiving arrangements

The trial essential documents along with the trial database will be archived in accordance with the sponsor SOP JREOSOP0016. The agreed archiving period for this trial will be 5 years.

Each PI at any participating site will archive the trial essential documents generated at the site for the agreed archiving period.

6 STUDY SETTING

ICUs from the UK will be invited to take part in the study. In the first instance, we will send an invite to all sites that were involved in VIP 1 and / or 2. Other interested sites can also sign up. We will ask all sites that register to enrol the first 20 consecutive patients fulfilling inclusion criteria during a 6-month period (as for VIP studies).

All data will be collected on site from the patient, next of kin or the patient records. Data will be entered directly on to the eCRF.

St George's will be the co-ordinating site for the UK.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Observational study conducted mainly in Europe but also in non-European countries. All consecutive eligible patient should be included.

In the UK we will recruit patient aged 75 and over admitted as an emergency to an ICU in England or Wales and expected to have a length of stay of 3 days or more.

7.1.1 Inclusion criteria

Inclusion criteria:[1] (up to 20 consecutive patients per ICU)

Patients admitted to the ICU of participating centres

Age 75 years and above

Expected LOS $\geq$ 3 days

[1] It is important to include all patients and not only patients with formal family meeting. The % of stays with such meeting is one of the endpoints.

7.1.2 Exclusion criteria

Exclusion criteria:

Refusal to participate.

Limitation of treatment upon ICU arrival (other than Cardiopulmonary Resuscitation-CPR).

Planned admission.

7.2 Sampling

7.2.1 Size of sample

Given our active VIP network through Europe and previous co-operation, we estimate we will recruit 20-50 ICUs, each with 20 patients, resulting 600-1000 patients.

7.2.2 Sampling technique

Normally distributed continuous data will be described as means with 95% CI, and non-normal distributed data as median with 25 to 75 percentiles. Continuous variables will be compared between groups using Mann-Whitney U test, and categorical variables using the Chi-square test or Fisher test as appropriate.

The analysis will be performed using R (R Foundation for Statistical Computing, Vienna, Austria)

7.3 Recruitment

Patient recruitment at a site will only commence once evidence of the following approval/essential documents are in place:

1. REC approval, if applicable, HRA approval
2. Final sponsorship and host site permissions (confirmation of capacity and capability),

All subjects who wish to enter the study will be fully screened and consented by the Chief Investigator, or an appropriate delegate. As detailed below:

Where a patient presents at a centre and dies prior to the assent/consent process being initiated, anonymised data from routine medical history available to the routine care team of the unit, can be provided for the purpose of the study.

During VIP 1 and 2 approximately 90 hospitals in the UK recruited patients. Consequently, these hospitals will be contacted and able to register their interest in participation via the VIP website which will list the contact details of the PI of the study. After a hospital has contacted the central research team to register interest, they will send them details of the study and the local PI at each trust will be required to obtain local approval. The sponsor will ensure that the ethical and HRA approval is obtained for each hospital that wishes to participate. Once local and ethical approval has been obtained the site will be provided with the hospital specific login details for the e-CRF.

7.3.1 Participant identification

All patients acutely admitted to the participating intensive care unit, age 75 and above with an expected length of stay of more than 3 days will be included in the study. The patients will be identified by the research nurses or clinical staff. The patient or their next of kin (if they don't have capacity) will be approached by the research team after the first FM or on discharge. They will be given a patient information sheet to read so they can make an informed decision about participation. The following patients will be excluded, those who refuse to participate, those with limitation of treatment in place upon admission to ICU (other than CPR) or those admitted electively (planned admission).

The participants in this research will be identified as follows:

Site identifier no. (3 digits) - Sequential enrolment number for the site (3 digits).

This reference number is unique and will be used for the entire duration of the study.

7.3.2 Consent

Please note, it is essential that all trial personnel/staff undertaking the informed consent process has signed the Sponsor's Delegation of Responsibilities Log JREOLOG0004 to ensure that the person has been delegated the responsibility by the study CI/PI.

Only members of the direct care team will approach participants prior to consent.

Informed consent from the participant or a legally authorised representative via consultee declaration to be obtained following explanation of the aims, methods, benefits, and potential hazards of the trial and before any trial specific procedures are performed. The only procedures that may be performed in advance of written informed consent being taken are those that would have been performed on all participants in the same situation as routine clinical practice. For patients who lack capacity, consultee declaration can be obtained from a consultee/ next of kin, who is a person that is engaged in caring for the patient and who is willing to be consulted. If no appropriate person can be identified, the local research team should identify a third party unconnected with the research who is willing to act as a nominated consultee. This can be another clinician within the unit not involved in the study. The consultee will only advise though and will not provide consent.

The Investigator or designee will explain that the patients are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason.

A copy of the signed Informed Consent Form (ICF) /consultee declaration form along with a copy of the most recent approved Patient Information Sheet (PIS) will be given to the study participant or their next of kin. An original signed & dated consent form will be retained in the ISF, and a copy will be placed in the medical notes.

Informed consent will be obtained by the research nurses. Patients who are deemed eligible to participate will be identified by the research nurses and given a PIS or if they are not thought to have capacity, a consultee information sheet will be given to the NOK. They will be given approximately 24 hours to read and think about their involvement. The research team will then return to answer any questions.

Where a patient has died prior to the consent/consultee declaration process being initiated, existing anonymised (outside of the direct care team/unit) routine clinical information can be included for the purpose of the study. This should only include clinical information readily available from the patients' medical history and should not involve requesting additional information from any other sources. Consultee declaration from next of kin/personal consultee should not being sought due to the potential distress/burden it may cause. These data are valuable to the outcomes of the study as it ensures data from a more representative patient population are captured.

When a relative / carer is given a consultee declaration form to sign, they will have the opportunity to provide feedback on their thoughts / understanding of communication during the FM (should it have occurred) or on general communication regarding their relative whilst they were on the ICU (should a FM not have occurred). This will be done voluntarily using a QR code which they can scan using their smart phone.

Discontinuation/withdrawal of participants and stopping rules
In consenting to the trial, participants are consenting to trial interventions, trial follow up and data collection. However, an individual participant may stop the intervention early or be stopped early for any one of the following reasons:

Withdrawal of consent from the participant

As participation in the trial is entirely voluntary, the participant may choose to withdraw at any time without penalties or loss of benefits to which they may be entitled. Although not obliged to give a reason for discontinuing their trial intervention/ protocol inclusion a reasonable effort should be made to establish this reason, whilst remaining fully respectful of the participant's rights. Participants who discontinue protocol intervention, for any of the above reasons, should remain in the trial for the purpose of follow up and data analysis.

Consent provisions for collection and use of participant data and biological specimens

No biological specimens are being collected.

7.3.3 **Data collection tool**

Case Report Forms have been designed by the VIP team. All data will be entered electronically on a secure CRF. It is the Investigator's responsibility to ensure the accuracy of all data entered and recorded in the CRFs. The Staff Delegation of Responsibilities Log JREOLOG0004 will identify all trial personnel responsible for data collection, entry, handling and managing the database.

Data will be recorded directly onto the e-CRF which will be completely anonymised. No data relating to the study will be kept in the notes. Data recorded for each patient includes basic demographic non-identifiable data and reason for admission to ICU. Specific information relating to frailty will be collected using the Clinical Frailty Score. Information regarding activities of daily living will be collected using the KATZ INDEX for activity of daily living. Co-morbidities will be collected using the co-morbidity polypharmacy score (CPS). All of these are standardised and well-known validated scoring systems. Once data has been collected on the e-CRF form, this data is submitted electronically to the secure

database based in Denmark. Only anonymised and un-identifiable data will be submitted. Data will then be downloaded from the database in Denmark and analysed.

7.3.4 **Biological Sample Handling**

- No biological samples in this study

7.4 **End of Study Definition**

The study recruitment period will run from April 25 to November 26. For individual ICUs the study will end once the first 20 consecutive patients are recruited or the 6 months enrolment window is closed, which ever happens sooner.

The study will end in December 26, one month after the end of the recruitment period.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

This is a purely observational study with no change in routine care or introduction of additional clinical procedures. Therefore, there is no risk to the patient.

COVID-19 Risk Assessment and Management Strategy

All staff employed by SGUL and/or SGH NHS Foundation Trust are required to complete an ongoing COVID-19 risk assessment prior to undertaking any work on site, which includes research activity. This process is continuously monitored by the responsible line manager.

Participants (unaffected or affected) will not be recruited if they are deemed high risk or are in close contact with someone at risk. The Research Team will contact research participants ahead of scheduled study visits on-site to check for COVID-19 symptoms and the symptom check will be repeated when patients attend the hospital site for the study visit.

Participants will receive information regarding the extra precautions that will be taken in light of the COVID-19 pandemic in the Patient Information Sheet. This will detail steps that patients should take if they have concerns about exposure to COVID-19 through participating in the research or believe that they are symptomatic or have been in close contact with another person believed to be symptomatic. The Patient Information Sheet will also have contact details for the Research Team for patients to get in touch if they have any concerns or queries about this.

All research personnel are expected to comply with the NHS Trust and University policies on COVID-19.

All patients attending the hospital site for research visits and/or routine clinical follow-up will be expected to abide by the NHS Trust and University policies on COVID-19 which include wearing suitable PPE (provided by the NHS Trust on arrival), adhering to the visitor policy on social distancing and following the one-way routing systems whilst on site.

Due to the nature of this study [i.e. family interviews] it is not possible to align the schedule of study assessments with the routine clinical pathway. The additional risk of exposure to COVID-19 has been assessed by the Chief Investigator and Research Team as well as the relevant Trust Clinical Care Group Lead and deemed acceptable.

Patients will be made explicitly aware of the additional risk of a research-specific visit on site, that they are under no obligation to participate in the research without prejudice to their routine care and will be checked for symptoms by the research team prior to attending the site and again on the day of the visit.

The schedule of study assessments has been designed so that they align with the current routine clinical pathway for this patient population.

Therefore, research participants and site staff are not perceived to be at any additional risk of exposure to COVID-19 through participation in this research study.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an appropriate REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

For HRA- NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- It is the Chief Investigator's responsibility to produce the annual reports and submit the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- The Chief Investigator will notify the REC of the end of the study within one year after the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

Amendments

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.3 Peer review

This study has been reviewed during the application for a European Society of Intensive Care research award. It was granted the family partnership award.

8.4 Patient & Public Involvement

There will be no direct patient or public involvement in the acceptability, design, management, undertaking, analysis or dissemination stages of research.

Relatives/next of kin will be required to answer questions relating to their family member's baseline functions. In addition, after the first FM or on discharge from ICU relatives will be able to provide voluntary feedback on their thoughts about communication with the medical team while their relative was on intensive care. This will be done by scanning a QR code.

The study team has identified this area for research due to the increasing numbers of elderly and co-morbid patients admitted to the ICU. The study team felt that due to the observational nature of the study, public involvement would be achieved during the study whilst exploring the contents of family meetings and the communication relatives receive whilst their family member is a patient on the ICU.

Through the completion of these interviews, participants will be providing detailed feedback which will inform future interventions, thereby providing public contribution through the study medium.

8.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

All protocol deviations must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

All data should be handled in accordance with the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)).

Any Case Report Forms (CRFs) will not bear the participant's name or other directly identifiable data. The participant's trial Identification Number (ID) only, will be used for identification. The Subject ID log can be used to cross reference participant's identifiable information.

8.7 Indemnity

St George's University Hospitals NHS Foundation Trust sponsored research:

St Georges University Hospitals NHS Foundation Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

8.8 Access to the final study dataset

The data set will be kept on a secure server running the REDCap-software (www.redcap-project.org) hosted at Aarhus University, Aarhus, Denmark. Only the steering group will have access to the full dataset. The study will allow site investigators to access the full dataset if a formal request describing their plans is approved by the steering group.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Publication: "Any activity that discloses, outside of the circle of trial investigators, any final or interim data or results of the Trial, or any details of the Trial methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations."

All scientific contributors to the Trial have a responsibility to ensure that results of scientific interest arising from Trial are appropriately published and disseminated. The Sponsor has a firm commitment to publish the results of the Trial in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Trial, data shall be consolidated over the duration of the trial, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Trial shall lie with the Sponsor in the first instance.

Before the official completion of the Trial

All publications during this period are subject to permission by the Sponsor. If an investigator wishes to publish a sub-set of data without permission by the Sponsor during this period, the **Steering Committee/the Funder** shall have the final say.

Exempt from this requirement are student theses that can be submitted for confidential evaluation but are subject to embargo for a period not shorter than the anticipated remaining duration of the trial.

Up to 180 days after the official completion of the Trial

During this period the Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

- The Chief Investigator shall be senior and corresponding author of the Main Publication.
- Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.
- Providers of analytical or technical services shall be acknowledged but will only be listed as co-authors if their services were provided in a non-routine manner as part of a scientific collaboration.
- Members of the Steering Group shall only be acknowledged as co-authors if they contributed to other capacities as well.
- If there are disagreements about the substance, content, style, conclusions, or author list of the Main Publication, the Chief Investigator shall ask the Steering Group to arbitrate.
- Intensive care medicine will have first refusal for publication as per the rules of the ESICM award.

Beyond 180 days after the official completion of the Trial

After the Main Publication or after 180 days from Trial end date any Investigator or group of investigators may prepare further publications. To ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor's reasonable comments shall be reflected. All publications related to the Trial shall credit the Chief and Co-Investigators as co-authors where this would be in accordance with normal academic practice and shall acknowledge the Sponsor and the Funders.

9.2 Archiving Arrangements

Each site will be responsible for their onsite level study archiving. The trial essential TMF along with any central trial database will be archived in accordance with the sponsor SOP.

10 REFERENCES

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11. APPENDICIES

11.1 Appendix 1

Schedule of Procedures						
Procedures	**Visits (insert visit numbers as appropriate)**					
	ICU admission	**Baseline**	**ICU discharge**	**Hospital discharge**	**Family meeting on ICU**	
Screening	x					
Demographics		x				
Medical history		x				
Physiological data and outcome		x	x	x		
Details of Family Meetings					x	
Consent/Consultee declaration			x			

11.2 Appendix 2

Amendment Log				
Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**

11.3 Appendix 3

eCRF- see separate document

11.4 Appendix 4

KATZ Activities of Daily Living

This simple questionnaire assesses six usual activities: Bathing, dressing, toileting, transferring, continence and feeding.

A short explanation is given to each score where 1 represents Independence and 0 Dependence.

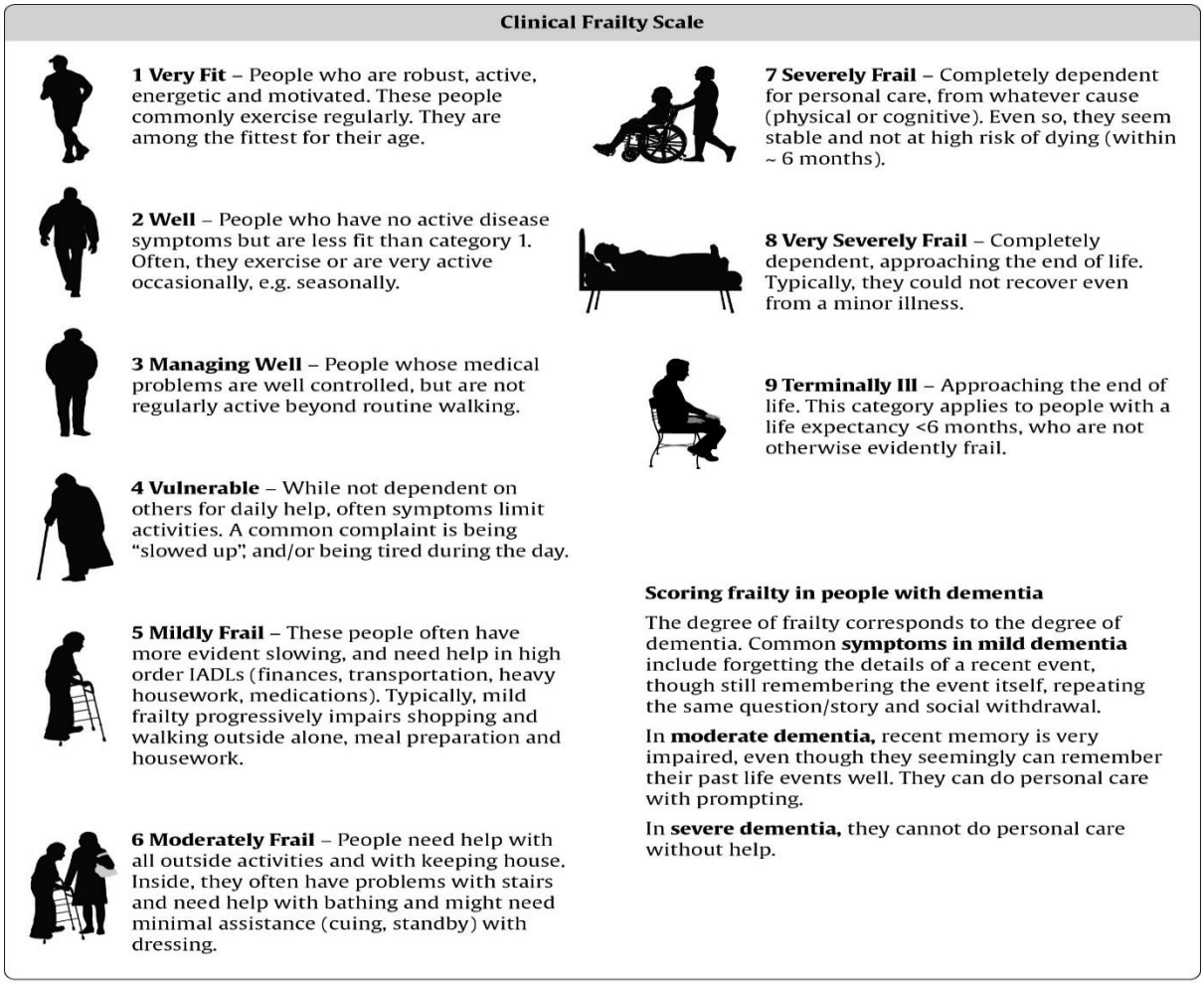
The higher the score (max 6) the better the function of ADL is.

Katz Index of Independence in Activities of Daily Living

Activities Points (1 or 0)	**Independence** (1 Point) **NO** supervision, direction or personal assistance.	**Dependence** (0 Points) **WITH** supervision, direction, personal assistance or total care.
BATHING Points: _____	**(1 POINT)** Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	**(0 POINTS)** Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing
DRESSING Points: _____	**(1 POINT)** Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	**(0 POINTS)** Needs help with dressing self or needs to be completely dressed.
TOILETING Points: _____	**(1 POINT)** Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	**(0 POINTS)** Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
TRANSFERRING Points: _____	**(1 POINT)** Moves in and out of bed or chair unassisted. Mechanical transfer aids are acceptable	**(0 POINTS)** Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE Points: _____	**(1 POINT)** Exercises complete self control over urination and defecation.	**(0 POINTS)** Is partially or totally incontinent of bowel or bladder
FEEDING Points: _____	**(1 POINT)** Gets food from plate into mouth without help. Preparation of food may be done by another person.	**(0 POINTS)** Needs partial or total help with feeding or requires parenteral feeding.
TOTAL POINTS: _____	**SCORING:** 6 = High (*patient independent*) 0 = Low (*patient very dependent*	

Clinical Frailty Scale

This pictogram shows the categories of the Clinical Frailty Scale



Co-morbidity and Polypharmacy score (CPS)

In this score, the number of chronic conditions and the number of different medications taken daily will sum up the score. The number can be from 0 (no co-morbid condition, no medication) to infinity, although in most patients the number will remain < 20. The score can be put into four groups:

- Minor: 0-7 points
- Moderate: 8-14 point
- Severe: ≥ 15 points

SOFA score

A score form 0-24 will be given according to the severity of organ dysfunction in each vital organ system (Circulation, Respiration, CNS, Renal, Coagulation and Liver function)

Table 1. The Sequential Organ Failure Assessment (SOFA) Score*

	SOFA Score				
Variables	**0**	**1**	**2**	**3**	**4**
Respiratory Pao_2/Fio_2, mm Hg	>400	≤400	≤300	≤200†	≤100†
Coagulation Platelets $\times 10^3/\mu L$‡	>150	≤150	≤100	≤50	≤20
Liver Bilirubin, mg/dL‡	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12.0
Cardiovascular Hypotension	No hypotension	Mean arterial pressure <70 mm Hg	Dop ≤5 or dob (any dose)§	Dop >5, epi ≤0.1, or norepi ≤0.1§	Dop >15, epi >0.1, or norepi >0.1§
Central nervous system Glasgow Coma Score Scale	15	13-14	10-12	6-9	<6
Renal Creatinine, mg/dL or urine output, mL/d‖	<1.2	1.2-1.9	2.0-3.4	3.5-4.9 or <500	>5.0 or <200

*Norepi indicates norepinephrine; Dob, dobutamine; Dop, dopamine; Epi, epinephrine; and Fio_2, fraction of inspired oxygen.
†Values are with respiratory support.
‡To convert bilirubin from mg/dL to µmol/L, multiply by 17.1.
§Adrenergic agents administered for at least 1 hour (doses given are in µg/kg per minute).
‖To convert creatinine from mg/dL to µmol/L, multiply by 88.4.

Research Data Protection Impact Assessment (DPIA)

Data Protection Impact Assessments (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations under the Data Protection Act 2018 (DPA 18) and meet individuals' expectations of privacy.

A DPIA helps identify data privacy risks when planning new, or revising existing, projects and to identify actions to mitigate these risks. In the rare cases where risks cannot be mitigated at all it may

be necessary to consult with the Information Commissioner's Office (ICO). Under data protection legislation it is a legal requirement to complete a DPIA in the following circumstances:

- • where data processing is likely to result in a high risk of harm to individuals, e.g. new, invasive technology is proposed
- • when large volumes of personal data are processed, e.g. use of behavioural profiles based on website usage
- • when processing special category personal data on a large scale, e.g. healthcare data, genetic tests to assess and predict the disease/health risks

• where publicly accessible areas are monitored, e.g. CCTV or when filming public areas

Therefore, a DPIA will be carried out for both internal and partnership projects which require the collection/processing of personal data in any format for the purpose of research.

The DPIA should be carried out towards the start of the project, in order to identify any associated information risks and mitigate in the early stages, before you start processing.

Study Title/Acronym:	VIP-3 Decision-making in the older ICU patient: How are family meetings implemented across diverse European cultures?
JRES Reference Number:	2023.0182
Chief Investigator Name:	Susannah Leaver
Chief Investigator Email Address:	susannahleaver@nhs.net

PROJECT DETAILS
Project / process description: **- include / attach processing operations (include a flow diagram or another way of explaining data flows), the purpose and, where applicable, what St George's lawful basis is for the processing of the information.**
We plan to determine the current practice of communication between ICU staff, patients and their relatives. We expect to find a substantial variation in approaches to family meetings. This information may then help design and further investigate targeted interventions enabling shared decision-making focused on family and patient values. Therefore, our research aim is to to investigate whether Family meetings are used in ICUs in Europe and other regions and, if so, how they are conducted and the influence patient-centred outcome measures.
What personal data do you intend to use, and why? (List all categories)
PI: Susannah Leaver Research nurses: to consent patients and to upload the data onto the eCRF Administration: to support the UK co-ordination
Will the personal data be identifiable, pseudonymised or anonymised (if a mix tick accordingly)

Identifiable		
*Pseudonymised	x	
Anonymised		

**Confirm that the key to this data is kept securely away from the used data with strict controlled access*

List all organisations / agencies which will have access to the personal data collection used for this project / process

The database will not be transferred outside Europe and only to personnel authorised by the steering committee.
If requested and approved by the steering committee, data originating for a specific country might be transferred to this country for national analysis as per previous VIP projects.

Length of the study – include an assessment of the necessity and proportionality of the processing in relation to the purpose. Also include who, internally & externally, has been consulted in the preparation of this DPIA.

The expected duration is from July 24 to July 25. However, the exact duration will depend on the start date. The VIP steering committee has been consulted in the preparation of this DPIA.

If external organisations / agencies are involved, is there a contract or information sharing agreement in place with suitable clauses for data protection and data incident reporting,? If not, why not?

No external agencies are involved outside the steering group. However, agreements concerning sharing of data within the group, where there will be shared data responsibility, will be created. The steering group members will be notified of any incidences and are responsible to their national authority.

RISK

Can you achieve your objectives using anonymised data? – see ICO Code of Practice on Anonymisation

Yes	x		
No		Why not?	

What are the benefits to the individual of their personal data being used for this purpose?

It will help to determine the current practices of communication between ICU staff, patients, and their families across Europe and whether this has an impact on outcome. In the future this will help us improve communication and therefore outcome in this important patient population.

What are the organisational benefits of the individual's personal data being used for this purpose?
It will help improve quality of care of these patients now and in the future.
What are potential negative impacts to the individual of their personal data being used for this purpose in the event of a Data Breach occurring?
There will be no negative effects on individual patients.
How will you avoid causing unwarranted or substantial damage/distress to the individual when using their personal data for this purpose?
The data will be anonymised

Is the data already held by St George's?			
Yes			
No	x	The data will be in the patients notes	
Is it held by one of the partner organisations / agencies involved in this process/project?			
Yes	x		
No		Which agency will be collecting the data	
Have you told the individuals whose personal data you want to use for this purpose, how and why you intend to use their data?			
Yes	x		
No			
If not, are you intending to tell them?			
Yes	x		
No		Why not?	
Do you already have the individual's consent to use their data for this purpose?			
Yes			
No	x	Why not?	Study not started. We will once the study commences.
If not, are you going to ask for their permission?			
Yes	x		
No		Why not?	
Have individuals been given the opportunity to refuse us permission to use their data for this purpose?			
Yes	x		
No			
How will you make sure that the personal data you are using is kept accurate and up to date?			

Meticulous collection on the eCRF

What steps or controls are you taking to minimise risks to privacy? Please tick those which apply and provide details of how each is ensured	
• Risks to individual privacy are minimal	X
• Personal data is pseudonymised	X
• Encryption of data at rest, i.e. when stored	X
• Encryption used in transfers	X
• Information compliance training for staff has been completed - data protection, information security, FOI Adherence to privacy by design principles	X
• Special category personal data is not used	
• Participant opt out at any stage of the research	X
• Personal data kept in the UK	
• Research is not used to make decisions directly affecting individuals	X
• Short retention limits	
• Restricted access controls	X
• Other (please specify)	

How long will you need to hold the personal data for after the study has completed?
For 5 years
How will you make sure that you are holding data for the appropriate length of time and no longer?
The data will be kept on a database for the appropriate length of time and no longer.
How will the data be held /stored?
On a secure server running the REDCap-software (www.redcap-project.org) hosted at Aarhus University, Aarhus, Denmark.
Will you be using any electronic and/or paper Case Report Forms (CRFs) to collect data? If so, what are these and how will they be held securely and managed at the end of the project?
We will be using an electronic CRF. Data will be entered directly into the database and there will be no paper trail.
Will personal data be transferred/shared between the organisations involved in this project? If so how?
A participating ICU can retrieve data entered for the respective ICU. A country coordinator can retrieve data for the respective country. The complete dataset is not distributed containing any identifiable information. Identifiable columns are removed. Date values are shifted. When anonymised (as best as possible) the dataset can be shared between the participating project organisations as a prior GDPR-compliant data sharing agreement is in place. Data will never be shared outside the project group. Data will only ever be transferred via encrypted channels (i.e. SSL-encrypted browser session).

Will you be transferring personal data to a country or territory outside of the UK? *If yes, name countries and receiving parties*.		
Yes – within EEA	x	

Yes – outside of EEA		
No		
How will you ensure that third parties will comply with data protection obligations?		
The project organisations all agree in writing to a GDPR-compliant data sharing agreement drafted by Aarhus University. This agreement outlines data protection obligations.		
What measures are in place to ensure only appropriate and authorised access to and use of personal data?		
This broadly include safe storage of data on local hard drives under double lock (i.e. password protected drives/computers in a locked cupboard/room). Local project members will not distribute or email the dataset. Only the project data manager distributes the dataset which ensures safe, secure, encrypted data transfers.		
How will technical and organisational security be monitored/audited?		
Aarhus University IT-department run the REDCap-server. The REDCap-software is used world-wide and follows industry standards as far as security and encryption. The server rooms at Aarhus University have physical access control and logging of personnel entry. The software itself logs entries and failed login attempts.		

Declaration

I confirm that the information recorded on this form is, to the best of my knowledge, an accurate and complete assessment of the potential privacy impacts of this study.

Name: Susannah Leaver

Signature:

Date: 12/06/24

Institute Director (SGUL) or Care Group Lead (SGHFT)

Name: Nirav Shah

Signature: 

Date: 12/06/24

JRES Reviewer

Name: Lauren Thomson

Signature: 

Date: 12/06/2024