RESEARCH PROTOCOL

FULL/LONG TITLE OF THE STUDY:

Intensive care decision-making, survival and dying well:

How do the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival?

SHORT STUDY TITLE / ACRONYM:

Intensive care decision-making, survival and dying well

(IRAS – A1)

Contents

1) RESEARCH TEAM & KEY CONTACTS

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STUDY SUMMARY

Study Title	Intensive care decision-making, survival and dying well: How do the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival?
Internal ref. no. (or short title)	Intensive care decision-making, survival and dying well
Study Design	This is a mixed method study [1] (utilising qualitative and quantitative methods), based on a "pragmatic approach"[2] focussing on the best methodological approach to answering my research questions, rather than based on a commitment to any particular metaphysical concern or paradigm. A purposeful sample[3] of patients will be recruited through ICU recovery clinics and ICU steps groups. A purposeful sample is a recognised approach to qualitative research, where informants who have undergone the experience to be studied are purposefully selected for interview as they represent a source of information rich data regarding the phenomenon of study.[3] The mixed methods approach will involve triangulation of: • Thematic analysis[4] of semi-structured interviews (data can be transformed by creating frequencies of themes). • Quantification of patient's ICU experiences through the ICU Memory Tool[5][6][7], their functional status before and after their critical illness through the EQ-5D-5L tool[8], their preferences for end of life using the Concept of a Good Death Measure,[9] and whether their ICU experience would have been a good death using the QODD questionnaire[10][11][12][13]. • Integration of quantitative and qualitative data by asking "what chance of survival would make you willing to go through that experience again", combined with an adapted version of the WALT questionnaire[14] to assess the effect of functional decline on that decision. The use of quantitative data will allow for a "thick description" to support the transferability of the findings of this study and any analytic generalisations resulting from it.[15]
Study Participants	People who have previously experienced intensive care treatment, recruited through ICU review clinics and ICU steps groups.
Planned Size of Sample (if applicable)	50

Follow up duration (if applicable)	N/A
Planned Study Period	2 years
Research Question/Aim(s)	Research Questions What can ICU survivors' experiences of ICU treatment tell us about what it would be like to die whilst receiving ICU treatment? How do ICU survivors' reflections about what it might be like to die on ICU relate to their own preferences for their end-of-life care? What chance of survival would make ICU survivors willing to go through ICU treatment again, in light of the fact that the alternative chance is dying whilst experiencing ICU treatment? How does the possibility of reduction in health-related quality of life and functional decline as a result of critical illness impact ICU survivors' willingness to accept ICU treatment again?

2) INTRODUCTION (IRAS A6-1)

Many critically unwell patients who are faced with the decision of whether or not to accept intensive care treatment have no previous experiences of what it is like to be an intensive care patient. The experiences of previous intensive care patients are, therefore, a valuable source on information for patients facing this important life or death decision. This study aims to investigate how the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival.

Participating in this study will involve filling out a questionnaire and then taking part in an interview. Anybody who is over 18 and has previously experienced intensive care treatment will be eligible to participate in this study. Participants will be recruited through ICU review clinics and ICU steps groups.

The study will last for two years and will be conducted at locations convenient to the participants or via zoom.

3) Background (IRAS A12)

The ageing population of many countries has led to more elderly and increasingly co-morbid patients accessing healthcare services, and intensive care is no exception. There is an increasing proportion of elderly patients on intensive care units,[16][17] and both age and co-morbidity are predictors of mortality at 1 year.[18] At 1 year, only 26% of patients aged 80 and above have achieved a recovery to baseline function[16] and the 1-year mortality of ICU patients older than 85 years is 56%, compared to 36% for patients aged 65 to 75 years.[17] Poor outcomes from intensive care treatment have been linked to patients with more than one co-morbid condition,[19] and co-morbidity is common in elderly patients.[20] This creates an increasing demand for intensive care treatment for patients with a low chance of surviving their critical illness, even with intensive care treatment.[21]

A sedated intensive care patient receiving mechanical ventilation may have the appearance of being unconscious, but follow-up studies with survivors show that many patients have memories of their experiences, which have been described as frightening and chaotic, leading to feelings of instability, vulnerability and fear.[22] Studies have reported recall of pain (52%), disturbing dreams (21–73%), procedures (69%), thirst (62–76%), noise (38–49%), difficulty communicating (65%), difficulty swallowing (44%), awareness of invasive tubes (17%), panic/fear (32–41%), helplessness (44%), lack of control (46%), feeling tense (46%) and patients thinking they were dying (36–38%).[23][24][25] In one study, 67% of patients had recollections of stressful experiences whilst receiving intensive care treatment and 66-92% of these experiences were rated as moderately to extremely distressing[24]. It must be assumed that all intensive care patients (survivors and non-survivors) have similar experiences of their treatment. Therefore, the negative experiences described by survivors must be assumed to be shared by patients who die whilst receiving such treatment. Consequently, dying whilst receiving intensive care treatment is likely to be a significantly distressing experience.[21]

Intensive care treatment may not be beneficial for patients with a low chance of surviving critical illness if the treatment has a high chance of exposing them to a negative dying experience. For intensive care treatment to be ethically justifiable it should offer patients a reasonable chance of survival to justify the burdens inherent in the treatment, and the risks of a negative dying experience. Therefore, a key question in the provision of intensive care treatment is at what chance of survival is this treatment ethically justifiable? An adequate answer to this question will require consideration of both the quantitative benefits of the treatment, such as survival, and the qualitative harms, including suffering and the risk of exposure to a negative dying experience.[26]

Even though dying whilst receiving intensive care treatment is likely to be a negative dying experience, it is not possible to ask patients who did not survive their critical illness about their dying experience or whether they retrospectively agree with the decision to provide them with intensive care treatment. However, all intensive care patients (survivors and non-survivors) have experiences of what it is like to receive intensive care treatment. All ICU patients can be considered a population whose experiences can be represented by the survivors of ICU.[12] Therefore, the experiences described by survivors can provide a window into the experience of patients who die whilst receiving such treatment.[21]

Research to establish the harm-to-benefit ratio that most people would be willing to accept with regards to intensive care treatment is, therefore, of great importance to guide ethical decision-making regarding the provision of intensive care treatment. Of particular importance will be elderly and co-morbid patients' evaluations of their negative intensive care experiences, as these patients are likely to be the ones with the lowest chance of surviving a critical illness. This information could be used to guide intensive care decision-making and to better inform patients of the harms of intensive care treatment. Such research could provide guidance regarding what chance of survival makes the suffering involved in intensive care treatment, acceptable to patients and ensure that intensive care treatment is not routinely offered to patients with a very low chance of surviving their critical illness, for whom the benefit does not outweigh the cost.[21]

THEORETICAL FRAMEWORK

This study will utilise a mixed method approach [1] (combining qualitative and quantitative methods) based on a "pragmatic approach"[2] focussing on the best methodological approach to answering my research questions, rather than based on a commitment to any particular metaphysical concern or paradigm.

The mixed methods approach will involve triangulation of:

- Thematic analysis[4] of semi-structured interviews (data can be transformed by creating frequencies of themes).
- Quantification of patient's ICU experiences through the ICU Memory Tool[5][6][7]. The ICU Memory tool is a validated tool for investigating the memories of patients who have received intensive care treatments of their experiences of these treatments. In a cohort study of intensive care patients, the ICU memory tool has demonstrated internal consistency, good test-retest reliability, and evidence of construct validity.[5]

- Quantification of ICU patient's functional status before and after their critical illness through the EQ-5D-5L tool[8]. The EQ-5D-5L is a broadly used patient reported generic multi-attribute health utility measure. It has been shown to have excellent psychometric properties across a broad range of populations, conditions, and settings.[8]
- Quantification of ICU patient's preferences for end-of-life using the Concept of a Good Death Measure.[9] The good death measure is a self-report index for measuring the factors that people consider important to a good death. It has demonstrated internal consistency, reliability, test-retest stability, and good item frequency distribution in a study of four different cohorts of participants.[9]
- Quantification of whether patient's ICU experience would have been a good death using the QODD questionnaire[10][11][12][13]. The Quality of Death and Dying Tool is a questionnaire for assessing the quality of death and dying that has been used with family members and staff in multiple contexts including the ICU. In a cohort study it demonstrated good cross-sectional validity, construct validity and excellent internal consistency reliability.[11]
- Integration of quantitative and qualitative data by asking "what chance of survival would make you willing to go through that experience again", combined with an adapted version of the WALT questionnaire[14] to assess the effect of functional decline on that decision. The Willingness to Accept Life-Sustaining Treatment instrument (WALT) is a patient centred measure of treatment preferences. In a population of older seriously ill patients, it has shown good internal consistency, good evidence of reliability and construct validity as well as sound psychometric properties.[14]

The use of quantitative data will allow for a "thick description" to support the transferability of the findings of this study and any analytic generalisations resulting from it.[15] A thick description describes the provision of detailed descriptive information from rich complementary data sources (e.g., qualitative and quantitative) about the context of the study (to facilitate well-guided meta-inferences and enhance analytic generalisations).[15]

Research participants will only encounter the questionnaires and tools used in the quantification of their experiences as ICU's patients as a result of their of involvement in this study. These questionnaires and tools do not represent existing interventions that are performed routinely in a patient's assessment or care.

4) STUDY OBJECTIVES

4.1 Primary Question/Objective: (IRAS A10)

What chance of survival would make ICU survivors willing to go through ICU treatment again?

4.2 Secondary Question/Objective: (IRAS A11)

What can ICU survivors' experiences of ICU treatment tell us about what it would be like to die whilst receiving ICU treatment?

How do ICU survivors' reflections about what it might be like to die on ICU relate to their own preferences for their end-of-life care?

What chance of survival would make ICU survivors willing to go through ICU treatment again, in light of the fact that the alternative chance is dying whilst experiencing ICU treatment?

How does the possibility of reduction in health-related quality of life and functional decline as a result of critical illness impact ICU survivors' willingness to accept ICU treatment again?

5) STUDY DESIGN & PROTOCOL

5.1 Participants: (IRAS A15)

50 adult (over the age of 18) participants who have experience as a patient on an intensive care/critical care unit will be recruited in this study.

5.2 Study Intervention and/or Procedures: (IRAS A13, A18, A19)

This is a mixed method study (utilising qualitative and quantitative methods), based on a "pragmatic approach" focusing on the best methodological approach to answering my research questions, rather than based on a commitment to any particular metaphysical concern or paradigm. A purposeful sample of patients will be recruited through ICU recovery clinics and ICU steps groups. A purposeful sample is a recognised approach to qualitative research, where informants who have undergone the experience to be studied are purposefully selected for interview as they represent a source of information rich data regarding the phenomenon of study.

Recruitment:

Participant information sheets will be provided to adults who have been patients on an intensive care/critical care unit in the past, both in ICU review clinics (by the individual's clinical team) and through the critical care support network. Potential participants will be approached by the clinicians running the ICU review clinics or research nurses and given the participant information sheet. Those who are willing (after having a chance to ask any questions and take time to consider it) to participate in the study and who are willing to either meet in person or have access to a computer, tablet or mobile phone with video and a stable internet connection (for a Zoom conversation) can then be recruited into the study. No compensation is available for participating in this research study.

Inclusion/Exclusion:

The inclusion criteria for participation in this study are being 18 years or older, having previously been a patient on an intensive care/critical care unit in the past and being willing to talk about experiences of intensive care treatment, end-of-life wishes, and the context (chances of

survival/functional decline) which would make intensive care treatments acceptable. The exclusion criteria are being under the age of 18, having had a planned admission to an intensive care/critical care unit (e.g. after an elective operation), having a significant Language Barrier (there is no available funding to pay for translation) or being unable to consent to participate in research.

Consent:

Informed consent will be sought prior to the participant being enrolled in the study. The process of gaining informed consent will involve discussion, either face to face, over the phone or via zoom, between the potential participant and Dr Tom Donaldson about the nature and objectives of the study and possible risks associated with their participation. The potential participant will have already received and had a chance to consider the participant information leaflet and consent documents and will be given the opportunity to ask questions. If they wish to consent to participate in the study they will sign a paper consent form. This will be sent to the participant in the post with a stamped addressed envelope for them to post the consent form back in. They will also be sent a paper pre-interview questionnaire to fill out (with support if necessary), which can be returned in the stamped addressed envelope with the consent form.

Then at a time and place convenient to them (ideally face-to-face, or via Zoom if the participant prefers this), research participants will have a one-on-one, semi-structured, in-depth interview with Dr Tom Donaldson. The interview is expected to last for approximately one hour, but can be stopped at any point if the participant needs a break, and recommenced at a later time if the participant is happy to do so. An audio recording of the interview will be made to allow transcription of the interview for thematic analysis. The interviews will ideally occur face-to-face (if COVID-19 guidance allows), but can occur via Zoom if the participant prefers. If the interview will occur via Zoom then the participant will be asked to make sure that a supportive person (e.g. friend or family member) is available to provide the participant any support necessary during the interview. The Zoom interviews will be recorded using zoom and face-to-face interviews will be recorded using an encrypted audio recorder.

The pre-interview questionnaire will provide quantification of participants' ICU experiences through the ICU Memory Tool, their functional status before and after their critical illness through the EQ-5D-5L and their end-of-life preferences using the Concept of a Good Death Measure. At the end of the interview quantification of whether their ICU experience would have been a good death will be undertaken using the QODD questionnaire. This data will allow for a “thick description” to support the transferability of the findings of this study and any analytic generalisations resulting from it. Thematic Analysis of the semi-structured interviews will them be triangulated with the questionnaire data (data will be transformed by creating frequencies of themes). Further integration of quantitative and qualitative data will occur by asking “what chance of survival would make you willing to go through that experience again”, combined with an adapted version of the WALT questionnaire to assess the effect of functional decline on that decision.

Data analysis methods will include thematic analysis of the semi-structured interview transcripts. Then a mixed methods approach will involve triangulation of:

- Thematic analysis[4] of semi-structured interviews (data can be transformed by creating frequencies of themes).
- Quantification of patient's ICU experiences through the ICU Memory Tool[5][6][7], their functional status before and after their critical illness through the EQ-5D-5L[8], their preferences for end-of-life using the Concept of a Good Death Measure,[9] and whether their ICU experience would have been a good death using the QODD questionnaire[10][11][12][13].
- Integration of quantitative and qualitative data by asking "what chance of survival would make you willing to go through that experience again", combined with an adapted version of the WALT questionnaire[14] to assess the effect of functional decline on that decision.

The use of quantitative data will allow for a "thick description" to support the transferability of the findings of this study and any analytic generalisations resulting from it.[15]

An interview guide was prepared by Dr Tom Donaldson under the supervision of Professor Soren Holm and Ms Kirsty Keywood. Public and patient consultation of the research protocol, consent form, participant information sheet, pre-interview questionnaire and interview guide has been undertaken with individuals from the critical care support network (registered charity 1182307).

5.3 End of study:

The end of study will be when the last participant has completed their interview with Dr Tom Donaldson. End of study notification will be submitted to the HRA within 90 days of the end of study.

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria: (IRAS A17-1)

The principle inclusion criteria are being 18 years or older and having previously been a patient on an intensive care/critical care unit in the past.

Being willing to talk about experiences of intensive care treatment, end-of-life wishes, and the context (chances of survival/functional decline) which would make intensive care treatments acceptable and being willing to either meet in person or have access to a computer, tablet or mobile phone with video and a stable internet connection (for a Zoom conversation) are also inclusion criteria.

6.2 Exclusion Criteria: (IRAS A17-2)

The exclusion criteria are being under the age of 18, having had a planned admission to an intensive care/critical care unit (e.g. after an elective operation), being unable to consent to participate in the research and having a significant language barrier (as there is no available funding to pay for translation).

6.3 Recruitment: (IRAS A27-1 – A35)

In this study, a purposeful sample of participants will be recruited through the ICU review clinics of the Countess of Chester Hospital, the Royal Liverpool University Hospitals Trust (The Royal and Aintree Hospitals) and Warrington Hospital, as well as through the critical care support network. This research setting is appropriate for addressing the research question, as all of these settings have people who have experienced what it is like to receive intensive care treatment and these locations have been chosen as a pragmatic way of accessing people who have experienced what it is like to receive intensive care treatment.

Participant information sheets will be provided to adults who have been patients on an intensive care/critical care unit in the past, both in ICU review clinics by the individual's clinical team and through the critical care support network. Potential participants will be approached by the clinicians running the ICU review clinics or research nurses and given the participant information sheet. Those who are willing (after having a chance to ask any questions and take time to consider it) to participate in the study can then contact or be contacted by Dr Thomas Donaldson to seek consent to enrol in the study.

Informed consent will be sought prior to the participant being enrolled in the study. The process of gaining informed consent will involve discussion, either face to face, over the phone or via zoom, between the potential participant and Dr Tom Donaldson about the nature and objectives of the study and possible risks associated with their participation. The potential participant will have already received and had a chance to consider the participant information leaflet and consent documents and will be given the opportunity to ask questions. If they wish to consent to participate in the study they will sign a paper consent form. This will be sent to the participant in the post with a stamped addressed envelope for them to post the consent form back in. They will also be sent a paper pre-interview questionnaire to fill out (with support if necessary), which can be returned in the stamped addressed envelope with the consent form.

To assess the capacity of the potential research participant, Dr Tom Donaldson will check that the potential participant can:

- understand the purpose and nature of the research
- understand what the research involves, its lack of clinical benefits, and potential risks and burdens
- understand the alternatives to taking part
- retain the information long enough to make an effective decision.
- make a free choice for this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
- understand that they may withdraw from the research process at any point and for any reason
- understand that if, during the study, there are concerns about the participant's safety or the safety of others, we will inform their GP/emergency community mental health team/family member.
- understand that if, during the study, information is disclosed about misconduct/poor practice, there is a professional obligation to report this to the relevant NHS trust.

- understand that individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.

If after this discussion the individual wishes to participate in the study then their consent to do so will be documented on the consent form.

A minimum of 24 hours will be required between receipt of the patient information leaflet and seeking consent for participation in the study, to give people time to consider fully the implications of taking part. However, there will be no upper limit to the time that participants can take to consider involvement in the study (up to the two year duration over which the study will run).

A significant language barrier is one of the exclusion criteria for involvement in this study. This is because there is no available funding to pay for translation services.

6.4 Participants who withdraw consent [or lose capacity to consent]:

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected.

If a participant loses capacity to consent between the original seeking of consent for their participation in the study and the interview then they will be withdrawn from the study. Capacity assessment will be undertaken by Dr Tom Donaldson, who will be performing the interviews. The decision to withdraw a participant from the study due to loss of capacity to consent before the interview and the results of the capacity assessment will be recorded with the participant's consent form and communicated to the study team. It will not be possible to monitor capacity after the interview has taken place as this will be the last contact with the participant. (IRAS A35)

7) OUTCOME MEASURES (IRAS A57, A58)

The primary outcome measure of the study is the chance of survival that would make ICU survivors willing to go through ICU treatment again.

The study will generate a mix of qualitative and quantitative data about research participant's experiences of ICU treatment, their health-related quality of life and functional status before and after their critical illness, their end of life wishes and their treatment preferences with regards to intensive care treatment in the context of different chances of survival and different expected functional recoveries.

The analysis (and triangulation) of these data will inform how the experiences of intensive care patients and their end-of-life wishes affect at what chance of survival they would be willing to accept intensive care treatment.

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY (IRAS A36-A45)

As part of this study identifiable information will be collected including participants' names, contact details, ethnicity, and record of consent. Audio recordings will also be made during the one-to-one interviews with an encrypted audio recorder and will consist of voices only. If zoom is used to record the interview the video files that are recorded separately to the audio files will be deleted. This data will be collected and stored in accordance with UK data protection law to protect the rights and dignity of participants. The legal basis for collecting these data in this study is that it is "a public interest task" and "a process necessary for research purposes." Participants can request a copy of the information we hold about them, including audio recordings.

Audio recordings for the face-to face interviews will be made with an encrypted audio recorder. The audio recordings will be used to create transcripts. Dr Tom Donaldson or a University of Manchester approved transcription service will be performing the transcribing. The audio recordings will be transferred to a University of Manchester approved transcription service to undertake the transcription of the interview. Personal identifiable information will be removed in the final transcript. The audio recordings will be deleted after transcription.

If Zoom is used to conduct the interview, then the audio recording will be recorded in Zoom and so personal data will be processed by Zoom and participants' personal data will be transferred to the EEA. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection. On Zoom both the video and audio of the interview will be recorded, but the video file will be deleted immediately at the end of the interview and only the audio file retained for transcription.

Dr Tom Donaldson (or a University of Manchester approved transcribing service) will transcribe and code the interview data using the NVivo software package. Identifying details will be removed from the final transcripts. The data (transcriptions and survey data) will be de-identified by replacing identifying information with a random ID number, only known to the research team (pseudonymisation). The research team will have access to the key that links this ID number to the personal information, to enable them to identify the specific participants if necessary. The data will become fully anonymised (e.g., key link broken for pseudonymised data) before publication of the results, after this it will no longer be possible to identify individual data. Audio recordings will be deleted after transcription.

Personal data will be held temporarily in encrypted files on a specific secure laptop (not a personal laptop), accessible only by Dr Thomas Donaldson. These encrypted files will then be transferred as soon as possible to be stored on the University of Manchester Research Data Storage system in line with the University of Manchester Research Data Management Policy. The study team - Dr Thomas Donaldson, Professor Soren Holm, and Ms Kirsty Keywood will have access to the full dataset.

In accordance with data protection law, The University of Manchester is the Data Controller for this project and will be responsible for making sure personal information is kept secure, confidential, and used only in the ways participants have consented to. All researchers are trained with this in mind.

The study team at The University of Manchester will have access to personal information and they will anonymise it as soon as possible. Name and any other identifying information will be removed and replaced with a random ID number, only known to the research team (pseudonymisation). The research team will have access to the key that links the ID numbers to the personal information, enabling them to identify the specific participants if necessary. Secure maintenance of the data will be ensured by keeping the linking code in a separate location (a locked filing cabinet at the University of Manchester) and by using encrypted digital files within password protected folders and storage media.

The data will become fully anonymised (e.g., key link broken for pseudonymised data) before publication of the results, after this it will no longer be possible to identify individual data in the case that participants request that data is withdrawn.

Participants will be asked to consent to the use of anonymous quotations from the transcript of their interview being used in the final study report. All quotations will be fully anonymous.

The data will be stored for five years after completion of the research study. Paper consent forms and questionnaires will initially be kept in a locked cabinet on University of Manchester premises until the end of the study when they will be scanned and then disposed of. The digital copy of the consent form will be retained for 5 years for audit purposes. With participant consent, we will retain contact details for 5 years in order to provide participants with a summary of the findings for this study and also to inform them about future studies that they may be interested in. If consent is provided for this, participant details will be safely stored on University of Manchester servers in a digital folder only accessible to the study team and used only for the purposes described above, in accordance with The University of Manchester's Research Privacy Notice.

Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information. Individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to the research participants. Participants are informed of this possibility in the participant information sheet and will be asked to consent to this on the consent form.

The consent of participants will be taken for the use of the dataset for secondary analysis. This is reflected in the consent form and patient information leaflet. Therefore, with participant consent, anonymised study information about may be provided to researchers running other studies at the University of Manchester or at other organisations. With consent, anonymised information will be shared in order to support additional research in accordance with The University of Manchester's Research Privacy Notice. This information will not identify participants and will not be combined with other information in a way that could identify individuals. The information will only be used for the purpose of research and cannot be used to contact participants regarding any other matter.

At the end of the project, we will deposit a fully anonymised dataset [e.g., including de-identified interview transcripts] in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check

our analysis and results. Participants are informed of this in the participant information sheet and will be asked to consent to this on the consent form.

The data custodian will be Professor Soren Holm.

9) STATISTICAL CONSIDERATIONS

9.1 Data Analysis: (IRAS A56, A62)

Dr Tom Donaldson (or a University of Manchester approved transcribing service) will transcribe and code the interview data using the NVivo software package. The data analysis method will include thematic analysis of the semi-structured interview transcripts, initially by Tom Donaldson, with checking by another member of the research team.

Then a Mixed Methods approach will involve triangulation of:

- The Thematic Analysis of Semi-structured interviews (data can be transformed by creating frequencies of themes).
- Quantification of patient's ICU experiences through the ICU Memory Tool, their functional status before and after their critical illness through the EQ-5D-5L, their preferences for end of life using the Concept of a Good Death Measure, and whether their ICU experience would have been a good death using the QODD questionnaire.
- Integration of Quantitative and Qualitative data by asking "what chance of survival would make you willing to go through that experience again", combined with an adapted version of the WALT questionnaire to assess the effect of functional decline on that decision.

The use of quantitative data will allow for a "thick description" to support the transferability of the findings of this study and any analytic generalisations resulting from it.

9.2 Sample Size: (IRAS A59, A60)

The aim is to sample 50 participants. The rationale for this number is that 50 patients represents a practical number of qualitative interviews to undertake and transcribe for the qualitative analysis, whilst still providing a sufficient number to produce meaningful results from the quantitative survey element of the study.

A number of qualitative interview-based studies investigating people's attitudes towards death and dying have been undertaken, with sample sizes ranging between 20 and 50.[27][28][29][30][31][32][33] Qualitative interview-based studies of attitudes of ICU staff towards dying on ICU and end-of-life decision-making on ICU have also been undertaken, with sample sizes ranging between 18 and 75.[34][35][36][37] Therefore, a sample size of 50 for this study is practically feasible and in keeping with these previous studies.

This sample size will be reviewed if thematic saturation occurs. Thematic saturation describes the situation where additional interviews reveal no new themes or concepts into the analysis.[3] This

will ensure that additional research participants are not unnecessarily subjected to emotionally burdensome interviews, which will not add any new information into the study.

10)MONITORING AND QUALITY ASSURANCE (IRAS A74, A75-1)

The one-on-one, semi-structured, in-depth interviews will be conducted with the research participants by Dr Tom Donaldson. The transcripts of these interviews will be transcribed and analysed by Dr Tom Donaldson under the supervision and monitoring of Professor Soren Holm and Ms Kirsty Keywood.

The study will be subject to the audit and monitoring regime of the University of Manchester. Individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality.

Accidental protocol deviations will be documented and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur will not be accepted, will be immediate acted on and could potentially be classified as a serious breach.

All correspondence with the REC will be retained and the Chief Investigator will produce the annual reports as required. The Chief Investigator will notify the REC of the end of the study and an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

SAFETY CONSIDERATIONS AND ADVERSE EVENTS

This study investigating how the experiences of intensive care treatment and the end-of-life wishes of intensive care patients seeks to generate new knowledge to inform ethical intensive care decision-making in the public interest. However, the study itself represents no clinical benefit to the participants.

In fact, critical illness and receiving intensive care treatment are very significant and potentially traumatic life events. Therefore, participants will be asked about things that may have been painful, difficult, or confusing. Discussing these experiences may bring up distressing emotions and unpleasant memories, which will impact everyone differently. Discussion of end-of-life wishes can also bring up a range of negative emotions. It might be difficult and potentially upsetting to talk about these things. Participants will be advised that they can take a break, arrange the interview for another time or stop altogether if they start to feel these things. They will also be advised that they do not have to talk about any questions or subject areas that they don't want to talk about. At the

end of the interview, they will be provided with information about potential sources of support for people who have been ICU patients (e.g., ICU steps groups/the critical care support network). If the participant feels that they require psychological support as a result of emotions and memories brought up by the research interview, it will be possible to re-refer them to the ICU review clinic at the trust where they were a patient to access these services.

Another risk to participants arises from the need for personal information about them to be stored for transcription, analysis, and the production of the results of the study. Personal identifiable information will be stored in accordance with UK data protection law to protect participant's rights and dignity. The legal basis for collecting data for this study is that it is "a public interest task" and "a process necessary for research purposes." Participants will be able to request a copy of the information we hold about them, including audio recordings. In accordance with data protection law, The University of Manchester is the data controller for this project and will be responsible for making sure personal information is kept secure, confidential, and used only in the ways that participants have consented to.

Personal identifiable information will be stored in accordance with UK data protection law to protect participant's rights and dignity. The legal basis for collecting data for this study is that it is "a public interest task" and "a process necessary for research purposes." Participants will be able to request a copy of the information we hold about them, including audio recordings. In accordance with data protection law, The University of Manchester is the data controller for this project and will be responsible for making sure personal information is kept secure, confidential, and used only in the ways that participants have consented to.

Assessment and management of risk

A potential risk to participants in this study arises from the fact that critical illness and receiving intensive care treatment are very significant and potentially traumatic life events. Therefore, participants will be asked about things that may have been painful, difficult, or confusing. Discussing these experiences may bring up distressing emotions and unpleasant memories, which will impact everyone differently. Discussion of end-of-life wishes can also bring up a range of negative emotions. It might be difficult and potentially upsetting to talk about these things. Participants will be advised that they can take a break, arrange the interview for another time or stop altogether if they start to feel these things. They will also be advised that they do not have to talk about any questions or subject areas that they do not wish to talk about. At the end of the interview, they will be provided with information about potential sources of support for people who have been ICU patients (e.g., ICU steps groups/the critical care support network). If the participant feels that they require psychological support as a result of emotions and memories brought up by the research interview, it will be possible to re-refer them to the ICU review clinic at the trust where they were a patient to access these services.

If the participant was to say that they were suicidal then this information would be shared with their GP and/or the emergency community mental health team to ensure safeguarding of the participant. If the participant discloses information about intention to harm others, then this information would

be shared with their GP, the emergency community mental health team and/or the police to ensure safeguarding of the other individuals mentioned.

In order to best mitigate the risks to research participants arising from emotional distress resulting from the topics covered in the interview a distress protocol has been produced:

Distress Protocol

Rationale: Because the topics involved in this study are potentially distressing to research participants, a distress protocol is needed that will cover both steps to take to prevent participant distress as much as possible, and the actions to be undertaken should participants become distressed during the interview process.

Minimising participant distress:

- The interviewer will be Dr Tom Donaldson, an experienced consultant anaesthetist who is skilled at communicating with patients who are undergoing stress, critical illness and end-of-life decision-making.
- Advice on interview topic guides has been taken from a stakeholder organisation during patient and public consultant - the critical care support network (registered charity 1182307).
- Interviews will be semi-structured and questions will be open ended. The Participant will be allowed both to answer at their own pace and to take the time to collect their thoughts.
- Interviews will be audio-recorded if the participant consents.
- Interview transcripts will be anonymised.
- The interviews will be structured in order to gradually introduce the topic to the participants. Participants will be given an opportunity to wind down before the interview terminates.
- Research participants will be given contact information about the critical care support network as a source of support for them if they want to access it after the interview (on the debrief/signposting sheet).
- Participants will be given the choice of where to be interviewed.
- Research participants will be given the opportunity to be interviewed with a friend or family member present to support them if they would like this.
- Prior to interview potential participants will be given information about the interview process, and will be asked to provide their written, informed consent before the start of the interview.

Managing participant distress:

- Before the interview commences the participant will be informed that they may pause or stop the interview at any time should they feel upset.
- Should the participant begin to show signs of distress during the interview process, the interviewer will ask if they are all right and if want to take a break or stop the interview.
- Should the participant request it, the interview and recording will be paused at once. The interview may be concluded at this point at the participant's request.
- Should the participant be unresponsive or show signs of inconsolable distress, the interview and recording will be paused at once.
- Notwithstanding the above, the Interviewer will stop recording if the participant needs time to "let go" and cry.

- The participant will be given an opportunity to wind down. If appropriate this will be assisted by the interviewer interjecting questions to shift the focus away from the distressing topic or episode.
- The interviewer will remain with the distressed participant until they regain their composure.
- Should the interview be stopped at this point, the interviewer will make sure participant is in control of their distress. They may ask the participant if there is somebody they wish them to telephone before they leave. The interviewer will not leave the participant alone if they are concerned.
- If the participant feels that they require psychological support as a result of emotions and memories brought up by the research interview, they will be re-referred to the ICU review clinic at the trust where they were a patient to access these services.
- If the participant was to say that they were suicidal then this information would be shared with their GP and/or the emergency community mental health team to ensure safeguarding of the participant.
- The interview will only be recommenced if the participant fully consents and the interviewer is satisfied that the participant is in control of their distress.
- The interviewer will make note of any topic or question that causes distress.
- The interviewer will review the topic or question that causes the distress and discuss its appropriateness for inclusion in future interviews with his academic supervisors.
- Topics or questions that repeatedly cause distress in interviews will be revised or removed entirely if this is appropriate.

This protocol will be reviewed as the interviews are undertaken, and refined as appropriate.

Distress Protocol Flow Chart

Should a participant become distressed during the interview the following will be followed:

Distress: Participant shows signs that they are experiencing distress or exhibits behaviours associated with distress such as crying. This might suggest that the questions asked have caused stress to the participants or that the responses given have triggered personal and traumatic memories

↓

Step 1:

- Researcher offers immediate emotional support
- Ask participants if they would like to pause the interview
- If no, continue with the interview
- If yes, researcher offers support to the participant
- Explore distress level and assess risk

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Step 2:

- If risk is highlighted, assess and proceed to follow risk protocol
- Researcher remains with the participant
- If there is immediate risk then the police or an ambulance would be called
- If not immediate risk, ask the participant if there is anyone that can be called to come and meet the participant or to let them know they are feeling some distress
- When participant is ready to leave, they will be reminded of the support numbers to use if necessary (on the debrief/signposting sheet)
- Researcher to seek support from supervisors
- If any information in the interview has been raised which the researcher believes may cause harm to the participant or someone the participant knows, then mental health services may need to be contacted

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Follow up:

- If participant consents, follow up with a courtesy call or email the next day
- Encourage participants to use provided support numbers on the debrief/signposting sheet

There is also the possibility that a participant could make a disclosure of abuse involving themselves or someone else. Should this happen, the researcher would have a professional duty to act in accordance with the NHS England Safeguarding Policy (2015) and the BPS Professional Practice Guidelines (2008).

Risk Protocol

Should a participant disclose information that implied a risk to the participant or someone else the following steps would be taken:

Risk: Participant discloses information which implies risk to themselves or to another person.

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Step 1:

- Researcher will accurately document the information disclosed.
- Researcher will contact their research team supervisor to discuss the information disclosed and the most appropriate course of action.

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Step 2:

- If action is felt to be required the researcher will immediately report these concerns to the most appropriate child or adult safeguarding team
- Where possible, any concerns would be discussed with the individual and they will be informed that the researcher will be sharing information to respect confidentiality
- All actions will be completed with priority and done so at the soonest available opportunity.
- The researcher will keep a clear written record of the concern and all steps taken to deal with the matter, for example who the concern has been raised with and on what date.

Should a participant behave in a way (e.g. violent) that posed a risk to the researcher (or others) the following steps would be taken:

Risk: Participant poses a risk to the researchers and/or others.

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Step 1:

- The researchers would immediately stop the interview and if possible get themselves (and any other people at risk) out of the room and into a more public space
- If the risk was imminent, the researcher would immediately call the police

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Step 2:

- The researcher would contact the research team supervisor to discuss the risk and whether any further actions needed to be taken
- The researcher would accurately document the risk to others that had taken place

Participant Debrief Sheet

Thank you for participating in this interview. We hope that you have found it interesting and have not been upset by any of the topics discussed. However, if you have found any part of this experience to be distressing and you wish to speak to one of the researchers, please contact:

Dr Thomas Donaldson

Centre for Social Ethics and Policy, School of Social Sciences

University of Manchester

Oxford Road

Manchester

M13 9PL

Telephone Number: 07737298024

Email Address: thomas.donaldson-2@postgrad.manchester.ac.uk

There are also a number of organisations listed below that you can contact.

Organisations	
Critical Care Support Network (CC-SN) www.cc-sn.org Free informal drop in meetings, exercise/yoga sessions, relaxation workshops and social events	Free counselling on the NHS: https://www.nhs.uk/service-search/find-a-psychological-therapies-service/
Samaritans 24-hour free phone line Number: 116123 https://www.samaritans.org/how-we-can-help/contact-samaritan/	Please also consider contacting your GP if you feel that you require additional support due to distress caused by participation in this research

PEER REVIEW: (IRAS A54-1)

The research protocol, participant information sheet, consent form, pre-interview questionnaire and interview guide were prepared by Dr Tom Donaldson under the supervision of Professor Soren Holm and Ms Kirsty Keywood.

Public and patient consultation of the research protocol, patient information sheet, consent form, questionnaire and interview guide was undertaken with individuals from the critical care support network (registered charity 1182307) to review the acceptability of the research, the design of the research, the management of the research, the undertaking of the research, the analysis of results and the dissemination of findings. Changes to the study documents were made in light of comments received during the patient and public consultation.

Then high quality, independent, expert, and proportionate peer review was undertaken by two external reviewers in line with the National Institute Health Research (NIHR) Clinical Research Network (CRN) for peer review for studies. Two researchers from different institutions who had undertaken research with similar methodologies involving intensive care patients and their families were contacted and asked if they would peer-review the study documents. They were e-mailed the study documents and provided comments on them. Changes to the study documents were then made in light of these comments.

11)ETHICAL and REGULATORY CONSIDERATIONS

Approvals:

NHS HRA Research Ethics Committee favourable ethical opinion has been obtained from the North West – Liverpool Central Research Ethics Committee (REC reference: 23/NW/0091, Protocol number: NHS002026).

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

This study has received NHS Health Research Authority REC favourable opinion for the study protocol, informed consent forms and other relevant documents. If substantial amendments are needed that require review by NHS REC, they will not implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained and the chief investigator will produce the annual reports as required. The chief investigator will notify the REC of the end of the study and an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the chief investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

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.

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 that the necessary arrangements can be put in place to implement the amendment to confirm their support for the study as amended.

Amendments:

If amendments to the study protocol are required then the online Amendment Tool will be used to submit notice of amendments to the REC for consideration. The sponsor or authorised delegate will be responsible for deciding whether an amendment is substantial or non-substantial, for ensuring that the amendment tool is completed correctly, and for comparing the outcomes against their own expectations of how the amendment should be processed. The Amendment Tool will be used to categorise the amendment being made.

Category:	This category includes any amendment to a research project that has:
A	Implications for, or affects, all participating NHS/HSC organisations hosting the research project.
B	Implications for, or affects, specific participating NHS/HSC organisations hosting the research project.
C	No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However, the amendment should still be provided for information.
New NHS/HSC site	Guidance on adding additional NHS/HSC sites is provided in the section below. Where the amendment is to add a new NHS/HSC site to the project, the set-up of this new site should proceed according to the process for local study set-up for the nation where the new site is located.

Amendments will also be notified to the national coordinating function of the UK country where the lead NHS Research and Development (R&D) office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site (by e-mail to the PIs at each different site). Even some non-substantial amendments *(*for the purposes of REC*)* may still need to be notified to NHS R&D (e.g., a change to the funding arrangements). Once the amendment has been submitted, the completed Amendment Tool will be shared with confirmation of amendment category and, if applicable, amended documents with relevant participating NHS organisations in

England and/or Wales. In doing so, the NHS R&D Office, Local Clinical Research Network (LCRN) (where applicable) as well as the local research team details will be included.

A record of all amendments and different versions of the study protocol will be kept by the research team and updated versions of the study protocol will be e-mailed to the PIs at each NHS organisation in the event of any amendments becoming necessary. If applicable, other specialist review bodies (e.g., Confidentiality Advisory Group (CAG)) will be notified about substantial amendments in case the amendment affects their opinion of the study.

Protocol compliance

- Accidental protocol deviations will be documented and reported to the chief investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur will not be accepted, will be immediate acted on and could potentially be classified as a serious breach.

Risks: (IRAS A22 and A26)

A potential risk to participants in this study arises from the fact that critical illness and receiving intensive care treatment are very significant and potentially traumatic life events. Therefore, participants will be asked about things that may have been painful, difficult, or confusing. Discussing these experiences may bring up distressing emotions and unpleasant memories, which will impact everyone differently. Discussion of end-of-life wishes can also bring up a range of negative emotions. It might be difficult and potentially upsetting to talk about these things. Participants will be advised that they can take a break, arrange the interview for another time or stop altogether if they start to feel these things. They will also be advised that they do not have to talk about any questions or subject areas that they do not wish to talk about. At the end of the interview, they will be provided with information about potential sources of support for people who have been ICU patients (e.g., ICU steps groups/the critical care support network). If the participant feels that they require psychological support as a result of emotions and memories brought up by the research interview, it will be possible to re-refer them to the ICU review clinic at the trust where they were a patient to access these services.

If the participant was to say that they were suicidal then this information would be shared with their GP and/or the emergency community mental health team to ensure safeguarding of the participant. If the participant discloses information about intention to harm others, then this information would be shared with their GP, the emergency community mental health team and/or the police to ensure safeguarding of the other individuals mentioned.

Another risk to participants arises from the need for personal information about them to be stored for transcription, analysis, and the production of the results of the study. Personal identifiable information will be stored in accordance with UK data protection law to protect participant's rights and dignity. The legal basis for collecting data for this study is that it is "a public interest task" and "a process necessary for research purposes." Participants will be able to request a copy of the information we hold about them, including audio recordings. In accordance with data protection law, The University of Manchester is the Data Controller for this project and will be responsible for

making sure personal information is kept secure, confidential, and used only in the ways that participants have consented to.

There is a risk to participants of situations where confidential information would have to be disclosed. These situations are described in the participant information sheet and consented for on the consent form. If, during the study, there are concerns about participant safety or the safety of others, then their GP/emergency community mental health team/police/family member will be informed. Also if, during the study, participants disclose information about misconduct/poor practice, the study team have a professional obligation to report this to the relevant NHS trust. Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident. Also if, during the study, participants disclose information about any current or future illegal activities, the study team have a legal obligation to report this and will therefore need to inform the relevant authorities. Individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to research participants.

Dr Thomas Donaldson is likely to undertake interviews as a lone researcher interviewing patients at home. He has clinical experience of undertaking home visits for patients at their homes as a lone practitioner. He will ensure that a third party "buddy" is aware of his location and expected completion time for these visits and will check in with them at the end of the interview. We will be following the University of Manchester Safety Service Guidance: Guidance on lone working.

In light of the psychological burden that undertaking a large number of emotionally intense interviews, psychological support will also be available to Dr Thomas Donaldson throughout the study, both from his supervisors, the University of Manchester and his mentor at the Countess of Chester Hospital.

12)STATEMENT OF INDEMNITY (IRAS A76-1,-2,-3, A77)

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

The University of Manchester provides insurance cover in respect of research involving human subjects undertaken in the United Kingdom for:

- harm to participants, on a “no-fault” or “non-negligent harm” basis, and
- financial loss by participants and participating organisations, on a legal liability basis.

The insurance cover is available for research sponsored, managed, designed or conducted by, or on behalf of, the University (including research undertaken by students under supervision).

The University of Manchester will arrange insurance for research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions.

13) FUNDING and RESOURCES (IRAS A65)

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
School of Social Sciences, University of Manchester, Oxford Road, Manchester, M13 9PL **Tel:** 0161 306 1340 **Email:** Jackie.Boardman@manchester.ac.uk	Law Studentship (£7804.50 per annum)
National Institute of Academic Anaesthesia RCOA Small Research, Education and Travel Grant Churchill House, 35 Red Lion Square, London, WC1R 4SG **Tel:** 020 7092 1726 **Email:** info@niaa.org.uk	£ 3,600

ROLE OF STUDY SPONSOR AND FUNDER:

The School of Social Sciences at the University of Manchester provided funding for the project in the form of a Law Studentship for Dr Tom Donaldson's PhD, which is being undertaken at the University of Manchester. The National Institute of Academic Anaesthesia has agreed to offer full funding of £3,600 to cover the transcription costs for the study through a RCoA Research, Education & Travel Grant from the Foundation Fund.

The University of Manchester are providing supervision and oversight of the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results through the project supervisors Professor Soren Holm and Kirsty Keywood. The final decision regarding any of these aspects of the study rests with Professor Soren Holm.

The University of Manchester will act as the data controller for the project.

14) PUBLICATION POLICY (IRAS A50-1 – A53)

On completion of the study, the data will be analysed and tabulated, and a final study report prepared. The full study report will be accessible on the University of Manchester Website.

Participants of the study will be provided with a report of the results of the study if they consent to their contact information being kept for this purpose. The results of the study will also be provided to the NHS trusts and critical care support network which have participated in the study.

It is possible for the participants to specifically request results from Tom Donaldson and this information will be provided after the final study report had been compiled or after the results had been published.

An anonymised study report will be made publicly available via peer-reviewed publication after completion of the study.

The data (transcriptions and survey data) will be de-identified by replacing identifying information with a random ID number, only known to the research team (pseudonymisation). The research team will have access to the key that links this ID number to the personal information, to enable them to identify the specific participants if necessary. The data will become fully anonymised (e.g., key link broken for pseudonymised data) before publication of the results, after this it will no longer be possible to identify individual data.

The data arising from the study will be owned by the University of Manchester. Dr Thomas Donaldson will have rights to publish any of the study data.

Authorship eligibility guidelines and any intended use of professional writers

Authorship for the final study report will be granted based upon:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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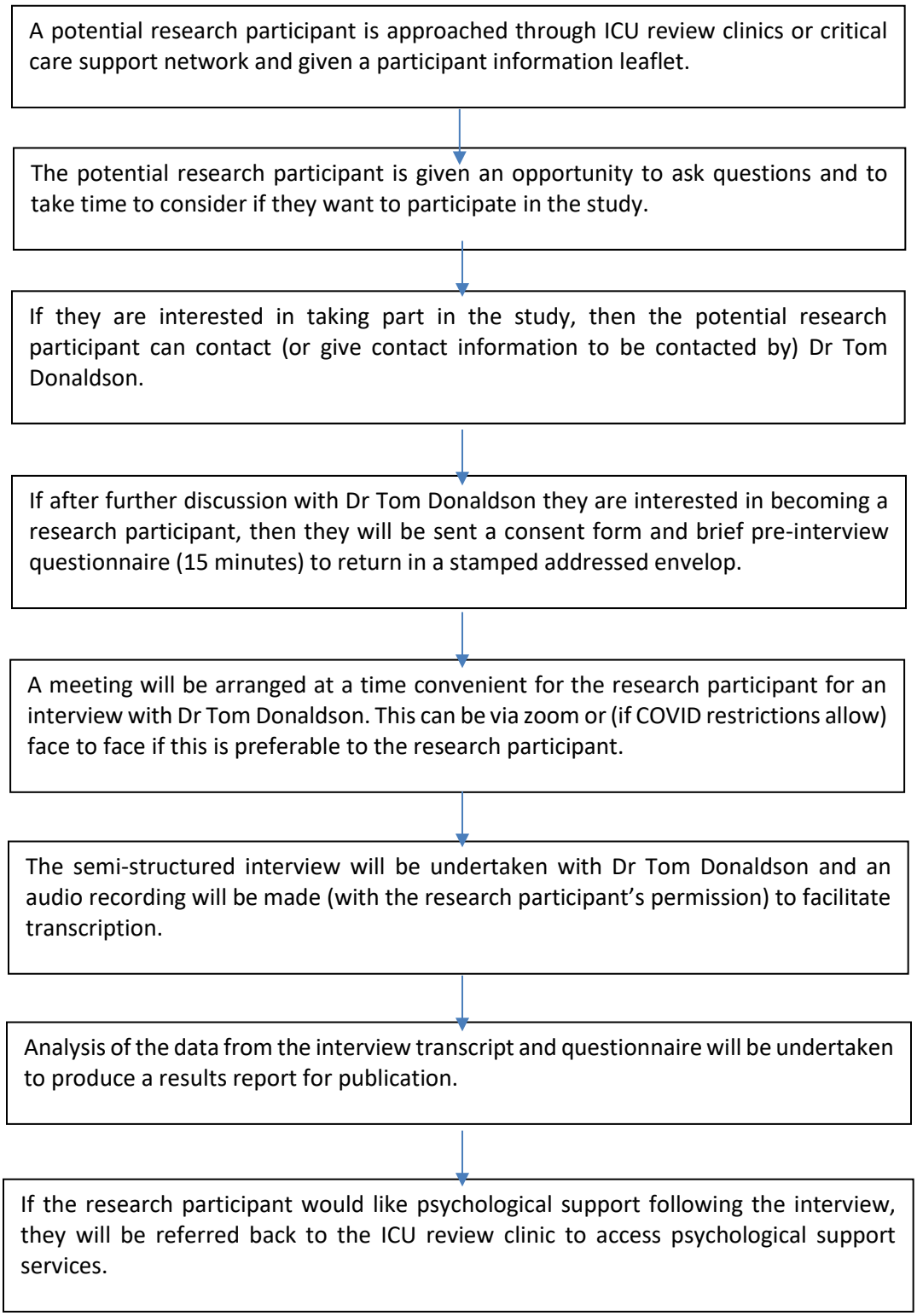
STUDY FLOW CHART:



PROTOCOL CONTRIBUTORS:

Dr Thomas Donaldson (School of Social Sciences, University of Manchester) has undertaken the study design, and will undertake the conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

Professor Soren Holm and Dr Kirsty Keywood (School of Social Sciences, University of Manchester) are providing supervision of the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

Patient and Public Involvement - Public and patient consultation of the research protocol, patient information sheet, consent form, questionnaire and interview guide has been undertaken with individuals from the critical care support network (registered charity 1182307) to review the acceptability of the research, the design of the research, the management of the research, the undertaking of the research, the analysis of results and the dissemination of findings.

KEY WORDS: Intensive Care, clinical decision-making, ethics, end-of-life, good death, functional status

Appendices

Appendix 1 – Patient Information Sheet

Participant Information Sheet (PIS):

Intensive care decision-making, survival and dying well:

How do the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival?

Invitation and Summary:

You are being invited to take part in a research study. The aim of the research, which is being done as part of a PhD at the University of Manchester, is to explore how people's previous experience of intensive care treatment and their end-of-life wishes affects their willingness to accept intensive care treatment again. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research:

Many critically unwell patients who are faced with the decision of whether or not to accept intensive care treatment have no previous experiences of what it is like to be an intensive care patient. The experiences of previous intensive care patients are, therefore, a valuable source on information for patients facing this important life or death decision. This study aims to investigate how the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival. Participating in this study will involve filling out a questionnaire and then taking part in an interview.

Who will conduct the research?

Dr Tom Donaldson, who is a PhD student in medical ethics at the University of Manchester School of Social Sciences and Consultant Anaesthetist at the Countess of Chester Hospital. Tom's PhD is supported by a Law studentship from the University of Manchester.

What is the purpose of the research?

Intensive care treatment offers the only chance of survival for patients who are critically unwell (whose organ systems are failing). However, the experience of receiving these treatments can be negative and not all patients survive their critical illness, despite receiving intensive care treatment. Decisions about whether or not to accept intensive care treatment have to be made rapidly by patients who will die if they do not accept intensive care treatment, but who often do not know what it is like to receive intensive care treatment.

The only people who really know what it is like to receive intensive care treatment are patients who have been through intensive care treatments in the past. Therefore, this research aims to find out how the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival. This will be done through a combination of an interview and a questionnaire. These reflections can then inform clinicians, families and patients facing these difficult and uncertain decisions.

We ask you to consider taking part in this research due to your previous experiences of receiving intensive care treatments. We are hoping to talk to fifty patients who have received intensive care treatment in the course of this study.

Am I suitable to take part?

We would be very grateful to speak with you if you:

- Are at least 18 years or older
- Have been a patient on an intensive care/critical care unit in the past
- Were admitted to the intensive care/critical care unit as an emergency (not as a planned admission after an elective operation, for example).
- Are willing to talk about your experiences of intensive care treatment, what your end-of-life wishes are (what a good death/dying well means for you), and what chance of survival would make you willing to accept intensive care treatments. Some people may find discussion of these topics distressing, so please consider this carefully before deciding whether or not to participate in the research.
- Are willing to either meet in person or have access to a computer, tablet or mobile phone with video and a stable internet connection (for a Zoom conversation)
- Are able to participate in the interview in English.

Will the outcomes of the research be published?

On completion of the study, the data will be analysed and tabulated, and a Final Study Report prepared as part of a PhD thesis. The full study report will be accessible on the University of Manchester Website. All published results will be fully anonymised.

If you would like to receive a report of the results of the study, then this can be provided to you upon completion of the study, if you consent to your contact information being kept for this

purpose. The results of the study will also be provided to the NHS trusts and critical care support network which have participated in the study.

It is possible for you to specifically request results from Tom Donaldson and this information will be provided after the Final Study Report had been compiled or after the results had been published.

An anonymised study report will be made publicly available via peer-reviewed publication after completion of the study.

Disclosure and Barring Service (DBS) Check:

Dr Tom Donaldson has undergone an appropriate level of DBS check to work with vulnerable adults as required by his role as a Consultant Anaesthetist at the Countess of Chester Hospital.

Who has reviewed this study?

This study has been approved by the North West – Liverpool Central Research Ethics Committee.

REC reference: 23/NW/0091 (Protocol number: NHS002026).

What would my involvement be?

What will I be asked to do if I take part?

Before you can enroll in the study, you will be asked to give informed consent to your participation the study. The process of gaining informed consent will involve discussion, either face to face, over the phone or via zoom, with Dr Tom Donaldson about the nature and objectives of the study and possible risks associated with their participation. You will have already received and had a chance to consider the participant information leaflet and will be given the opportunity to ask questions. As part of the process of providing consent to participate in the study you will be asked to consent to us providing information about your participation in this study to your GP. If you wish to consent to participate in the study then you will be asked to sign a paper consent form. This will be sent to the you in the post with a stamped addressed envelope to post the consent form back in.

You will also be sent a paper pre-interview questionnaire to fill out (with support if necessary), which can be returned in the stamped addressed envelope with the consent form. The questionnaire will take approximately 10-15 minutes to complete. Part of this questionnaire will involve, if you consent, the collection of some demographic details, including your name, contact details, ethnicity, religion, and employment status. If you require support in completing your questionnaire then this can be provided prior to the interview.

You will be asked to take part in a one-to-one interview with Tom. The interview will last approximately 1 hour, but can be paused at any point if you need to take a break, and then restarted at a later time if you are happy to do so. Ideally interviews will take place in-person (at a location of your choice) or if you prefer it can be done using Zoom. If you would like to have a Zoom interview then you will need to have a supportive person (e.g. friend or family member) available to provide any necessary support to you during the interview. The interview will be arranged at a date and time that is convenient for you. An audio recording of the interview will be made with your permission. An audio recording of the interview is necessary to allow transcription of the interview for analysis. Face-to-face interviews will be recorded using an encrypted audio recorder.

If Zoom is used to conduct the interview, then your participation in this research will be recorded in Zoom and your personal data will be processed by Zoom. Your personal data is transferred to the EEA. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection. On Zoom both the video and audio of the interview will be recorded, but the video file will be deleted immediately at the end of the interview and only the audio file retained for transcription.

What are the risks if I take part?

Critical illness and receiving intensive care treatment are very significant and potentially traumatic life events. In sharing your story, you will be asked about things that may have been painful, difficult, or confusing, as well as distressing emotions you may have had. Discussing these experiences may bring up negative and unpleasant memories, and these will impact everyone differently. Discussion of end-of-life wishes can also bring up a range of negative emotions. It might be difficult and potentially upsetting to talk about these things, so please consider this before deciding whether or not to participate in the research.

If you do decide to participate in this study but during the interview you begin to feel upset or distressed, we can take a break, arrange the interview for another time or stop altogether. You can also let the interviewer know if there's any questions or subject areas that you don't want to talk about. If as a result of emotions and memories brought up by the research interview you feel you need psychological support, it will be possible to re-refer you to the ICU review clinic at the trust where you were a patient, to access these services. Your GP will be informed if any distress symptoms arise through participation in this study.

Will I be compensated for taking part?

No financial compensation is available for participating in this research study and there is no intended clinical benefit to you from participation in the study. If you choose to take part you will receive a letter of thanks from the chief investigator.

What happens if I don't want to take part or change my mind?

It is up to you to decide whether or not to take part. If you would like to, then please get in touch with Tom using the contact details at the end of this information sheet. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. If you would like for us to delete the data that we have collected up until that point, we will do so. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you do decide not to take part, you do not need to do anything further.

Audio recordings will be used to document the interview. You should be comfortable with the recording process at all times and are free to request that we stop recording at any time. However, an audio recording of the interview is necessary to allow transcription of the interview for analysis, so if you decide not to consent to audio recording of the interview then you will be withdrawn from the study.

Data Protection and Confidentiality

What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify you, called "personal identifiable information." Specifically, we will need to collect:

- Your name,
- contact details,
- ethnicity,
- religion,
- employment status,
- record of consent.

The audio recordings obtained during the one-to-one interviews will consist of voices only.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes."

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research:

https://documents.manchester.ac.uk/display.aspx?DocID=37095

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential, and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number, only known to the research team. This process is known as pseudonymisation as the research team will have access to the key that links this ID number to your personal information, enable them to identify the specific participants if necessary.
- The data will become fully anonymised (e.g., key link broken for pseudonymised data) before publication of the results, after this it will no longer be possible to identify individual data in the case that you request that your data is withdrawn.
- Data will be held in encrypted files on a specific secure laptop, accessible only by Dr Thomas Donaldson. These encrypted files will also be stored on the University of Manchester Research Data Storage system in line with the University of Manchester Research Data Management Policy.
- Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.
- The audio recordings will be used to create transcripts. Dr Tom Donaldson or a University of Manchester approved transcribing service will be performing the transcribing.
- Personal identifiable information will be removed in the final transcript.
- The audio recordings will be deleted after transcription.

- If Zoom is used to conduct the interview, then your participation in this research will be recorded in Zoom and your personal data will be processed by Zoom. Your personal data is transferred to the EEA. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection. On Zoom both the video and audio of the interview will be recorded, but the video file will be deleted immediately at the end of the interview and only the audio file retained for transcription.
- The data will be stored for five years after completion of the research study. Your consent form will initially be kept in a locked cabinet on University of Manchester premises until the end of the study when it will be scanned and then disposed of. The digital copy of the consent form will be retained for 5 years for audit purposes. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.
- When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with the UK Policy Framework for Health and Social Care Research - Health Research Authority (hra.nhs.uk): https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.
- If you consent, your contact details will be retained for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies. If you consent to this, your details will be safely stored on University of Manchester servers in a digital folder only accessible to the study team and used only for the purposes described above.
- At the end of the project, we will deposit a fully anonymised dataset [e.g., including de-identified interview transcripts] in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Potential disclosures:

- If, during the study, we have concerns about your safety or the safety of others, we will inform your GP/emergency community mental health team/care team/police/family member.
- If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this to the relevant NHS trust/professional body.

- Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.
- If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

Contact details for complaints:

If you have a complaint that you wish to direct to members of the research team, please contact:

Professor Soren Holm

Email: soren.holm@manchester.ac.uk

Tel: 0161 275 3588

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information

Tel: 0303 123 1113
Make a complaint |https://ico.org.uk/make-a-complaint/ ICO

Additional information in relation to COVID-19

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

Are there any additional considerations that I need to know about before deciding whether I should take part?

The ongoing COVID-19 pandemic creates additional risks for participants if face-to face interviews occur. These will not be necessary, as interviews can occur via zoom instead, but if the participant would prefer a face-to-face interview, then this should occur in line with current COVID-19 infection control guidance.

What additional steps will you take to keep me safe while I take part?

Due to the additional risks to the participants of infection through face-to-face interviews, the option of undertaking the interview via zoom will be made available to all participants. However, if participants would prefer a face-to-face interview, then this can be undertaken using appropriate PPE. Face-to-face interviews will not occur with participants in a vulnerable group or if participants or the researcher have symptoms.

Is there any additional information that I need to know?

What if the Government Guidance changes?

If Government Guidance regarding infection control for COVID-19 changes, then it may be necessary to change PPE arrangements, re-schedule, postpone or cancel face-to-face interviews. In the case that face-to-face interviews have to be cancelled, interviews can be conducted via zoom instead.

What if I have additional queries?

Additional Queries to:

Dr Tom Donaldson **Email:** thomas.donaldson-2@postgrad.manchester.ac.uk
Telephone: 07737298024

Contact Details:

If you have any queries about the study or if you are interested in taking part, then please contact the researcher:

Dr Tom Donaldson

Email: thomas.donaldson-2@postgrad.manchester.ac.uk

Telephone: 07737298024

Appendix 2 – Consent Form

Intensive care decision-making, survival and dying well:

How do the experiences of intensive care patients and their end-of-life wishes affect their willingness to accept intensive care treatment at different chances of survival?

Consent Form

If you are happy to participate please complete and sign the consent form below

	Activities	Initials
1	I confirm that I have read the attached information sheet (**Version 4, Date 19/10/2022**) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set. I agree to take part on this basis.	
3	I agree to my GP being informed of my participation in this study. Please provide your GP's address: ……. ……. …….	
4	I agree to the interviews being audio recorded to enable a transcript of the interview to be produced. The audio recording will be destroyed once the transcription is completed.	

5	I agree that any data collected, including anonymous quotations from the transcript, may be included in anonymous form in publications/conference presentations and in the final study report.	
6	I understand that a fully anonymised dataset will be deposited in an open data repository at the end of the project and that any anonymised data collected may be made available to other researchers	
7	I understand that data collected during the study will be stored securely in line with the University of Manchester data protection policy and that the data may be looked at by individuals from The University of Manchester, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research to make sure the project is being carried out as planned. This may involve looking at identifiable data but, all individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant. I give permission for these individuals to have access to my data.	
8	I understand that there may be instances where during the course of the research information is revealed which means the researchers will be obliged to break confidentiality and this has been explained in more detail in the information sheet.	
9	I agree to take part in this study.	

The following activities are optional, you may participate in the research without agreeing to the following:

15	I agree that any personal data collected may be made available to other researchers	
16	I agree that the researchers may contact me in future about other research projects.	
17	I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study.	

Data Protection

The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the **Privacy Notice for Research Participants**.

_____	_____	_____
Name of Participant	Signature	Date

Dr Thomas Donaldson

(Researcher)

_____	_____	_____
Name of the person taking consent	Signature	Date

Please keep one copy of this form for yourself, and return the original signed copy of this form to the research team in the stamped addressed envelope.

Appendix 3 – Schedule of Procedures

Participant Consent Procedures	Take informed consent	15	Principal Investigator
Interventions non clinical	Subject Questionnaire	15	Principal Investigator
Interventions non clinical	Interview of Participant	60	Principal Investigator
Other Procedures or Activities	Sign posting to sources of psychological support/offer of referral back to local ICU review clinic/GP at end of interview	10	Principal Investigator
Other Procedures or Activities	Dissemination of study results to participants	10	Principal Investigator

Appendix 4 – Amendment History

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

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.