UNIVERSITY OF BIRMINGHAM

NHS Sandwell and West Birmingham NHS Trust

Participant Information Sheet

Full Study Name: Optimising dEcision-making and support for famiLies of PatIentS who have life-sustaining treatments withheld/withdrawn in adult intensive care units (ELPIS study)

Study Lead Investigators:
Dr Nikolaos Efstathiou, Professor Anne Topping.

Sponsor: University of Birmingham.

Invitation to take part in this study

You are invited to take part in a research study. We would like you to consider taking part in this study because you have experienced the death of a relative in ICU.
Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide, whether or not you wish to take part. You can also change your mind at any time. This study is not a clinical trial, you will not be given any medical intervention. Any reference to "we" within this document refers to the research team and/or the sponsor organisation.

Background to the study

In intensive care units (ICUs), patient deaths often occur after decisions to limit life-sustaining treatments. This may happen when a patient deteriorates and does not show any signs of recovery and involves shared decision-making between families and clinicians regarding limiting or stopping interventions. Since many patients haven't expressed their preferences, families are expected to advocate for them. However, this decision-making and witnessing the dying process can have an impact on family members that may lead to psychological distress and short or long-term negative emotions. There is limited research on how family members experience end-of-life decision-making and the patient's dying process in United Kingdom ICUs and what may be perceived as compassionate care during this time. Hence, with this study we aim to explore these experiences with the intention of developing a model of care to be used by ICU clinicians to improve decision-making and reduce psychological distress for families.

What does the study entail?

We will ask you to take part in an interview, either via telephone/Zoom/Microsoft Teams or if you prefer, we can offer a face-to-face in-person interview at the University of

Birmingham or at your home. If you prefer, you can have a friend or relative accompany you. All interviews will be conducted sensitively by members of the research team who are highly experienced interviewers. We expect that the interview will last no longer than 90 minutes.

Who is organising and insuring the study?
This study is organised by researchers from the University of Birmingham (the sponsor organisation) and ICU clinicians from Sandwell and West Birmingham Hospitals NHS Trust.
The University of Birmingham has in place Clinical Trials indemnity coverage for this study which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion, provide cover for non-negligent harm to participants.
The NHS have a duty of care to its patients, whether or not they are taking part in a clinical trial and in the event of clinical negligence being proven the normal NHS complaints mechanisms will still be available to you.

Who has funded this study?
This study is funded by the National Institute for Health and Care Research (NIHR) [Research for Patient Benefit (RfPB) Programme (NIHR206331)]. The views expressed are those of the research team and not necessarily those of NIHR or the Department of Health and Social Care.

What would taking part involve?
Consent
You will be asked to sign a consent form so we have a record that you fully understood the research and voluntarily consented. If you choose to take part, you are expected to complete the consent form. The consent form can be completed on paper or a device. For completion on paper, initialling the boxes next to the consent statements will be required. For electronic completion, clicking in the square boxes enters a "tick" for you. The form can be signed by hand, electronically, or by typing your name. You will then be offered a copy of the consent form to keep, which you can accept or decline. You can choose to have a paper copy or have this emailed to you.

Interview
If you are willing to take part, you will take part in one interview to explore your experience as a family member of someone who had died in ICU due to the withholding/withdrawing of life-sustaining treatments and your involvement in end-of-life decision making. The interview will be with a member of the research team. Just before the interview starts, we will ask you for some personal information (age, gender, ethnicity, religion, relation to deceased, education level, country of birth) that you will have the option to decline if you do not want us to record this information.
Interviews will ask you about your experience and views of withholding/withdrawing life sustaining treatment. Exploring how families handle decisions about withholding or withdrawing life-sustaining treatments in ICUs can provide valuable insights into the

difficulties they encounter, the ways they cope, and how we can improve support for them during the dying process, after death, and throughout bereavement. The research team will have some set questions to ask you, but you can also talk about anything else relevant. The interview timing will be flexible to meet your needs. You can take breaks whenever you need. The interview is expected to take no longer than 90 minutes. However, the length of the interview can be guided by you and how you are feeling. The interview can take place in person (e.g. at your home or the University of Birmingham), on the telephone, or online (Microsoft Teams or Zoom). The interview will be private and confidential. The research team will arrange the interview time and date with you. You will be able to let the research team know your preferences and we will do our best to accommodate them. The research team will record the interview. Recording the interview helps the research team by making sure we know what you said and nothing is missed. Interviews will be audio recorded on an encrypted recording device. The original audio file will be deleted as soon as possible after the research team has received the transcription of the interview by the professional transcribing company and checked the interview transcript against the original audio recording. The interview transcript will then be stored as part of the research data. If you feel uncomfortable during the interview at any time you can pause or stop completely. Even if the interview has started, we can stop. We can then either reschedule or you can withdraw from the study. You are also welcome to take a break at any time. If you don't like a question or it makes you feel uncomfortable, we can skip it. You do not have to say or talk about anything you do not want to.

Voluntary participation
Taking part in the interview is entirely voluntary. You are invited to take part in one interview only. You will be given 15 days to decide whether or not you would like to take part in this study. Before taking part in the interview, a member of the research team will ask whether you have read and understood this information sheet – the research team will be happy to answer any questions you may have.

Expenses and payments
All participants in the study will be offered a £40 voucher. If you decide to be interviewed at the University of Birmingham, travelling expenses will be reimbursed.

If you would like to take part, please contact one of the following members of the research team:
Dr Nikolaos Efstathiou Email: n.efstathiou@bham.ac.uk
Dr Sepideh Setayesh Email: s.setayesh@bham.ac.uk

Do you have to take part?
No. Participation in this study is completely voluntary and choosing not to take part will not affect your legal rights in any way. If you do not want to take part, you do not need to do anything further. Please note, you may be reminded about this study invitation by a member of the research team. You can choose to withdraw your participation, and decline any reminders, without giving a reason by contacting the research team. Further details

about withdrawing from the study are provided later in this document. You should only take part in this study if you understand what is involved and choose to do so.

Who are the research team?
The research team is made up by academics and researchers working at the University of Birmingham with experience in qualitative end-of-life research, ICU clinicians who work at Sandwell and West Birmingham Hospitals NHS Trust, and a member of the public. A research fellow will also support the research team.

Who has reviewed and approved the study?
All research in healthcare is looked at by an independent group of people, called a Research Ethics Committee; this is to protect all participants' interests. The study has been approved by the Ethics Committee (Reference: 24/PR/0871). The study is sponsored by the University of Birmingham.

What are the possible benefits of taking part in this study?
While you may not experience personal benefits from participating in this research, your views will help us to understand the challenges families face in making decisions regarding life-sustaining treatments in ICUs and how they experience the death of their loved ones. By sharing your experiences, you can help us identify effective coping strategies and suggest improvements in support services for those going through similar situations during the dying process, after death, and throughout bereavement. An anonymised acknowledgement of the contribution of study participants will be provided in all study outputs, such as publications.

What are the risks?
There are no obvious risks for you in taking part in this study. However, we appreciate that talking about complex life experiences is an emotive issue and that sharing experiences may be upsetting.

What will happen to my information?
The information that you provide will be treated in accordance with the General Data Protection Regulation (GDPR) Act. This means that we will treat it with the highest level of protection.
Personal information will be used only as a summary of all the participants' characteristics in future publications. The interview will be audio-recorded using an audio recording device but will not include your name (and we will remind you to avoid using identifiable information). The use of audio-recording is necessary for the interview to be analysed. In research, it is helpful to turn an audio-file into written words, so that we can analyse it more easily. This process is called 'transcription'. The interview will be heard by a third party who will be employed to transcribe the recorded interview. This third party is a professional transcriber who has clearance and is an authorised supplier of the University of Birmingham, and they are bound by the same confidentiality requirements as all researchers involved with this project, this means they also cannot share anything they hear on the interview recording. Any potentially identifiable information (e.g., place name) will not be transcribed/will be deleted from the transcription. Once the transcription has

been checked the audio recording will be deleted. No write-up of the research will contain any personally identifying information and will therefore not include your name or any other personal details.

Participation in the study is entirely voluntary and participants are free to refuse to take part or to withdraw without having to give a reason and without this affecting the relationship with members of the project team, or the service you receive from the project. Withdrawal can be either during interview or even after interview we can still withdraw your information if you ask us to do so. However, you will only be able to withdraw the interview we conducted with you within five working days after it was completed, as after that time it will be anonymised and imported in a computer programme for analysis.

No personally identifying information from the interview will be transcribed. Each interview will be given a study number. Only the member of the research team conducting the interview will know which interview is associated with which person. These study numbers will then be assigned pseudonyms, or fake names, which will be used in any reports about the study.

How will we use the information about you?
We will need to use information from you for this research project.

This information will include your contact details, initials, age, gender, ethnicity, religion, relation to deceased, education level, country of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will use your contact details to send you a thank you letter/e mail.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information

- **at www.hra.nhs.uk/information-about-patients/**
- **this study information leaflet**
- **by asking one of the research team who's contact details are provided towards the end of this information sheet**
- **by sending an email to the University of Birmingham's Data Protection Officer on dataprotection@contacts.bham.ac.uk**
- **by ringing us on 0121 415 8587.**

Who should you contact if you wish to make a complaint about the research?
Any complaint about the way you have been treated during the study or any possible harm you might have suffered will be addressed. If you feel you have been harmed by participating in this research, in the first instance please speak to the organisation who sent you the study invitation or the project lead.
If your concerns are not dealt with, the sponsor's Research Ethics Governance and Integrity team, via email: researchgovernance@contacts.bham.ac.uk

If you wish to raise a concern on how we have handled your data, you can contact our Data Protection Officer who will investigate the matter: legalservices@bham.ac.uk
If you are not satisfied with our response, you can complain to the Information Commissioner's Office (ICO).

Who should you contact for support after the interview?
If you feel sad, lonely or confused, and would like support and someone to talk to, there are several services available to help you:

At a Loss (bereavement signposting and information).
Website: https://www.ataloss.org/

Good Grief Trust
Website: https://www.thegoodgrieftrust.org/

Cruse Bereavement Support
Website: www.cruse.org.uk
Helpline: 08088081677

Sue Ryder
Website: https://www.sueryder.org/

Age UK
Website: www.ageuk.org.uk
Advice Line: 0800 678 1602

The Compassionate Friends
Website: www.tcf.org.uk/
Helpline: 0345 123 2304

Bereavement Advice
Website: www.bereavementadvice.co.uk/

Next phase of the study
We would like to inform you that following the analysis of the data of this phase of the study (interviews), we will organise an online workshop with various stakeholders to discuss the supportive care model we have developed based on the data that you and other participants have contributed. This online workshop will help us refine the model we have developed and will give us the opportunity to also discuss future research plans. If you are interested in participating in the next phase of the study, you will be able to record this in the consent form.

Who should you contact if you want further information?
If you have a concern or any questions, please contact the research team. Research team contact details:

Dr Nikolaos Efstathiou (Project Lead)

Email: n.efstathiou@bham.ac.uk Tel: 0121 415 8587

Dr Sepideh Setayesh (Clinical Research Fellow)
Email: s.setayesh@bham.ac.uk

Thank you for taking the time to read this Participant Information Leaflet.
This information is for you to keep.