Brief Title: A Needs-focused Palliative Care Intervention for Older Adults in ICUs (PCplanner)

Official Title: Operationalizing PCplanner, a Needs-focused Palliative Care for Older Adults in Intensive Care Units: a Randomized Clinical Trial

NCT#: NCT04414787

Informed consent document date: 12/05/2022

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study

Operationalizing Needs-Focused Palliative Care for Older Adults in Intensive Care Units (ICU)

Concise Summary

The purpose of this study is to understand family members' unique experiences of having a loved one in an intensive care unit (ICU). We think that we can learn a lot from allowing family members to describe, in their own words, what they feel went well and what perhaps did not go well during their loved one's care in an ICU setting. This knowledge may help us to highlight new ways to improve ICU care.

There are no known physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. There may be no direct benefit to you.

If you choose to participate in this study, you will be asked to complete a single zoom interview with the study team. This interview will last approximately 60 minutes and will be recorded. During this interview you will be asked questions related to your experience as a family member who had a loved one in the ICU. The purpose of recording the call is to allow the study team to review your answers and study them.

If you are interested in learning more about this study, please continue to read below.

You are eligible for this study because you recently participated in a study of ours called, 'Operationalizing Needs-Focused Palliative Care for Older Adults in Intensive Care Units (ICU)', also know as PCPlanner. We are reaching out to you because we want to hear the unique perspectives of people who are diverse in age, race, and other factors. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your research study doctor or staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the research study doctor or the staff if you are taking part in another research study.

Grants from the National Institutes on Aging (NIA) as well as the Duke Center for Research to Advance Healthcare Equity (REACH Equity) are sponsoring this study. Portions of ***Dr. Christopher Cox's*** and his research team's salaries will be paid by these grants. We will recruit participants from Duke University Medical Center (DUMC) over approximately one year from the time of study initiation.

Who will be my doctor on this study?

If you decide to participate, ***Dr. Christopher Cox*** will conduct the study and will be available to you if you have any questions or concerns.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study

Operationalizing Needs-Focused Palliative Care for Older Adults in Intensive Care Units (ICU)

Why is this study being done?
The purpose of this study is to understand family members' unique experiences of having a loved one in an intensive care unit (ICU). We think that we can learn a lot from allowing family members to describe, in their own words, what they feel went well and what perhaps did not go well during their loved one's care in an ICU. This knowledge may help us to highlight new ways to improve ICU care so that ICU teams can provide higher quality care, communicate better with families, improve spiritual support, and learn to appreciate what families need in the future

How many people will take part in this study?
Approximately 50 people will take part in this study at Duke.

What is involved in this study?
If you agree to be in this study, you will be asked to sign and date this consent form.

You will then be asked to complete a single zoom interview with the study team. This zoom call will last about 60 minutes and will be recorded. You will be asked a series of questions during the interview. Examples of questions that will be asked are listed below:

- *Tell me about the role you played during your loved one's ICU stay..*
- *Tell me about the role that religion or spirituality play in your daily life.*
- *Tell me about your experience with any hospital resources or policies that supported your needs.*
- *How did the app allow you to communicate to the ICU care team?*

The study team member may also ask and record information about you and your loved one's race, gender, ethnicity, age, general medical condition, and overall socioeconomic and health status.

The purpose of recording the zoom call is to allow the study team to review your answers and study them after the interview is over. From studying your answers, along with the other participants, we hope to better understand family members unique experiences of having a loved one in an ICU.

How long will I be in this study?
If you choose to participate, you will be in the study for one day with a singular visit that last approximately 60 minutes in total.

Your participation is completely voluntary. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study principal investigator (Dr. Christopher Cox) first.

What are the risks of this study?
There are no known physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Operationalizing Needs-Focused Palliative Care for Older Adults in Intensive Care Units (ICU)

Are there benefits to taking part in this study?
If you agree to take part in this study, there may be no direct benefit to you. We anticipate that the study may highlight new ways that ICU teams can provide higher quality care, communicate better with families, improve spiritual support, and learn to appreciate what families need in the future. Additionally, we hope the information learned from this study will benefit other ICU patients, ICU medical teams, and family members in the future.

Are there alternatives to taking part in this study?
You are free to choose not to participate in this study.

Will my information be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related interview may be reported to the National Institutes of Health (NIH) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the NIH, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

What are the costs?
There will be no additional costs to you as a result of being in this study.

What about compensation?
You will receive $25.00 for the completion of the single study visit.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or any Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Cox at 919-681-7232 during regular business hours and at 919-358-6451 after hours, on weekends and holidays.

What about my rights to decline participation or withdraw from the study?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. Nonparticipation or withdrawal from this study will not affect your job status if you are a Duke employee. If you do decide to withdraw, we ask that you contact Dr. Christopher Cox in writing and let him know that you are withdrawing from the study. His address is DUMC, Division of Pulmonary and Critical Care Medicine, Box 102043, Durham, NC 27710. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. The sponsor or regulatory agencies may stop this study at any time without your consent. The investigators also have the right to stop your participation at any time. If this occurs, you will be notified.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Operationalizing Needs-Focused Palliative Care for Older Adults in Intensive Care Units (ICU)

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ct2/home as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Whom do I call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Christopher Cox at 919-681-7232 during regular business hours and at 919-358-6451 after hours, on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Research Participant	Date	Time

_____
Printed Name of Research Participant

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

_____
Printed Name of Person Obtaining Consent