NCT03506438

Full Title: Addressing Palliative Care Needs Among Intensive Care Unit Family Members

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Informed Consent Form (Pro00090202)

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Addressing Needs Among
Intensive Care Unit Family Members

Concise Summary

The purpose of this study is to better understand what family members of patients report as their needs in an ICU setting. We also want to see if showing this information to ICU clinicians can help the ICU medical team meet these needs more effectively, and can help in integrating palliative care into the ICU (palliative care is care which focuses on treating symptoms and improving quality of life rather than treating the disease). Participants will sign this consent form and then be randomized into one of two groups. Family members in both groups will complete four surveys, one on the day of enrollment, one three days later, one a week later, and one three months later. Family members in Group 1 will receive access to the ICUconnect web app program. Group 1 family members' survey results will be visible to the participating clinicians. Family members in Group 2 will receive the normal, standard care in the ICU. While Group 2 will have access to the ICUconnect web app program, their survey results will not be visible to participating clinicians. Participation in this study will last about 3 months.

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. We anticipate that the study may improve the ICU team's ability to meet your palliative care needs in a timely fashion—though this is not certain. Additionally, we hope the information learned from this study will benefit other ICU patients, ICU medical teams, and family members in the future.

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

You are being asked to take part in this research study because your loved one received care in an intensive care unit (ICU). 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 study doctor or study staff discusses this consent form with you, please ask him/her 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 study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of ***Dr. Christopher Cox's*** and his research team's salaries will be paid by this grant. We will recruit participants from Duke University Medical Center (DUMC), and Duke Regional Hospital (DRH) over approximately three and a half years 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, as needed, can be in contact with your loved one's regular health care provider throughout the time that you are in the study and afterwards.

Why is this study being done?
The purpose of this study is to help understand what patients and their family members report as their needs in an ICU setting. These needs may be related to needing more information, spiritual support, and other factors such as

these. We also want to see if showing this information to ICU clinicians can help the ICU medical team meet these needs more effectively.

How many people will take part in this study?
Approximately 880 people will take part in this study at Duke. This includes 370 people who were treated in an ICU, 380 of their family members, and 115 physicians and nurses.

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 be assigned to one of two study groups, depending on who the attending physician is during your loved one's stay in the ICU. Of the 380 ICU family members enrolled, we expect roughly half will fall in each group. Family members in **both groups** will participate in four surveys. These surveys can be completed online on a smartphone or a computer, or, if needed, in person or over the telephone. In these short surveys (which take about 10 minutes to complete), we will ask you about your needs for support, level of distress, and other relevant elements related to receiving care in an ICU.

If you are assigned to **Group 1**, you will receive the ICUconnect web app program. This program does three things:
1. you receive access to our ICUconnect web app, which provides a list of helpful questions to ask the ICU medical team,
2. part of your survey results (your reported needs) will be shown to the ICU medical team, and
3. you will have a family meeting with the ICU medical team to discuss your needs (or anything else you would like).

If you are assigned to **Group 2**, you will receive all of the normal, standard care provided in the ICU. While you will have access to the ICUconnect web app content, your survey results will not be reported to the ICU medical team, and you will not have a required, formal family meeting to specifically talk about your reported needs.

No travel or additional blood tests or x-rays are required of your loved one. If you do not want to participate in this study, there will be no penalty or loss of benefits to which you are entitled.

For **both groups**, we will be texting you reminders to complete surveys. Texting may be convenient but does not provide a completely secure and confidential means of communication. Please initial on the line below if you wish to keep your reminders private and we will communicate with you through regular channels like the telephone or email:

_____ I choose to OPT OUT of text reminders

How long will I be in this study?
If you choose to participate, the study will last about 3 months. No further study procedures will be necessary. You will complete surveys at four different time points:

- Survey 1: within 24 hours of consent

- Survey 2: approximately 3 days after completing survey #1
- Survey 3: approximately 1 week after completing survey #1; a 'mini-survey'
- Survey 4: approximately 3 months after completing survey #1

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 of up to 30 minutes at any time during the study.

Because e-mail and text messages do not provide a completely secure and confidential means of communication, please do not use email or text messages if you wish to keep your communication private. Instead, please let us know and we will communicate with you only through regular channels like the telephone.

The website used in this study is developed by an outside party specifically for use in this study. As with any website that you visit or software that you download, there may be potential security risks and Duke cannot guarantee that the website/software is free of risk. In general, it is recommended that you run a current operating system (OS) on your computer, review the privacy/security settings on your web browsers, run antivirus software, make sure that your connection is encrypted (look for the lock icon when you connect), and log off of websites when you are done. When viewing the website on a mobile device or tablet, it is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. If you do not have an unlimited data/text plan, you may incur additional charges.

We are not asking you to make any health decisions based on the use of this website. You should discuss health decisions directly with your healthcare provider. As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

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 improve the ICU team's ability to meet your and your loved one's ICU care needs in a timely fashion—though this is not certain. 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. Your loved one will continue to receive regular clinical care regardless of whether or not you choose to participate.

Will my information be kept confidential?

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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.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Cox's office.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the DUHS Institutional Review Board. The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information will be destroyed or information identifying you will be removed from such study results at DUHS.
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. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name 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).

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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 $20 for each survey completed and $10 for the mini survey for a total up to $70.

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. For after hours, on weekends and holidays, contact 919-684-8111 and ask to have Dr. Cox paged.

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.

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.

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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. For after hours, on weekends and holidays, contact 919-684-8111 and ask to have Dr. Cox paged.

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 Subject	Date	Time
_____		
Printed Name of Subject		
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____		
Printed Name of Person Obtaining Consent		