COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title:
Feasibility, Acceptability, and Barriers to Implementation of a Geriatrics Bundle in the ICU: a Pilot Study (ACE-ICU)

Principal Investigator (the person who is responsible for this research):
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Phone Number (via the Yale Program on Aging): (203)737-1800

If you are signing this form as the legal proxy of the subject, please note that all instances of "you" in this form refer to the subject's participation in the study.

Research Study Summary:

- We are asking you to join a research study because you are age 65 or older and in the intensive care unit.
- Our purpose is to gather information about certain parts of care in the ICU, including rehabilitation treatments, medication reviews, and the use of aids to help with hearing. We are also trying to learn about your health and functioning before and after the ICU. There is no intervention in this part of the study. (In a later part of the study that enrolls future ICU patients, there will be an intervention that is compared to this part of the study).
- Study procedures will include answering questions via an interview and through written questionnaires. This initial assessment will take approximately 45 minutes and will be completed in the ICU.
- A second 45-minute assessment completed before hospital discharge will include additional questions as well as a few simple clinical tests: walking down a short hall, squeezing a small object that measures grip strength, squeezing different muscles, and looking at an eye chart to check your vision. There are no blood draws involved in this study, and this study will not involve any changes to your hospital care.
- There are some risks from participating in this study. There is a minor risk of falling during the short hallway walk, but the walk will be supervised closely by study personnel to minimize this risk. There is a small risk of breach of confidentiality, but there are many layers of security to keep study information confidential, which minimizes this risk.
- The study may not benefit you directly, though there is the possibility of benefit via the extra attention paid to you by the research nurse. The information gathered in this study is likely to benefit future patients who are age 65 and older and are admitted to an ICU.

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- There are other choices available to you outside of this research. The alternative is to not participate in this study. Your regular hospital care will not be changed by your participation or lack of participation in this study.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you are age 65 or older and were admitted to the medical intensive care unit (MICU).

Who is paying for the study?
This study is funded by the Yale Claude D. Pepper Older Americans Independence Center, which is funded by the National Institute on Aging.

Who is providing other support for the study?
N/A

What is the study about?
Our purpose is to gather information about certain parts of care in the ICU, including rehabilitation treatments, medication reviews, and the use of aids to help with hearing. We are also trying to learn about your health and functioning before and after the ICU. There is no intervention in this part of the study. (In a later part of the study that enrolls future ICU patients, there will be an intervention that is compared to this part of the study).

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen: There will be one study visit while you are in the ICU that takes approximately 45 minutes. Study personnel will first interview you and/or your proxy for about 5 minutes each to learn more about your health and cognitive function before coming to the hospital. Trained research personnel will do the interview, and will administer a short questionnaire (called the “Confusion Assessment Method for ICU” or “CAM-ICU” to make sure that you aren’t confused from the hospital environment). We use these questionnaires to make sure that you are able to answer questions or whether your proxy should answer certain questions. If we aren’t sure about your ability to consent for the study, we will administer an additional questionnaire (called the “UBACC”) to see if you are able to provide consent, or whether we should talk about the study with a proxy.

Next, study personnel will ask you (or your proxy) questions about your health and other factors important to daily functioning (such as whether you have social support at home).

We will also review your electronic hospital record for information about medical status such as admitting diagnosis, medical conditions you had in the hospital and have had in the past, what type of care you received in the ICU, and how long you were in the ICU and the hospital.

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Before you are discharged from the hospital, there will be a second study visit that lasts 45 minutes. Study personnel will ask you additional questions about your health and functioning, and will administer a few simple clinical tests: walking down a short hall, squeezing a small object that measures grip strength, and squeezing different muscles in your body.

At one of the two study visits, you will also be asked to look at a vision chart to check your vision.

What are the risks and discomforts of participating?
There is a minor risk of falling during the short hallway walk, but the walk will be supervised closely by study personnel to minimize this risk. There is a small risk of breach of confidentiality, but there are many layers of security to keep study information confidential, which minimizes this risk. All of these risks are uncommon.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
The study may not benefit you directly, though there is the possibility of benefit via the extra attention paid to you by the research nurse.

How can the study possibly benefit other people?
The study is likely to benefit future patients age 65 and older who are admitted to an ICU. At the end of the study, we will have more information about whether ICU patients in this age group would benefit from a different type of rehabilitation service, a different type of medication review, and assessment of hearing problems. This new information may help future patients.

Are there any costs to participation?
You will not have to pay for taking part in this study.

Will I be paid for participation?
You will be paid for taking part in this study. After you complete all study assessments, you will be mailed a $50 gift card to thank you for your participation in the study. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments. Payment will not be prorated for only completing part of the study. Payment is conditional upon completing all study procedures (the in-hospital visits and follow-up phone call).

How will you keep my data safe and private?
We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

Your research records will be kept confidential. Only a code number will identify research records. The code number will not be based on any information that could be used to identify you. The master list linking names to code numbers will be kept separately from the research data. All research information will be kept in locked files or cabinets at all times. All research data collected in this study will be entered into a secure computer database. Both the database and computers are password-protected. Only members of the research database staff and

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researchers who have received the approval of the Yale University IRB (the body that approves and oversees research involving human subjects) will know your identity.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, 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.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Any medical records held by Yale-New Haven Hospital created from: January 1, 2020 through December 31, 2022. The information we will collect includes: medical conditions, what medicines you take, age, sex, race, date of birth, Medicaid status, weight over time, height, and details about any hospitalizations or ICU admissions (such as diagnoses, lengths of stay, and treatments).

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

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- Health care providers who provide services to you in connection with this study.
- The PI, Lauren Ferrante, M.D., M.H.S.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Lauren Ferrante, the study's principal investigator, at the Yale School of Medicine, 300 Cedar St., TAC S-431, PO Box 208057, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

There is minimal risk to participate in this study. The minimal risk is due to the small risk of falling during the short walk, or of having a home medication discontinued. To minimize these risk, the study personnel will undergo training in safe mobilization, and an ICU pharmacist will carefully perform a medication review and reconciliation. Before the walk, the study personnel will speak with your nurse. Study personnel will then supervise the walk. If you become injured during this study (such as during the walk), your insurance may be billed for the cost of treatment.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

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The researchers may withdraw you from participating in the research if necessary. For example, if you remain in the hospital for a prolonged period of time, we may need to withdraw you from the study.

What will happen with my data if I stop participating?
When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used until the end of the research study as necessary to ensure study integrity and/or study oversight.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at (203)737-1800.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Authorization and Permission
Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Legally authorized representative or surrogate	Signature of representative or surrogate	Date

Description of legally authorized representative or surrogate's relationship to the patient

Witness (if verbal proxy consent via phone)	Signature of witness	Date

Description of witness' relationship to the patient

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Future research studies

Can we contact you in the future to ask about your interest in participating in other research studies being done at the Yale Program on Aging?

Circle one: Yes No

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