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Developing and Testing a Nurse-Led Technology-Enhanced Family Engagement Program **(Nurse-TECH-Family)** Among Critically Ill Patients in ICU: A Feasibility Trial

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RUTGERS
School of Nursing | Camden

Cooper
University Health Care

INFORMED CONSENT AND HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AUTHORIZATION FORM

Title of Study: Developing and Testing a Nurse-Led Technology-Enhanced Family Engagement Program **(Nurse-TECH-Family)** Among Critically Ill Patients in ICU: A Feasibility Trial

Principal Investigator: Brigitte S. Cypress, EdD, RN, CCRN (Rutgers University, School of Nursing Camden)
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Co-Principal Investigators: Mei Rosemary Fu, PhD, RN, FAAN (University of Missouri-Kansas City School of Nursing)

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Study Sponsor: This study is supported by South Jersey Institute for Population Health Grant Program.

Subject Name: _____

What does informed consent for a research study involve?

- The investigator or their staff will explain this research study to you.
- Participation is voluntary. This means you choose whether or not you want to take part in this research study.
- You do not have to take part in this study to receive treatment at Cooper.
- You can agree to take part, and then later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want.
- You will receive a copy of this form to keep.

STUDY SUMMARY

This consent form is part of an informed consent process for a research study. It will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The purpose of the research is to test the impact of the **Nurse-TECH-Family** program during patient-and-family-centered interdisciplinary rounds (PFCC-IR) in the CCU.

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the two study groups (Group #1 and Group #2). There are no special requirements or criteria to be in either group. You will have a 50% chance of being assigned to either Group #1 or Group #2.

If you take part in the research and are in Group #1, you will be asked to participate in daily patient-and-family-centered interdisciplinary rounds in person if you are in the CCU until the day your loved one is discharged or leaves the CCU. If you are not in CCU, a nurse will call or contact you via Webex or Microsoft Teams daily to update you about the care of your family member until the day of discharge from the unit. If you take part in the research and are in Group #2, you will receive the standard communication process.
Regardless of the group you are in, you will also be asked to complete study questionnaires on day 1, and the day of your loved one's discharge from the CCU, and it will involve 40-60 minutes of your time. Your time in the study will take the days that your family member is in the CCU.

Possible harms or burdens: There are no known harms of taking part in the study, and the burden of taking part in the study is minimal. There are no expected risks to participating in patient-and-family-centered interdisciplinary rounds, or when the nurse contacts you about your family member's care. No injuries or complaints have been reported from our previous research.

Possible Benefits of Taking Part in the Study:
Whether you are assigned to Group#1 or Group #2, you may or may not receive some benefits from your participation in this study.
(a) May feel less stressed by learning about your family member's medical condition and plan of care.
(b) May help or relieve your physical and mental symptoms related to your family member's admission to ICU.

(c) May help your quality of life because of the lessened stress related to your family member's admission to ICU.

An alternative to taking part in the research study: Participation in this study is completely voluntary and you are not obligated to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask the questions and should expect to be given answers. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

What is the purpose of this research study?

This study is being done to determine the feasibility of conducting a randomized controlled trial (RCT) to implement and test the impact of a **Nurse**-Led-**T**echnology-**E**nhan**C**ed **Family** Engagement Program **(Nurse-TECH-Family)** on ICU length of stay and reducing stress and improving quality of life and well-being among critically ill patients' families.

Who may or may not take part in this study?

Any family member of a patient in the CCU can take part in this study if they are:

- 18-80 years old
- Able to speak and understand English

How long will the study take and how many people will take part?

Your participation in this study will last as long as your family member is in the CCU. You will fill out a questionnaire on the day you start the study and the day your family member leaves the CCU ((40-60 minutes). We expect 30 people at Cooper will be in the study.

What will you be asked to do if you take part in this study?

If you choose to participate in this study, we will assign you at random to one of the two (2) study groups: Group #1 (study group) or Group #2 (standard care group). This

means we will put you into a group by chance, like flipping a coin or drawing names out of a hat. You will have an equal chance of being placed in either group.

If you are assigned to Group #1, you will receive the Nurse-TECH-Family intervention where you will participate in daily in-person patient-and-family-centered interdisciplinary rounds if you are present in the CCU. If you are not in the CCU, a nurse will call or virtually contact you via Webex or Microsoft Teams daily to update you about the care of your family member until the day of discharge from the unit.

If you are assigned to Group #2, you will receive standard CCU care and do not have to participate in patient-and-family-centered interdisciplinary rounds.

Both groups will participate in two 40–60-minute survey sessions to:

- Complete several questionnaires about your background (age, education, occupational status, etc.) and physical symptoms. You do not need to be physically present in CCU to fill out the questionnaires. You are free to skip any questions that you prefer not to answer.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

Who is conducting this study?

Dr. Brigitte Cypress is the Principal Investigator of this research study. Dr. Mei Rosemary Fu and Dr. Nowai Brapoh are Co-Principal Investigators (Co-PIs) for this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Brigitte Cypress may be reached via email brigitte.cypress@rutgers.edu, mobile phone (646) 724-4946, or office phone (856) 225-6790.

Dr. Mei Rosemary Fu may be reached via email mei.fu@email.gwu.edu, mobile phone (973) 986-1758, or office phone (571) 553- 0388.

Dr. Nowai Brapoh (AVP Nursing Quality, Professional Practice, and Innovation, 1 Cooper Plaza, Suite K213A, Camden, NJ 08103) may be reached via email brapoh.nowai@CooperHealth.edu or office (856) 342-2149.

The Principal Investigator, Co-PIs, and or other members of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

What are your alternatives (other choices) if you do not take part in this study?

Your alternative is not to take part in this study.

What are the possible risks or discomforts if you take part in this study?

There are no known harms of taking part in the study, and the burden of taking part in the study are minimal. Nurse-TECH Family is a safe and non-invasive intervention. No injuries or complaints have been reported from our previous research.

During the survey, we may ask you some questions that seem sensitive or personal, such as those related to your physical and mental health. You can skip any question you do not want to answer.

Will there be any benefits if you take part in this study?

You may or may not receive any benefit from participating in the study.

Whether you are assigned to Group#1 or Group #2, you may or may not receive some benefits from your participation in this study.

- May feel less stressed by learning about your family member's medical condition and plan of care.
- May help or relieve your physical and mental symptoms related to your family member's admission to CCU.
- May help your quality of life because of the lessened stress related to your family member's admission to CCU.

Will you be paid to take part in this study?

You will receive compensation for taking part in this study according to the following schedule:

- $25.00 Cooper cafeteria gift card on day 1 in the study
- $25.00 Cooper cafeteria on the day your family member is discharged from the CCU

Will there be any costs to you to take part in this study?

You will not have to pay money to participate in this study.

Will you be told about new information that might affect your decision to take part in this research?

During the study, we will tell you if we learn any new information that could affect your willingness to stay in the study.

What will happen if you decide not to stay in this study?
Participation is voluntary. You can decide after signing this informed consent document that you no longer want to take part in this study for any reason, at any time. You will not be penalized or lose any benefits that you are entitled. If you decide you want to stop taking part in the study, tell the study staff as soon as possible.

Even if you leave the study, we will keep the information we have already collected about you. No new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Who should you contact if you have questions?
If you have any questions about the research, you may contact the Principal Investigator listed on the first page of this consent form. They are responsible for the conduct of the research at Cooper.

If you have any questions about the research or your rights as a research participant, or any complaints about the research, you may contact the Cooper Institutional Review Board (IRB). The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is One Cooper Plaza, 4th Floor, Dorrance D431A Camden, NJ 08103. The phone number is (856) 757-7832.

VOLUNTARY PARTICIPATION

- I voluntarily consent to take part in this study.
- The study staff have discussed this research study with me.
- I have had adequate time to read this form and to ask questions about it.
- I understand that, by signing this form, I am not giving up any of my legal rights.
- I agree to the use and disclosure of my protected health information for this study.
- I will be given a copy of this consent and authorization form for my records.

Signature Page for Adult Subjects

SUBJECT:
Printed Name of Subject: _____

Signature: _____ Date: _____ Time: _____

INVESTIGATOR: I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: _____