University of Pittsburgh

School of Medicine
Department of Medicine – Division of Geriatric Medicine

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CONSENT TO ACT AS A PATIENT PARTICIPANT IN A RESEARCH STUDY

TITLE: Post-**I**ntensive **C**are: **T**ransitional *C*are, **R**ehabilitation, and **F**amily **S**upport (PIC-TRFS)

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Why is this research study being done?

The purpose of this research study is to test an intervention called PIC-TRFS which delivers extra support to critical illness survivors and their families throughout the hospitalization and into the community for people discharged home. If it works the way we expect, patients and families who receive the PIC-TRFS intervention will have improved function and quality of life compared to patients and families who receive enhanced usual care.

Who is being asked to take part in this research study?

Approximately 160 patients who are at least 50 years old admitted from home to an ICU for at least 48 hours and who are at risk for long-term functional changes, and 160 adult family caregivers who are supporting them after critical illness.

What are the procedures of this research study?

Regardless of whether you consent to participate, you will receive care as usual.

There are two phases: the Run-In and the Intervention Period. Everyone who is eligible and consents will receive the Run-In, which continues until the time of discharge. During the Run-In, the PIC-TRFS Team provides transitional care coordination, rehabilitation, and family support. That means the Team will:

- Get to know you (the patient) and your caregiver during the hospitalization. This includes screening assessments for health-related social needs, health literacy and some basic demographic information that will take about 15 minutes to complete.
- Help identify and plan for your needs after discharge;
- Be your go-to person across transitions in the hospital;
- Initiate early rehabilitation for physical or cognitive changes while you are still in the hospital.

At the time of discharge, patients and families who are discharged home will enter the Intervention Period. Those who are discharged to locations other than home will be disenrolled.

The Intervention Period involves a randomized control trial. That means some patients and families will receive usual care, while others will receive the PIC-TRFS intervention. Which group you are assigned to is randomly picked by a computer. Everyone will receive a study folder with an Event Calendar (to track appointments, hospitalizations, and falls), a To-Do list, discharge health information, rehabilitation information, and study contact information.

Those who are assigned to the PIC-TRFS intervention group will continue to receive support from the PIC-TRFS team, including:

- A check-in by phone or videoconference within 2 days of discharge (5-20 minutes);
- Meeting with the home health and primary care teams to help them understand the hospitalization and plan care going forward;
- 12-16 regular check-ins at decreasing intervals over the 6 months after discharge. Nothing needs to be filled out during these “check-ins” (5-20 minutes each). Some will focus on you (the patient) and some on the family;
- 7-10 phone- or videoconference-based rehabilitation sessions starting about 3 weeks after discharge and continuing every week or 2 until the you are able to keep progressing on your own or has completed 10 sessions (approximately 45 minutes each). These sessions focus on mobility and function beyond what the home health team provides. They involve a worksheet for you (the patient); families can attend as desired.
- Tailored resource referrals.
- Separate peer support groups for patients and families.

Whether you receive usual care or the PICTRFS intervention, you will be helping us evaluate PIC-TRFS in three ways:.

- Completing computer-based surveys at discharge, 3, 6 and 12 months. Each round of surveys will take about **30 minutes**, but you can take them at your convenience with breaks. We will ask about:
    - Your quality of life
    - Your mental health and experience of trauma symptoms
    - How you are coping with all the changes after critical illness
- Texting or mailing us photos of your Event Calendar every month. We will remind you to exclude identifiers from photos of the event calendars you text or email back to us. This will take about **5 minutes**.
- Competing exit interviews at the end of the study (12 months). This will take about **30 minutes** to give us more detailed feedback about your experiences with PIC-TRFS.

Neither you (the patient), your caregiver, nor your insurance providers will be charged for the cost of the procedures performed only for the purposes of this research study. You (the patient), your caregiver, and/or your insurers will be billed in the usual manner for your standard medical care (care you would receive even if you were not participating in this research study).

What are the possible risks and discomforts of this research study?

Most of the risks of participating are the same as receiving usual care. In addition:

- Participation takes additional time and energy, which may be limited after critical illness. We have done our best to ensure you have support without becoming overwhelmed. We have pilot tested the procedures and found that, with some flexibility, most patients and families find them manageable.

- Critical illness often causes long-term psychological trauma. The goal of PIC-TRFS is to provide support for people to heal from trauma. However, it is possible that some of the screening and functional testing could cause distress or retraumatization from contemplating what you've been through. If that occurs, the study team will connect you with resources to help.
- PIC-TRFS is designed to identify and address function, safety and mental health needs. Most of the time, PIC-TRFS team will address these needs themselves in collaboration with your usual care team. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law.
- While breach of confidentiality is possible, we have taken multiple steps to reduce this risk. Information obtained for this study will be assigned a research number. Personal identifiers (name, date of birth, etc.) will be removed. All information linking your name to your study information will be stored in a separate, secure location. All study-related documents will be stored in locked cabinets in the PI's office. All electronic data will be collected and stored on secure Pitt servers. Finally, we will be using secure telehealth resources to communicate with you after discharge. We will also be keeping data in a secure electronic research database. Although every reasonable effort has been taken, confidentiality during Internet, email, and text messaging communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Will I benefit from taking part in this research study?

If you participate, as part of either the PIC-TRFS group or the usual care group, you will:

- Have extra support across transitions after critical illness
- Get extra rehabilitation and training before hospital discharge
- Have a “go-to” team as new questions arise
- Help to make care better for others in the future

What will I learn about the study results?

- You will largely be reporting your own experiences, so we will not feed your individual results back to you.
- At the end of the study, we will publish our overall findings on the laboratory website, to which you have access: picturethis.pitt.edu
- Additionally, we will email flyers reporting the study results to people who participated in the study.

How much will I be paid if I complete this research study?

- You are not obligated to participate in this study.
- If you choose to participate, you will receive: $25 for completing the evaluations at discharge, $25 for completing them at 3 months, $25 for completing them at 6 months, and $50 for completing them at 12 months. (Total possible compensation for study participation = $125)

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a “Form 1099 – Miscellaneous” with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for ‘backup withholding;’ thus you would only receive 76% of the expected payment.

How will the confidentiality of my research records be maintained?

Every attempt will be made to ensure the confidentiality of your research information. The information obtained for this study will be assigned a research number. Personal identifiers (name, date of birth, etc.) will be removed. All information linking your name to your study information will be stored in a separate, secure location.

- Our text messaging will focus on scheduling and prompts to complete surveys and return event calendars. We will remind you to exclude identifiers from photos of the Event Calendars you text or email back to us, but any identifiers captured in the photos may be discoverable to outside parties.
- Research records will be maintained for at least 7 years following final reporting or publication of a project.
- If the investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- A description of this study 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. This website can be searched at any time.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).
- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study.
- Information collected from this study may be shared with other investigators. Before sharing, all identifiers will be removed (i.e., de-identified). De-identified data will be available from the PI upon request with a Data Use Agreement and may be shared with national repositories.
- This study is funded by the Agency for Healthcare Research and Quality (AHRQ).

HIPAA Authorization for Disclosure of Protected Health Information (PHI)

As part of this research study, we are requesting your permission to review your identifiable medical information to describe the medical details of your critical illness.

This authorization is valid for an indefinite period of time. We will obtain information about your demographic data including age, sex, race, ethnicity, health insurance status/provider, zip code of residence, medical history, dates of treatment, and details of your treatment during the hospitalization such as reason for ICU admission, ICU treatment (e.g., mechanical ventilation, pressers, dialysis), ICU symptoms (e.g., delirium), medications, receipt/order for physical or occupational therapy in the ICU and on the floors, discharge disposition, and readmissions. Your identifiable medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the study sponsor and the University of Pittsburgh Office of Research Protections for the purpose of monitoring the conduct of the study. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records once your personal information is disclosed to others outside UPMC or the University.

The PIC-TRFS Team may write standard clinical notes in the “telephone notes” section of your medical record to help coordinate care delivery. Entering notes in the telephone notes section means you will not be charged for services. We will not place the surveys connected to this research in your medical record, only notes that help coordinate care across the healthcare system.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

Is my participation in this research study voluntary?

Yes! Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will not affect your relationship with UPMC or the University. If you decide to withdraw, the research team will ask you to make the request in writing.

Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing

to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

How can I get more information about this study?

If you have any further questions about this research study, you may contact the investigators listed at the beginning of this consent form. If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

VOLUNTARY CONSENT

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form will be provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____ _____
Participant's Signature Date Time:

_____
Printed Name of Participant

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol beyond screening was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date

PROXY CONSENT

The above-named individual is unable to provide direct consent for study participation because:

_____

Therefore, by signing this form, I give my consent for his/her participation in this research study.

Representative's Signature _____

Representative's Name (Print) _____

Relationship to Participant _____

Date of Representative's Signature_____ Time: _____

Is Survivor able to sign **assent? _____**

_____ _____
Survivor's Signature Date of Survivor's assent

_____
Printed Name of Survivor

VERIFICATION OF EXPLANATION FOR ASSENT
I certify that I have carefully explained the purpose and nature of this research to the above-named participant in appropriate language. S/he has had an opportunity to discuss it with me in detail. I have answered all his/her questions and s/he provided affirmative agreement (i.e., assent) to participate in this research.

CERTIFICATION OF INFORMED CONSENT BY PROXY
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol beyond screening was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining PROXY Consent/Patient Assent Role in Research Study

_____ _____
Signature of Person ObtainingPROXY Consent Patient Assent Date

CONSENT FOR CONTINUED RESEARCH PARTICIPATION
I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative since I was unable to provide direct consent at the time that this initial consent was requested. I am now able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during the course of this study. Future questions, concerns or complaints will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain

information; offer input; or discuss situations in the event that the research team is unavailable. I agree to participate in this research study and provide my authorization for the use of my medical records.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

_____
Participant Signature

_____
Date

RE-CERTIFICATION OF INFORMED CONSENT AT THE TIME OF RANDOMIZATION

VOLUNTARY RE-CONSENT

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form will be provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- By signing this form after completing the "Run-In" period, I consent to continue participating in this research study and provide my authorization to share my medical records with the research team.

_____ _____ _____
Participant's Signature Date Time:

_____
Printed Name of Participant

CERTIFICATION OF INFORMED RE-CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol beyond screening was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date