Official Title: Implementation and Effectiveness of Engagement and Collaborative Management to Proactively Advance Sepsis Survivorship: A Hybrid Effectiveness-Implementation Randomized Controlled Trial
NCT04495946
IRB-approved Date: 5/6/24

ATRIUM HEALTH WAKE FOREST BAPTIST
Information Sheet for Qualitative Research Interviews and Observation with Nurse Navigators

Sponsor / Study Title:	**National Institutes of Health (NIH) / "A Sepsis Transition Program to Reduce Morbidity and Mortality in High Risk Individuals"**
Protocol Number:	**R01NR018434**
Principal Investigator: (Study Doctor)	**Marc Kowalkowski, PhD**
Telephone:	[redacted]
Address:	**Atrium Health** **1300 Scott Avenue** **Charlotte, NC 28204**

INTRODUCTION

Thank you for agreeing to take part in our qualitative research study about the Sepsis Transition and Recovery (STAR) Program. The study investigators are asking if you would like to take part in a research study so that we may learn more about the services you provide to sepsis survivors and your perspectives on the STAR

program. You are being asked to take part because you are a nurse navigator who provides medical care at Atrium Health as part of the STAR program.

HOW THE STUDY WORKS

The purpose of this study is to assess and understand barriers to and enablers of the STAR program's implementation and to help improve access to sepsis care. If you agree to take part in this study, you will complete multiple one-on-one interviews with a study team member and asked questions about your opinions and experiences with providing sepsis care at Atrium Health. A study member will also observe your telephonic interactions with sepsis survivors during a limited number of half-day shifts (no more than 4 shifts per implementation phase) to help the study team learn more about the navigator's role in the STAR program intervention. The interview and scheduled observations will be audio-taped and later transcribed. The interviews can last between 20-45 minutes and each observation can last up to 4 hours.

RISKS

There are no foreseen physical or psychological risks associated with this study. There may be other risks that are unknown.

BENEFITS

Taking part in this research study may or may not benefit you personally, but researchers may learn new things that will help us to better understand patient, provider, and clinician experiences with sepsis transition services and provide better care for sepsis patients.

ADDITIONAL COST

There is no financial cost to you to participate in this study.

COMPENSATION

If you volunteer to participate in this study, you will receive a $50 debit card upon completion of each key informant (survey based) interview and a $25 debit card upon completion of each ethnographic observation. If you previously completed an interview and/or ethnographic observation and were not reimbursed, you will now receive reimbursement at the rates listed above for your prior participation.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This, too, would not harm your relations with Atrium Health doctors or Atrium Health.

What Other Choices Are There?

You do not have to be in this study. Your alternative is to not participate in the study.

CONFIDENTIALITY:

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00081729
Meeting Date Approved 5/6/2024
Version Valid Until: 5/5/2025

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by the Sponsor, by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What Are My Rights as a Research Study Participant?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because you may no longer be eligible to participate. Information about you may be removed from the study data

and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence. Clinically relevant results regarding the treatment of sepsis survivors will be shared with you at the completion of the study.

FINANCIAL INTEREST OF INVESTIGATOR

None of the doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

WHOM TO CONTACT ABOUT THIS STUDY

For questions about the study or in the event of a research-related injury, contact the study investigator, Marc Kowalkowski at [redacted]. The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted]. You will be given a copy of this consent form.