

Official Title: Adapting a Sepsis Transition and Recovery Program for Optimal Scale-up

NCT05997420

IRB Approval Date: 09/18/2024

## ADAPTING A SEPSIS TRANSITION AND RECOVERY PROGRAM FOR OPTIMAL SCALE-UP (ASTROS)

Informed Consent Form to Participate in Research

Marc Kowalkowski PhD and Sarah Birken PhD, Principal Investigators

### SUMMARY

You are invited to participate in a research study. The purpose of this research is to examine strategies to optimize the Sepsis Transition and Recovery (STAR) program to fit well in other settings. The STAR program was designed to be scalable, and the newly expanded footprint of the Atrium Health (AH) and Wake Forest Baptist Health (WFBH) Enterprise provides a unique opportunity to successfully extend the STAR program and enhance post-sepsis care delivery to a large and diverse population of sepsis survivors. You are invited to be in this study because your perspective makes you a great candidate. Your participation in this research will involve one virtual interview and last about 1 hour.

Participation in this study will involve one interview. All research studies involve some risks. This study poses no more than minimal risk as it is only an interview about your own experiences and beliefs and responses will be kept confidential. You are not expected to receive any direct benefit from participation in this study

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Marc Kowalkowski. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [REDACTED].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED] or the Research Subject Advocate at Wake Forest at [REDACTED]

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

At most 50 people will take part in this study.

## WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

## WHAT ARE THE COSTS?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

## WILL YOU BE PAID FOR PARTICIPATING?

You will be paid \$100 by ClinCard if you complete the scheduled virtual interview.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: name, telephone or fax number, email address, address, and dates.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Marc Kowalkowski, PI that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:



However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

### **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 of schedule conflicts, for example. 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.