Institutional Review Board
Informed Consent Document for Research

Study Title: Addressing Post-Intensive Care Syndrome (APICS)
Version Date: 11/30/18

Part 1 of 2: MASTER CONSENT

Name of participant: _____ Age: _____

You are being invited to take part in a research study (by "you" we are referring to "you" the patient here and throughout the consent form and NOT your family member or surrogate). This study is a multi-site study, meaning it will take place at several different locations which include Vanderbilt University Medical Center, Johns Hopkins Medical Center, Beth Israel Deaconess Medical Center, Intermountain Medical Center, and the Salt Lake City Veterans Affairs Medical Center. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you. Note that this study is being funded by the United States Department of Defense.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

What is the purpose of this study?

You are being asked to take part in this research study because you are a survivor of critical illness and as such, you may experience unique challenges that we hope to better understand. After patients who have been in an intensive care unit (ICU) are discharged home, they continue to experience medical needs, such as medications, medical equipment, and ongoing care. We currently understand very little about the first weeks and months after hospital discharge. This study hopes to understand what needs and events occur for patients and their families in the first weeks to months after hospital discharge.

Approximately 200 people will take part in this study at 5 sites across the United States.

Please read this form and ask any questions you may have before you decide whether to be in this research study.

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What will happen and how long will you be in the study?

- ☑ **We will ask you to sign this form.** If you are eligible to participate in this study, the study team will give you (or your representative, if you are unable to decide for yourself) information about the study. You will have plenty of time to think this over and ask any questions. If you decide to join the study, we will ask you to sign this form. You will get a copy to keep for yourself. If a family member has signed you up for this study, we will check with you during the study to see if you would like to continue.

- ☑ **We will speak with you directly.** We will ask how to reach you and some of your family members and/or friends, so that we can remain in contact with you after you leave the hospital. This information includes, for example, names, addresses, phone numbers, and email addresses. We will confirm this information at the time you leave the hospital. Your contact information will be stored to contact you for involvement in future studies if you consent to it. We will also ask you questions about your general health before this hospitalization.

- ☑ **We will review your medical record.** While you are in the hospital, we will check your medical records to see how you are doing. We will collect information like your demographic information (including your date of birth), your medical history including use of alcohol, tobacco or other substances, your test results and vital signs, dates of medical treatments, your health insurance information, and how long you stayed in the hospital. We will confidentially and securely collect relevant personal information so that we can check national registries for your vital status at the end of the study. This may involve checking your medical record as needed for the entire length of the study.

- ☑ **We will talk with your doctors.** We will inform your doctors about your being in this study. Your doctors will decide on your actual treatments based on your needs. We will check in with your doctors and nurses to understand treatment plans, to see how you are doing, and to learn when you might be ready to leave the hospital.

- ☑ **We will check in with you by phone.** After you leave the hospital, we will call you on the phone to see how you are doing and feeling. Study personnel from John Hopkins Medical Center will be making the phone calls. They will contact you at three different times: the first time is 1-4 weeks after you leave the hospital, the second time is 3 months after you leave the hospital, and the last time is 6 months after you leave the hospital. These calls will try to understand how you're doing, how you're adapting to life after the hospital, and what your treatment plans are. Some participants may receive a separate call (from study personnel at Vanderbilt University Medical Center) at some point during the first 6 months to discuss these questions in greater detail. That

telephone interview may be recorded if you agree to the recording; if you are unavailable, we may interview your family member or surrogate.

Side effects and risks that you can expect if you take part in this study:

There are no physical risks to you, but it is possible that some of the questions we ask you might make you uncomfortable or embarrassed. You do not have to answer any questions that you do not wish to. We will do everything we can to protect your personal information, but there is a slight chance that a loss of privacy or confidentiality could occur, as in any study.

Risks that are not known:

We do not anticipate any unknown risks related to being in this study.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study include a better understanding of how to meet the many needs of ICU survivors more effectively.

We don't anticipate that participating in this study will benefit you directly.

Other treatments you could get if you decide not to be in this study:

This is not a treatment study – if you decide not to participate, there are no alternative treatments.

Reasons why the study doctor may take you out of this study:

You can be taken out of this study if your site investigator and your study team believe it is no longer in your best interest to participate. You will be notified if this is the case. We do not anticipate this happening.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. This is your choice and there are no negative consequences that will occur.

Confidentiality:

Data collected as part of this study will be carefully protected using a range of different methods. We will store paper copies of data in locked cabinets which are in locked offices and only a limited number of people will have access to these. Electronic data will be stored in a password protected database. Identifiers will not be used – instead, codes will be used in place of names to ensure confidentiality.

Your study hospital may share your information, without identifiers, to others or use it for other research projects not listed in this form. Data – including your contact information and related identifiable information - will be shared as needed to perform the study with study personnel at the sites that are partnering to conduct this study – Vanderbilt University Medical Center, Johns Hopkins Medical Center, Beth Israel Deaconess Medical Center, and Intermountain Medical Center. The Department of Defense, your study hospital, your study doctor, and your study team will comply with any and all laws regarding the privacy of such information. In particular, the Department of Defense will have access to all study records, including identifiable information, as a function of providing funding for the study. As part of overseeing the study, the Federal Government Office for Human Research Protections and the Vanderbilt University Medical Center Institutional Review Board may also need to review your information. There are no plans to pay you for the use or transfer of your information. Note that, in order to comply with regulations and local policies, some of this information about data confidentiality may be reported in Part 2 of this consent form.