INDIANA UNIVERSITY INFORMED CONSENT STATEMENT

Mobile Critical Care Recovery Program (m-CCRP) for Acute Respiratory Failure (ARF) Survivors

You are invited to participate in a research study of patient health after being discharged from intensive care. You were selected as a possible subject because you have recently been a patient in intensive care. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is led by Dr. Babar Khan, Department of Medicine. Dr. Khan is an Intensive Care Unit (ICU) doctor who specializes in the care of critically ill patients. He is a research scientist at Indiana University School of Medicine. The study is funded by the National Institutes of Health.

STUDY PURPOSE

The purpose of this study is to evaluate the impact of a recovery program on quality of life of ICU survivors and their family members who might assist an ICU survivor. The information you will provide can help determine the well-being and preparedness of people who may provide assistance to ICU survivors as they recover after critical illness.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of 620 people who will be participating in this research. Your participation will last for 1 year.

PROCEDURES FOR THE STUDY:

If you agree to be in the study you will do the following things:

A. All participants will have: 4 individual appointments with project personnel. The first appointment may take place in the hospital or in your home or other public meeting place such as a library, coffee shop or doctor's office or by phone. The second appointment will happen about 3 months from now, the third appointment will happen about 6 months from now and the fourth appointment will be about 12 months from now. Each of these follow up appointments will take place in your home or other public meeting place or by phone. The questionnaires could be modified if you are not able to complete them all These appointments include:

    1. Thinking and memory activities
    2. Questionnaires about your mood, memory, health, medications and daily activities
    3. Measurements of height, weight, blood pressure, muscle strength, and stepping and walking

    At the first appointment, we will also ask you to provide background information about yourself - things like age, race, ethnicity and education.

    These appointments take about 1½ - 2 hours to complete, and may be split into two sessions if needed.

B. You will have additional appointments that will depend on your study group assignment. This research compares two different types of patient care. Patients and their caregivers who agree to participate will be assigned to one of two groups. This assignment is random and will be done like flipping a coin. Group A will receive care from a care coordinator who is a Registered Nurse who works with the patient and his or her caregiver at home or other public meeting place such as a library, coffee shop or doctor's office. Group B will receive regular phone calls from project personnel to discuss their health and will be directed to local health care resources.

You will be assigned to one of the 2 groups below and will do these additional things depending on your assigned group:

Group A - nurse care coordinator visits

1. Answer questions about your mood, memory, health, medications and complete measures of muscle strength
2. Complete 18 interviews over the course of 12 months, every 2 weeks for the first 6 months, then every month for the following 6 months
3. The initial interview, month 3, month 6 and month 12 interviews with the Care Coordinator will happen in your home, with follow up interviews at home or on the phone. The interviews will take approximately 10 to 90 minutes.

Group B - project personnel phone contacts

1) Answer questions about your mood, memory, health, and medications
2) Complete 18 interviews over the course of 12 months. Interviews will be telephone based and will take approximately 5 minutes.

If you agree to participate in this study, you may be asked to participate in a second study for patients hospitalized for critical illness. This study, Examining Neuropsychiatric Disorders in Survivors of COVID-19 Related Critical Illness (EN-COV), is led by the same investigators and contains some of the same procedures and study visits. *Participation in EN-COV is optional, and all information will be presented in a separate informed consent document.* If you choose to participate in EN-COV, your data will be shared across the two studies, so study visits and procedures will not be repeated.

RISKS OF TAKING PART IN THE STUDY:

This study involves minimal risks. While on the study, the potential risks are:

Risk of loss of confidentiality: Our study team makes every effort to ensure all information collected about you remains secure and is viewed only by study personnel, but we cannot guarantee absolute confidentiality. The exceptions are if you are about to harm yourself or others if the law requires we make information known.

Risk of being nervous or anxious during the interview: It is possible that some of the study questions could make you uncomfortable or anxious. The care coordinator who will be asking the survey questions is trained to recognize and minimize this discomfort.

You may skip any questions you do not want to answer. You may stop the interview at any point or ask the care coordinator to contact you later.

BENEFITS OF TAKING PART IN THE STUDY:

You may not benefit directly from participating in this study. However, if you are found to have stress related symptoms, appropriate referrals will be provided. We hope that this research will interest you and help provide a better understanding of the impact of a recovery program on ICU survivors and their caregivers. You may learn more about patient's health and what to expect in the future. You may learn how to handle day-to-day problems in caring for the patient. This may also assist with the future care of an ICU survivor or loved one.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you have these options: If you decide not to participate in this study it will not affect your relationship with your physician. It will not affect the care you or your loved one receives from your physician. You will continue to receive the usual medical care.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which the results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, the National Institutes of Health (NIH), and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), etc., who may need to access your medical and/or research records.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information shared. Since identifying information will be removed, we will not ask for your additional consent.

COSTS

There is no cost to you for participating in this research study.

PAYMENT

You will receive payment for taking part in this study. You will receive a $10 gift card after the 3 month interview is complete. You will also receive a $25 Kroger gift card after completing your 6 month interview and another $25 Kroger gift card after completing your 12 month interview. If you complete all interviews, you will have received $60 in Kroger gift certificates.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is

no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research, which is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher Dr. Babar Khan at (317) 274-9132. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949. After business hours, please call at (317) 630-8000.

In the event of an emergency, you may contact the Eskenazi Health Connection 24-hour phone line at (317) 655-2255 or the Emergency Department at (317) 630-7532.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Eskenazi Health Services or Indiana University Health.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject received study recruitment packet:_____ **Date:** _____
Research Assistant's Initials)

Subject's Printed Name:_____

Subject's Signature:_____**Date:** _____
(must be dated by the subject)

Printed Name of Legally Authorized Representative (LAR):_____

Signature of LAR:_____**Date**:_____

Receipt of Signed Study Enrollment Documents:_____ **Date:**_____
(Research Assistant's Initials)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent:_____**Date**:_____