Project Title: Effect of alcohol and drugs of abuse on immune function in critically ill patients with respiratory failure

Principal Investigator: Ellen Burnham, MD

Information Sheet

In this form, we use the words 'you' and 'your'. If you are reading this form and deciding for the patient, the words 'you' and 'your' refer to the patient, not you.

You are getting this form because you are a part of this research study at the University of Colorado Hospital. This study plans to learn more about patients who have respiratory failure, or an inability to breathe on their own without the help of a ventilator (breathing machine). The research team may have already collected blood, urine, breath, hair, or lung fluid based on your condition. Due to your impaired ability to make decisions for yourself while in the ICU, this collection of samples was authorized by COMIRB, the agency which oversees research projects at the University of Colorado and other hospitals. The opportunity for these samples would have passed by the time you could approve their collection. Now that you have regained your capacity to make your own healthcare decisions (or if not, this form is given to your loved one), we are explaining our research project to you and giving you the option to opt-out of participating in our research study.

You fall into one of these two categories: Either you are a patient who is in the ICU because you are having difficulty breathing on your own, or you are a patient who is in the ICU and cannot breathe on your own (respiratory failure). If you cannot breathe on your own, you may be on a mechanical ventilator, or a machine that helps you breathe.

This study will allow us to get information on how your body is reacting to the medical condition or breathing problem that you have, and how this might be affected by different levels of hormones and infection mediators present in your blood, urine, nose, and in your lung fluid. We are collecting these items after you have been diagnosed as having respiratory failure, or the inability to breathe on your own. The reason for your respiratory failure and your overall medical condition will determine what types of fluid we collect from your body.

1. Data:

We will collect data about you, including information regarding your current and past medical and surgical history, social history, including any use of alcohol, cigarettes, and drugs (prescription or otherwise) and current laboratory information. We will collect information about the medicines you are receiving while in the hospital. All of this information will have already been collected by your doctors as part of your medical care or from a study questionnaire that family members completed.

2. Blood:

We will always collect blood through an IV or arterial line that has already been placed as a part of your routine clinical care in the ICU. If no IV or arterial line is present, we will not perform a blood draw while you are in the hospital.

Blood draws will occur soon after you are diagnosed with respiratory failure, then again 3-5 days later, and finally 8-10 days later. This is a total of 3 blood draws during your hospital stay. Each blood draw will remove 1-2 teaspoons of blood, for a total of approximately 3-6 teaspoons of blood.

3. Urine:

While you are hospitalized, urine collection will be performed via an indwelling catheter that has been specifically placed for this purpose. Urine will be collected soon after you are diagnosed with respiratory failure.

4. Lung fluid:

If you are on a breathing machine, your doctors may decide to perform a procedure known as bronchoscopy that is done with a special scope known as a bronchoscope. In this procedure, ½ cup of salt water (saline) is used to wash out part of the lungs and suctioned back through the bronchoscope into a container. If your doctors perform this test before the third day after you are diagnosed with respiratory failure, we would like to use a small amount of the fluid they collect that is not being used for clinical purposes. This will only occur once.

5. Tracheal Aspirate:

If a licensed respiratory therapist performs a tracheal aspirate as a part of your routine care, we will collect a leftover portion of this sample. While you are receiving oxygen from the ventilator, a sterile catheter is inserted into the endotracheal tube (breathing tube) and approximately 1 tablespoon of sterile saline is placed inside and immediately aspirated (sucked back out) out of the breathing tube into a sterile container. Some of this sample will be used as a part of your routine care, and the leftover portion will be given to the research team. This will only occur once.

6. Nasal brushes:

If you are on a breathing machine, we would like to obtain a small sample of the cells that line the inside of your nasal passage. In this procedure, a sterile, soft brush will be inserted into one of your nostrils, and the inside of your nose brushed in a circle. This process will be repeated in the other nostril with a new brush.

The risks of nasal brushings include eye tearing, runny nose, and bleeding from the nose.

Taking the samples from you will not change your care in any way.

After you regain the ability to make decisions for yourself, you may be invited to continue to participate with visits to the clinic after you are discharged from the hospital.

You will be paid for the optional follow up visits. If you do not want to come back for the optional outpatient visits, you may still participate in the study during your hospital stay.

If you receive outpatient care at the UCHealth-AMC ICU recovery clinic, we will review your medical records 12 months after you leave the hospital to see how much you have recovered during this time.

We will do everything we can to keep your records a secret but it cannot be guaranteed. We might talk about this research study at meetings. We might also print the results of this research in journals. But we will always keep the names of research subjects, like you, private.

This study is funded by the National Institutes of Health and data gathered may be used to develop a commercial product.

Participation in this study is voluntary. If you do not want your samples to be collected or if you do not want the samples we already collected from you to be used for the study, please tell your nurse or doctor or contact the study coordinator or investigator at the number below. The study coordinator or investigator will then remove you from the study. If you are removed from the study, your samples will be no longer used, and all data and samples collected from you will be destroyed.

If you have questions, concerns, or complaints later, you may call the principal investigator Ellen Burnham, MD at 303-724-6078 or the study coordinator Carrie Higgins, RN at 720-848-4210. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. If so, you can call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055.

If you **agree to continue** in this research study, you don't have to do anything. If you do not opt-out of the study, collected data, specimens and tissue as well as information from your medical record will be analyzed as a part of our research protocol.

If you **do not agree to continue** in this research study, please tell your nurse or doctor to contact the study coordinator or principal investigator so that you may be removed from the study.

Patient Name: _____

Patient Date of Birth: _____

_____ Opt-Out: I do not want to participate in the study and wish to have my data, specimens and tissue destroyed.