Project Title: Burn Trauma and Infection: Mechanisms by which inhalation injury exacerbates burn injury-induced pulmonary pathology

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 how individuals respond to burn or trauma during the first 72 hours after injury and during the next eight to ten days after injury. You were enrolled in this research study because you have a burn injury and may need to be on a breathing machine for at least 48 hours**, or** you are admitted to the intensive care unit but are not on a breathing machine. The research team may have already collected blood, lung fluid and stool based on your condition. The opportunity for these samples would have passed by the time you could approve their collection. Once you regain your capacity to make your own healthcare decisions we are explaining our research project to you and asking for your written consent to participate and allow us to keep and use the data and specimens collected. If you do not regain your decisional capacity, this form is given to your loved one, giving them the option to opt-out of participating in our research study on your behalf.

You are a patient who is in the ICU because you have a burn injury. You may have difficulty breathing on your own due to smoke inhalation, or just from your injury itself. You may be on additional oxygen. 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 in your blood, stool, 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 been placed as a part of clinical care. If no IV or arterial line is present, we will not perform a blood draw.

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. Each blood draw will remove 1-2 teaspoons of blood, for a total of approximately 3-6 teaspoons of blood.

3. Stool collection:

We will collect about 1/3 teaspoon of stool within the first 24 hours of your admission to the ICU. The stool will be collected during routine cleaning and bathing of you by staff. This procedure may be repeated up to two times for a total of <2 teaspoons stool over 10 days.

4. Lung fluid:

As a part of your clinical care, 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. This procedure is done to look at the inside of the lungs and also to obtain specimens from inside the lungs. 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 you have been on the respirator, we would like to use a small amount of the left-over fluid they collect. We will collect this left-over fluid only once.

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 303-724-6069 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.