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

Principal Investigator: Dr. Ellen Burnham
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You are being asked to continue to participate in a research study in which you have been enrolled while a patient in the ICU at the University of Colorado Hospital. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

While a patient within the ICU, you were incapacitated by your condition (you could not make medical decisions for yourself). Your enrollment in this research study was permitted in part by COMIRB (the organization that oversees research projects at the hospital according to Federal regulations). Now that you have regained the ability to make your own medical and research participation decisions, we are asking you to consent to *continue* your participation in the study.

Your consent to continue to participate in this study is necessary if the researchers are to continue. If you refuse to continue to participate, you will be removed from the study, your samples will be no longer used, and all data and samples collected from you will be destroyed.

Why is this study being done?

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 are being asked to be 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.

Certificate of Confidentiality

A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. But, if you request disclosure, we can release the information.

Initials_____

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).'

Other people in this study

Up to *125* people from your area will participate in the study. Up to *250* people around the country will be in the study.

What happens if I join this study?

You may have already had samples of blood, lung fluid, , and stool, collected from you. Those samples include:

1. Leftover lung fluid-within the first 24 hours of admission to the ICU, you may have had a bronchoscopy procedure done as part of your standard of care. A bronchoscopy procedure involves placing a thin scope into your lungs and washing areas of your lungs with saline. The saline was suctioned from the lungs and sent to the hospital laboratory for analysis. This procedure may be repeated throughout your ICU stay if your ICU doctor thinks it is medically necessary. For this research study, we will collect the leftover lung fluid that would normally be thrown away. If you are not on a breathing machine, we will not collect leftover lung fluid unless you are scheduled for a bronchoscopy procedure for standard of care.
2. Blood collection-we will collect about 1 teaspoon of blood within the first 24 hours of your admission to the ICU. The blood will be drawn from a line that you already have placed in one of your veins or arteries. This procedure may be repeated up to two times for a total of about 3 teaspoons over 10 days.
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. Data collection-we will also collect information from your medical record related to your burn injury. We will review and collect information about you and your burn injury from the medical record until you are discharged from the hospital.
5. We would like to ask you questions about your use of alcohol, tobacco, and other drugs (both legal, prescription drugs and illegal drugs) using specialized questionnaires designed for this purpose. If we learn information that is important to your care but that is not already in your medical chart, we will alert your doctors but we will not share this information with anyone else. The surveys will take approximately 30 minutes to complete.

Your participation in this research will last until you are discharged from the hospital.

 Initials_____

What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

Risks from leftover lung fluid:

There is no risk to you from collecting the leftover lung fluid from a standard of care bronchoscopy procedure.

Risks from blood collection:

The blood collected for this study will be drawn from an existing line in one of your large veins or arteries. There is no risk associated with this procedure.

Risks from stool collection:

There is no risk associated with stool collection procedure.

Risks from survey questionnaires:

Completing questionnaires related to alcohol, tobacco, and drug use may cause discomfort to some people. There is a risk of discovering information from completing questionnaires that may have an effect on your later health. If we discover that you have a problem with alcohol or drug use, we can help you with names and telephone numbers of agencies that may help alleviate your concerns, or may be able to address your needs through talking with your doctors.

Risks from data collection:

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about burn injuries that may include inhalation injuries.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored by the National Institute of Health (NIH).

Initials_____

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Ellen Burnham immediately. Her phone number is *(303) 724-6079.*

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Ellen Burnham. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Burnham at (303) 724-6079. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Burnham with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Initials_____

Optional Consent and Authorization for Data and Specimen Banking for Future Research

Dr. Burnham would like to keep some of the data, blood, BAL fluid, and stool that are taken during the study but is not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about burn injuries or lung injury. The research that is done with your data and samples is not designed to specifically help you. It might help people who have burn injuries or lung injuries and other diseases in the future. Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Burnham keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want Dr. Burnham to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Burnham decides to destroy them.

When your data and samples are given to other researchers in the future, Dr. Burnham will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes data and samples are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and samples include learning more about what causes burn injury, lung injury and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Burnham will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Burnham.

Please read each sentence below and think about your choice. After reading each sentence, circle “yes” or “no.” If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and samples, you may still take part in the study.

Initials_____

I give my permission for my data, blood and other samples to be stored in a central tissue bank at The University of Colorado Denver for future use by the study investigators:

1. I give my permission for my data, blood and other samples to be kept by Dr. Burnham for use in future research to learn more about how to prevent, detect, or treat lung diseases.

   ☐ Yes ☐ No _____Initials

2. I give my permission for my data, blood and other samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

   ☐ Yes ☐ No _____Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

   ☐ Yes ☐ No _____Initials

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital
- Loyola University Chicago

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary

Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Ellen Burnham
University of Colorado Denver
Division of Pulmonary Sciences & Critical Care Medicine 12700 E. 19th Ave.; C272
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- People at the Colorado Multiple Institutional Review Board (COMIRB)
- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you
- The study doctor and the rest of the study team.
- *NIH,* who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Alcohol and smoking survey questions
- Alcoholism, Alcohol or Drug abuse
- Tissue samples and the data with the samples.

What happens to Data, Blood and Specimens that are collected in this study?

Initials_____

Scientists at the University of Colorado Denver and the hospitals involved in this

study work to find the causes and cures of disease. The data, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, blood, or other specimens are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and blood, or other specimens collected from you.
- If data, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures – In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Initials_____

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness: _____ Date_____

Witness Printed Name:_____

Witness of Signature □

Witness of consent Process □

Witness: _____ Date_____

Witness Printed Name:_____

Witness of Signature □

Witness of consent Process □

Initials_____

Initials_____