COMIRB
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Study Title: CPARC: Colorado Pulmonary Alcohol Research Consortium

Principal Investigator: Dr. Ellen Burnham
COMIRB No: 12-0181
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Subjects

You are being asked to be in a research study. 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.

Why is this study being done?

This study plans to learn more about what heavy alcohol drinking does to the lungs.

People who drink too much alcohol appear to be at a higher risk for getting a bad lung condition known as the *acute respiratory distress syndrome*, or "ARDS". ARDS is a disease that affects people's lungs after a bad illness, such as a lung infection or other infection. People who drink too much have a higher likelihood of getting a lung infection, particularly a severe lung infection, and this might be part of the reason they often will develop ARDS.

People who drink too much alcohol have lungs that work differently than the lungs of people who don't use alcohol. Some of the cells inside the lungs that are important for fighting infections do not work well. Also, there are smaller amounts of natural substances which keep the lungs healthy. The thin layer of cells that keeps the inside of the lung dry may become leaky in people who drink too much alcohol. Alcohol is also toxic to bone marrow which may result in a decreased number of circulating primitive cells. All of this may explain why people who drink too much alcohol can get the lung disease ARDS. They may also explain why people who drink too much alcohol get lung infections more often.

You are being asked to participate in this study because you drink too much alcohol.

Other people in this study:

Up to *260* people from your area will participate in the study.
Up to 250 participants will be included in the control group

What happens if I join this study?

This study has two parts, Part 1 and Part 2, with all subjects screened to be in Part 1 of the study. 25 people will be in Part 2 of the study.

If you join this study, you will have the following procedures performed:

Part 1:

a. You will be asked to answer a survey that will include questions about your medical history, alcohol history, smoking history, and drug use history. There will also be questions about any troubles or concerns you have with getting health care. It will take 45 minutes for you to answer all the questions.
b. Blood sampling: Approximately 6 teaspoons of blood will be drawn to determine eligibility for the bronchoscopy portion of the study, to evaluate the primitive, or immature cells in your circulation, and to measure specific compounds that can indicate how healthy your body is to fight off lung diseases, such as infections and ARDS
c. Exhaled breath condensate (EBC): Another type of sample we will collect is called exhaled breath condensate, or EBC. EBC is the water vapor that you exhale as a normal part of breathing, and can give researchers an idea of what might be going on inside of the lung. To collect EBC, we will have you breathe through a mouthpiece into a small tube that will collect the water vapor in your breath. We will collect this for 10 minutes.
d. Urine sampling: Approximately ½ cup of urine will be collected to determine your eligibility for the bronchoscopy portion of the study and to evaluate proteins that may be seen if kidney damage is present. If you are a woman, you will have urine pregnancy test done before the chest x-ray, and will not be enrolled in the study if this test shows you are pregnant.
e. Chest X-Ray and Pulmonary Function Testing: the pulmonary function test is a breathing test that measures how fast air moves in and out the lungs. This will show us that your lungs work normally. The chest x-ray will assess for any abnormalities in the lungs. Both the chest x-ray and breathing test are done as an extra safety precaution before the bronchoscopy procedure.
f. Nasal Epithelial Brushing
Nasal epithelial brushing will be performed by placing a small, sterile cytology brush into each nostril, with your head slightly tilted back. The brushes will be rotated in a circle against the side of your nose to collect a small sample of cells with slight pressure will be applied to the nostril walls. The entire brushing procedure will last no longer than 5 seconds in

each nostril.

All of the above tests will take approximately 3 hours to complete and will be performed at the University of Colorado Hospital. If any of these tests are not normal, you will not be asked to continue in this study. We will make sure you have a follow up appointment with a doctor that can take care of the problem(s)

That is there. If the above tests are normal and you are being recruited from Denver CARES, you will spend the night in the hospital and have a bronchoscopy in the morning. If you are not being recruited from Denver CARES, you will have all portions of the study including the bronchoscopy performed in a single day and not spend the night. Regardless of where you are recruited from, we will watch you on the CTRC for signs of alcohol withdrawal, such as anxiety, high blood pressure, shakiness, or fever. One of the CTRC nurses will visit with you at regular intervals, and may offer you a medication commonly used for alcohol withdrawal if you have signs and symptoms of this. If you choose not to take part in the bronchoscopy portion of the study, the survey, blood sample, EBC, and urine sample can be collected at Denver CARES.

g. Bronchoscopy: The bronchoscopy test **must** be done at the University of Colorado Hospital CTRC. A separate consent form (other than this one) will need to be signed by you for the bronchoscopy. Before starting, your heart rate, blood pressure, breathing rate, and level of oxygen in the blood will be measured. You should not have eaten at least 6 hours prior to the procedure. You should not have had any alcohol to drink 24 hours before the procedure.

A small plastic catheter (IV) will be placed in a vein in your arm, and about one tablespoon of blood will be collected. The catheter will be taped into place. If you have not had exhaled breath collected already at Denver CARES, we will collect it before the bronchoscopy. Also, we will collect some of the saliva in your mouth by having you gargle for a total of 60-seconds with 2 tablespoons of salt water. After you gargle, we will have you spit the salt water into a cup.

A numbing medicine known as lidocaine will be sprayed in the back of your throat and inside of your nose. This is done to prevent coughing and discomfort. A small amount of relaxing medicine may be given through the IV catheter to help to comfort you as well. The relaxing medicines we commonly use during this procedure are called Midazolam (Versed) and Fentanyl. Many patients find that they do not remember the procedure being performed after receiving these medicines. You may fall into a light sleep after the medicine has been given. You should wake up easily if your name is called. The medicine starts working in about 5 minutes and lasts in your body for about one hour. These medicines can lower your blood pressure and cause your breathing to slow. We will watch your blood pressure and level of blood oxygen through the whole procedure. This is to make sure you are safe.

A bronchoscope is a thin tube with a camera to see your lung. This tube will be passed through your nose and into a part of your lung. It will be held steady in a part of your lung. First, we will use up to three soft, flexible brushes that we will insert one at a time through the bronchoscope to gently scrape off cells from

inside your lung. Once we have brushed the inside of your lung, we will remove the brushes. Next we will inject 1½ ounces of sterile salt water (saline) through

The bronchoscope into the lung. This may be done up to six times. The salt water be immediately taken out through the bronchoscope and collected in a container.

The total amount of time it will take from start to finish for the bronchoscopy procedure is about four hours. Most of this time will be spent making sure you are ready and comfortable for the procedure. The actual procedure takes about 20 minutes. You will be watched for about one more hour after the procedure and then discharged when you are fully awake and stable.

A responsible person must be available to drive you home. You will not be allowed to operate a car or heavy machinery after the procedure until the following day. If you do not have a ride, we will allow you to spend an additional night in the CTRC.

Study participation in Part 1 will last approximately 48 hours.

Part 2:

A small number of people will be asked to have a second bronchoscopy performed to help the researchers observe the effects on the lungs after 7 days of not drinking alcohol. If you participate in Part 2 of the study, you will be admitted to the CTRC at the University of Colorado Hospital for up to 9 days. In order to see if you qualify for this part of the study, we will review your complete medical history, and review your chest x-ray, routine blood work and drug screening, and measurements to see how well air moves in and out of your lungs (spirometry) that you have already completed for Part 1.

All procedures in Part 1 will be performed including a bronchoscopy on the day after you are admitted to the hospital (Day 0), and again on Day 8. After you leave the hospital, we will call you, 48 to 72 hours following your second bronchoscopy to ask how you are feeling. If you have complications arising from the second bronchoscopy, the investigators will direct you to appropriate care if necessary.

While you are in the CTRC, we will do blood tests on the day of each bronchoscopy and also on Day 4 of your stay. You will not be able to leave the hospital during this study. You will also not be able to smoke and must remain sober for 9 days while you are enrolled in this study.

Total study participation for Part 2 will last up to 11 days, including the time after you leave the hospital and we call you to see how you feel.

A responsible person must be available to drive you home on Day 8. You will not be allowed to operate a car or heavy machinery after the procedure until the following day. If you do not have a ride, we will allow you to spend

an additional night in the CTRC.

Timeline of Study Procedures

SCREENING DAY= Day 0
Parts 1 and 2
Informed Consent
Screening at Denver CARES
Transport/Admission to UCH CTRC
Blood Draw (Screening lab)
Pulmonary Function Test (PFTs)
Chest X-ray
Urine drug screen

Day 1 (Part 1 and 2)
Survey
Blood Draw (research)
Exhaled Breath Condensate (EBC)
Urine Collection (research)
Nasal Brushings
Bronchoscopy ($250)

Night 0: Parts 1 and 2

Night 1: Part 2 only $100

Day 2 (Part 1)
CTRC Discharge **(Part 1 only subjects)**

Day 2 - Part 2 only
CTRC admitted inpatient stay

Night 2: Part 2 only $100

Day 3- Part 2
CTRC admitted inpatient stay

Night 3: Part 2 only $100

Day 4- Part 2
CTRC admitted inpatient stay
Blood Draw (research)

Night 4: Part 2 only $100

Day 5 - Part 2
CTRC admitted inpatient stay

Night 5: Part 2 only $100

Day 6 – Part 2
CTRC admitted inpatient stay

Night 6: Part 2 only $100

Day 7 – Part 2
Blood Draw (research)
Bronchoscopy ($250)

Night 7: Part 2 only $100

Day 8 - Part 2
CTRC Discharge

Day 9-11 - Part 2
PI follow up phone call to subject

What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

Risks from Bronchoscopy: Overall, the risks for the bronchoscopy procedure are very low. Some patients do find the procedure uncomfortable. During the procedure, you may experience some coughing and a sensation of difficulty breathing. In the 24 hours following the procedure, fever is possible 8% of the time. The following have been reported less than 1% of the time: bleeding in the lungs, severe difficulty breathing or bronchospasm, and death. From the sedating medication alone, you may experience: momentary fall in blood pressure (5%), slowing of the breathing rate (10%), nausea and vomiting, headache, or hiccoughs (each less than 5% of the time). The numbers given in parentheses are the chance that that complication could happen to you. No long lasting effects on memory have been reported from this medication. Possible harmful side effects from the medication that have been noted less than 5% of the time include: hiccoughs, nausea, vomiting, coughing, headache, drowsiness, acute shortness of breath, heart problems (low blood pressure), and allergic reaction, such as itching. If you get medications for alcohol withdrawal symptoms, these may cause sleepiness (less than 10% of the time), low blood pressure, or allergic reactions (each less than 5% of the time).

Risks of lidocaine: There is a rare risk of an allergic reaction to the medication... If you have a known allergy to lidocaine, we will not use any lidocaine.

Risks from pulmonary function testing: You may experience a feeling of lightheadedness from breathing through the spirometry tubing. Also, there is a rare but serious risk of a collapsed lung (less than 1%).

Risks from completing survey: There are no known risks to filling out this survey.

Risks of having blood taken: In this study we will need to get about 6 teaspoons of blood from you. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

Risks of having urine taken: There are no known risks to providing a urine sample.

Risks of having an IV inserted into your vein: In this study we will insert a needle, connected to a plastic tube, into a vein in your arm. We will use the tube to take blood samples or give you fluids. You will feel some pain when we first insert the tube into your vein. You may have some redness, swelling, or bruising where the tube goes under your skin. In some cases, this type of tube can cause

an infection where it goes under the skin. In rare cases, it can cause a blood clot in the vein. You will have this tube inserted for less than 24 hours.

Risks from exhaled breath condensate (EBC) collection: You may experience a feeling of lightheadedness after breathing through the EBC collection tube for a few minutes. There are no other known risks of this procedure.

Risks from a chest x-ray: As part of this study we will perform an X-ray of your chest. X-rays are a type of radiation. Your natural environment has some radiation in it. This series of X-rays will give you about the same amount of radiation that you would get from your environment in 2 days.

Risks from nasal brushing: There is a minor risk of tears in your eyes, nose running and rare nose bleeding. We will not perform this procedure if you have a known risk of bleeding.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about alcohol and the lung. This study is not designed to treat any illness or to improve your health. The procedures may help you in earlier detection of a disease. The procedures used in this study are not available outside of research studies.

If you decide to take part in this study, there is no promise that your health will improve. Also, there are risks as mentioned in the Discomforts and Risks section above.

Who is paying for this study?

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

Will I be paid for being in the study?

For Part 1, you will be paid up to $250 for the bronchoscopy, in the form of supermarket gift cards for your participation in the study. Subjects who decide to not have the bronchoscopy test performed and who have all sampling performed at Denver CARES will receive $ 25 in the form of supermarket gift cards. The gift cards will not be able to be used for the purchase of alcohol or tobacco. If you do not qualify for the bronchoscopy test but complete other screening tests at the University of Colorado Hospital CTRC, you will be compensated for your time with a $25 supermarket gift card.

If you are in both Part 1 and Part 2 of the study, you will be paid $250 for each bronchoscopy and $100 for each night that you spend in the hospital, beginning on Night 1. You will not receive $100 for Night 0. This will add up to a total of

$1200 if you complete all of the visits. All payments will be in the form of supermarket gift cards for your participation in the study. If you leave the study early, or if we have to take you out of the study, you will be paid only for the first bronchoscopy.

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. This would be done if he or she thinks that being in the study may cause your harm, or for any other reason. Also, the sponsor may stop the study at any time.

It is your choice to decide to take part in this study. If you do take part in it and are currently being housed at Denver CARES your release date from Denver CARES or general living conditions will not change. If you decide not to take part, or decide to stop being in the study, your release date from Denver CARES, or general living conditions will not change either.

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 later, you may call Dr. Burnham at (303) 724-6079. A Research Subject Advocate is also available on the Clinical Translational Research Center at 720-848-6662 to answer questions relating to participation in this study. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, please call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055 or, CTRC Advocate at (720) 848-6662.

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
- Denver Health and Hospital Authority

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
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.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.

- *The National Institute of Health (NIH)* who is the agency 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.
- Your social security number
- 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
- Alcoholism, Alcohol or Drug abuse

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

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, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The 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 blood, or other specimens collected from you.
- If 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.

If you decide to take part in this research study, you will be required to give us information about your alcohol abuse. We have obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH). The CoC is issued to protect the investigators on this study from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. This protection will not apply until we have obtained the CoC, which may take a few weeks.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the CoC to withhold this information.

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.

☐ I will participate in **Part 1 of the study**, **including the bronchoscopy part**, which will be done at the University of Colorado Hospital CTRC. I understand that this requires me being transported from Denver CARES to this facility. I will also complete a survey, have blood, urine, and exhaled breath collected.

☐ I was asked by the study team and will participate in **both Part 1 and Part 2 of the study**, **including the bronchoscopy** parts, which will be done at the University of Colorado Hospital CTRC. I understand that this requires me being transported from Denver CARES to this facility and requires that I stay there up to 8 days. I will also complete a survey, have blood, urine, and exhaled breath collected.

☐ I will participate in **all parts of the study, EXCEPT the bronchoscopy** part. I understand that all samples and tests related to this study will be collected at Denver CARES. I will still complete a survey, and have blood, urine, and exhaled breath collected.

Subject Signature:_____Date:_____

Subject Printed Name:_____

Study Personnel explaining Consent form (printed name):_____

Date:_____

Study Personnel Signature:_____

Study Personnel Role/Title:_____

Witness signature:_____Date: _____

Witness printed Name: _____

Witness of Signature ☐

Witness of consent process ☐

Optional Consent and Authorization for Specimen Banking for Future Research

The following are additional optional study procedures that you are being asked to consider. You may choose to participate in any, or none, of the following procedures. Your decision to participate, or to not participate, in these additional procedures will not affect your ability to participate in the main study you agreed to above.

I give my permission for my data, blood and tissue 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 permissions for my blood, urine and bronchoscopy 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 permissions for my blood, urine and bronchoscopy 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 collected for these additional procedures?

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

We cannot do these additional procedures 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 take part in these optional procedures.

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 UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality 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 Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in these optional procedures will end and no further information about you will be collected. Your cancellation would not affect information already collected from these procedures.

Dr. Ellen Burnham
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.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- *The National Institute of Health (NIH)* who is the agency 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.
- Your social security number
- 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
- Alcoholism, Alcohol or Drug abuse

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, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The 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 blood, or other specimens collected from you.
- If 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.

Agreement to participate in the additional optional procedures and use my data

I have read this paper about the additional optional procedures above or it was read to me. I have indicated my choice to participate, or to not participate, in each additional procedure above. I understand the possible risks and benefits of these research procedures. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that participation in these additional procedures is voluntary. I choose to participate in these research procedures as I have indicated above: I will get a signed and dated copy of this consent form.

Subject Signature:_____ Date:_____

Subject Printed Name:_____

Study Personnel explaining Consent form (printed name):_____

Date:_____

Study Personnel Signature:_____

Study Personnel Role/Title:_____

Witness signature:_____Date: _____

Witness printed Name: _____

Witness of Signature ☐

Witness of consent process ☐