The University of New Mexico Health Sciences Center
Consent to Participate in Research

A Phase 1, open-label, evaluation of a ^{13}C-urea breath test for the detection of urease-producing bacteria in patients with pneumonia in the emergency department.

April 30, 2018

Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. Justin Baca, MD, who is the Principal Investigator, Dr. Jon Femling, MD and other hospital staff. This research is being done to evaluate the ability of a ^{13}C-urea breath test to aid in screening for pneumonia and selecting appropriate treatment in patients presenting to an emergency department (ED) or urgent care center. You are being asked to participate because you came to a University of New Mexico (UNM) ED (Main or Sandoval Regional Medical Center) with symptoms of pneumonia and are expected to be admitted for treatment. Approximately 60 people will take part in this study at UNM or Henry Ford Health Center in Detroit, MI.

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this Consent Form. <u>You will need to disclose any medical conditions that you may have</u>. After you sign the Consent Form, the following things will happen:

- A sputum sample (mucus from the lungs and respiratory tract) will be collected. A respiratory therapist or other study team member will collect a sputum sample from you. In brief, you will be asked to take several deep breaths and then produce a forceful cough. You will then be asked to cough up sputum and spit into a sample cup. If you have difficulty coughing up sputum, nebulized saline may be used to the loosen secretions and help you produce a sample.
- A swab of your throat will be performed. This sample will undergo microbiome testing that will help the researchers determine what organism or organisms are causing your pneumonia. The results of this testing will not be part of your medical record and will not be shared with the doctors taking care of you in the hospital.
- A pregnancy test will be performed if you are a woman of childbearing age.
- If you are pregnant, you will not be able to participate.
- If you have received treatment in the emergency department with oral or IV antibiotics greater than 4 hours prior to the breath test, you will not be able to participate.
- If you have had a recent mouth infection requiring antibiotics or oral surgery, you will not be able to participate.
- You will be asked to provide several breath samples by breathing into a collection bag and/or a breath capture device (up to six times).

- You will be given a dose of a compound called ^{13}C-Urea through a nebulizer. The ^{13}C-urea solution contains urea, a naturally occurring substance present in the human body, which contains ^{13}C, a non-radioactive form of carbon that has a different weight from the more common form of carbon that is found in all organic matter (^{12}C).
- After the nebulization is completed, you will breathe into additional breath collection bags and/or a breath capture device up to six times over the next 10 minutes.
- Your blood pressure, heart rate, respiratory rate, and oxygen saturation will be recorded at various times while you are receiving the ^{13}C-urea and providing breath samples.
- You will be monitored for a minimum of 20 minutes after nebulization for any adverse symptoms or signs of an allergic reaction.
- Once you are done giving breath samples and a sputum sample, and have been monitored for 20 minutes, you will have completed your participation in the study, and will continue to be treated by the hospital doctors according to standard practices.
- We will contact you 48-96 hours from when you received the breath test by phone (or in person if you are still in the hospital) to see how you are doing.
- We will record the results of any test you have done while in the hospital as well as what antibiotics you receive while in the hospital.

Participation in this study will take a total of 1-2 hours and will not interfere with your normal medical care. We will not delay your treatment for pneumonia or admission to the hospital because of participation in this study.

What are the possible risks or discomforts of being in this study?
Every effort will be made to protect the information you give us. However, there is a small risk of loss of privacy and/or confidentiality that may result in additional personnel having access to your treatment information.

Because this is an experimental test, participation may involve risks that have not yet been identified or foreseen. You will be notified of any new significant findings that may affect your willingness to continue in the study.

Risks associate with nose and throat (oropharengeal) swab may include:
- Mild discomfort (likely risk)
- Cough or sneezing (low risk)
- Epistaxis (bleeding from nose) (very low risk)

Risks associated with receiving the ^{13}C-urea breath test may include:
- Cough (likely risk)
- Shortness of breath (low risk)
- Irritation of the mouth, throat or airways (low risk)
- Anaphylaxis/hypersensitivity (allergic reaction) (extremely rare and unexpected risk)

Anaphylaxis would be an extremely rare and unexpected side effect as urea is naturally found in the body. In the case of an allergic reaction, you will be treated with standard medications including Benadryl (diphenhydramine) and Pepcid/Zantac (famotidine/ranitidine) for mild reaction (itching or mild rash). For moderate reactions (extensive rash or persistent itching), treatment will also include a steroid medication

such as prednisone or solu-medrol. For severe reactions (any difficulty breathing or low blood pressure), treatment will also include a shot of epinephrine in the muscle (similar to an epi-pen).

Some symptoms of anaphylaxis may appear as

- **Lightheadedness, dizziness, or fainting**
- **Difficulty breathing or wheezing**
- **Hives, swelling under the skin, rashes**
- **Nausea**

Evidence shows that, generally, symptoms of anaphylaxis appear between 1-15 minutes after exposure to an agent. The study team will monitor you for 20 minutes after nebulization for any adverse events. <u>However, if you should experience any of these symptoms after leaving the ER and believe them to be related to this study, you should immediately:</u>

- **Return to the ER**
- **Bring your copy of this signed consent form that contains contact information for the investigator.**
- **Upon returning to the ER, ask that the investigator, Dr. Baca, be immediately notified and contacted.**
- **Provide your copy of the signed consent form upon arrival.**

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505-272-5062

Dr. Justin Baca, MD, can be reached at 505-272-5062 during normal business hours. If you need to contact him after business hours or on weekends, please call 412-478-2723 and ask for Dr. Justin Baca.

How will my information be kept confidential?
Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by UNM investigators, the food and drug administration (FDA), federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the benefits to being in this study?
You are not expected to get any direct benefit from participating in this research study. However, your participation may help find out whether the ^{13}C-urea breath test could aid in the screening of pneumonia and selection of appropriate antibiotic therapy.

What other choices do I have if I don't participate?
Your participation in this study is completely voluntary. You will receive the standard treatments for pneumonia regardless of whether or not you participate in the study. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

Will I be paid for taking part in this study?
In consideration of your time and the inconvenience of participating in this study, you will receive a $50 merchandise card. If you qualify to participate in the study, you will receive the merchandise card even if you choose to withdraw part way through the study.

What will happen if I am injured or become sick because I took part in this study?
If you are injured, have an allergic reaction, or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost.

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at (505) 272-1129 for more information.

How will I know if you learn something new that may change my mind about participating?
You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your treatment and access to future care.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you which may be shared with other investigators. This information is "protected" because it is identifiable or "linked" to you. Personally identifying information will not be used to identify your data when provided to other investigators or in any publication that may present data collected in this study.

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Protected Health Information (PHI)
By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: results of urine pregnancy test, vital signs, and results of the ^{13}C-urea breath test.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

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Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Dr. Justin Baca, MD, or his associates will be glad to answer them at 505-272-5062 during normal business hours. If you need to contact someone after business hours or on weekends, please call 412-478-2723 and ask for Dr. Justin Baca. If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNMHSC and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

What are my rights as a research participant?
If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this Consent Form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

_____	_____/_____
Name of Adult Participant (print)	Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____	_____/_____
Name of Research Team Member	Signature of Research Team Member Date