INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Title of Study: THE AIRWAY MICROBIOME IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Principal Investigator: Adam Wanner, M.D.
Department: Medicine – Pulmonary, Critical Care and Sleep Medicine
Phone Number: (305) 243-3045 beeper: (305) 839-0549
Email Address: awanner@med.miami.edu

Study Contact Name: Eliana Mendes
Study Contact Email: smendes@med.miami.edu

READ THE FOLLOWING CAREFULLY
This consent form contains important information that will help you decide if you wish to take part in this study. If you have any questions that remain unanswered, please ask the study doctor or any research study personnel before signing this form.

You are being asked to volunteer as a participant in a research study. Before you give your permission to be part of this study, please read this document and ask as many questions as necessary to make sure you understand what your participation in the study will involve.

PURPOSE OF STUDY
The purpose of this study is to evaluate why some people develop Chronic Obstructive Pulmonary Disease (also referred as COPD, emphysema or chronic bronchitis; [a condition that makes you very short of breath]). In particular, the study will determine if there are differences in the microorganisms (bacteria and fungi) that “normally” live in the airways of people that develop this disease. It is possible that these microorganisms cause changes in the lung tissues (called inflammation) that can worsen the disease. The study will use new techniques to analyze the bacteria/fungi you have in your lungs. The findings of this study may lead to new approaches to treat and/or prevent COPD.

You have this consent form because you either have COPD, you smoked in the past or you have been invited to be part of a “control” group, that is, you don’t have COPD and never smoked. The investigators are recruiting for people for the control group to compare those with COPD and/or smokers with those who do not have the disease and/or did not ever smoke. The investigators want to collect clinical information and biological samples from you. No direct benefits can be promised to you from this research.
A total of 80 individuals will be recruited for the study.

PROCEDURES
Bronchoscopy
If you agree to take part on this study, the investigators will collect airway secretions and airway cells from your lungs while you are sedated during a procedure known as bronchoscopy. Bronchoscopy means that a pulmonary specialist will introduce a flexible tube with a camera into your airways (an instrument known as bronchoscope) usually through one of the nostrils. This will allow the study doctors to look inside your lungs, to inspect them and allow samples to be collected from your lungs. This is a regular procedure performed to diagnose and treat numerous lung conditions, but in this case will be performed solely for research purposes.

If you decide to participate in this study, and accept to have a bronchoscopy, the pulmonary specialist will insert a very small brush (less than 1/5 inch across) through the bronchoscope tube. The brush will be gently moved back and forth 10 times to get some cells from the airway lining. The brushing process will be repeated 5 times. The airway cells obtained from these “brushings” will be analyzed. Subsequently, the study doctor will perform a “lavage” in your lung. In other words, he will wash your lungs with a larger amount of salt water (about 20 ml 3 times). This fluid will be immediately suctioned and collected in plastic vials and will be used to determine the presence of microorganisms. This is a commonly performed diagnostic procedure during bronchoscopy and is known as a bronchoalveolar lavage.

Clinical Information
In order to learn about your lung condition, the following information and assessments will be performed before the bronchoscopy:
1. Spirometry Test: This is the standard test to measure how well your lungs are working by asking you to blow at different times into a machine.
2. Questionnaires: You will be asked to complete a number of questionnaires that assess your general health, yours and your family medical history, your occupational history and current COPD symptoms and care. Each questionnaire takes approximately 20 minutes to complete.
3. Six Minute Walk Test: You will be asked to walk up and down a corridor for 6 minutes and the distance you walk will be measured.
4. Blood Sample: This will involve putting a needle into a vein in your arm and collecting blood. No more than 20 ml will be collected. Your blood sample will be analyzed to evaluate chemicals associated with inflammation.
5. **Computed tomography of the chest:** This is a diagnostic test that uses X rays to visualize how your lungs look like. We will use it to determine if you have or the extent of your emphysema.

**POTENTIAL RISK AND DISCOMFORTS**

**Conscious Sedation:** Overall, bronchoscopies are invasive procedures that are usually performed under conscious sedation. This means that to avoid the discomfort of obtaining the airway samples, you will receive a sedative strong enough to relax you but not to induce deep sleep. You will still be able to breath normally. The potential risks of conscious sedation include a drop in blood pressure (hypotension) and slowing of breathing (respiratory depression). Because of this, skilled staff will constantly monitor your heart rate, blood pressure, breathing and oxygenation. All the precautions for reversal of sedative effects, if needed, will be available.

**Bronchoscopy:** The risks involved with microbrushings to obtain airway cells are rare and include cough, temporary airway irritation and rarely bleeding from the airway lining. The risk of obtaining the “lavage” includes a temporary drop in oxygenation. The investigator will have precautions in place to prevent and/or treat these complications if needed. Bronchoscopy with conscious sedation is a procedure that is routinely performed safely in people with breathing problems.

**Blood Draw:** The risks of blood drawing include: fainting, the occurrence of temporary discomfort and/or bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the vein and surrounding area may occur.

**Computed tomography:** If you take part in this research, you will have one medical imaging study, which use radiation. The test you will have is a chest CT scan. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 2 extra years' worth of this natural radiation.

**CONFIDENTIALITY**

By signing this consent, you authorize the Investigator(s) and his/her/their staff to access your medical records for the purposes of this study. This information will also be shared with the Sponsor of this study, and persons working with the Sponsor to oversee the study. Your records and results will not be identified as pertaining to you in any publication without your expressed permission. The Investigator and his/her collaborators, staff and the sponsor will consider your records confidential to the extent permitted by law. The Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) may review these research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.
University of Miami – Medical Informed Consent Form
EPROST # 20091147

You will be asked to sign a HIPAA form to authorize the study staff to have access to your medical records.

COSTS AND COMPENSATION
1. There is no charge to you to participate in this research study.
2. You will be paid $400.00 for participating in this study to compensate for your time.
3. It is not the purpose of this study to look for or provide you with any medical information or diagnosis. Your participation in this study is not a substitute for regular medical care or check-ups.
4. Although complications are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.
5. The University and/or investigators will own the rights to any drugs, tests and/or treatments that are developed from research on your tissue or blood samples. You will not share in any money received from such commercial products.

USE OF SAMPLES
1. Any present or future research on your tissue or blood samples must be approved by an authorized Institutional Review Board (IRB).
2. No identifying information will be shared with any collaborators outside of those associated with the University of Miami.
3. The sample(s) given by you will only be used for research. These samples are not available for your personal use or clinical (diagnostic) purposes. Therefore, any future diagnostic testing as a result of this or other research must be performed using a new sample.

RESEARCH RESULTS
1. The sample(s) and information collected are for research purposes only. In general, the results from laboratory studies using information collected for this research will be preliminary. Research laboratory findings may not be understood for years and may not be useful to any given individual.
2. It is possible that the research will identify information about you that was previously unknown, such as abnormal findings on physical exam or radiologic tests. In this occurs, such findings will be discussed with you. You will be encouraged to consult with your physician to clarify any such findings. Costs associated with a medical evaluation that is not part of the research study are the responsibility of the research subject.
BENEFITS
Research is designed to benefit society by gaining new knowledge. Though you will not benefit personally from being in this research study, knowledge will be gained that may ultimately benefit your family or others.

ALTERNATIVES
You have the alternative not to participate in this study. You can decide to stop participating in this study at any time. Not participating in this study will not affect your medical care.

RIGHT TO DECLINE OR WITHDRAW
Your participation is voluntary. You are free to refuse to participate in this research or withdraw your (his/her) consent at any time. If you withdraw from the research, you will continue to have access to health care at the University of Miami. The investigator reserves the right to remove you from the study without your consent at such time that they feel it is in the best interest for you.

If you decide to withdraw, we ask that you contact the principal investigator, Dr. Adam Wanner, in writing and let him know that you are withdrawing from the study. The mailing address is University of Miami, Division of Pulmonary and Critical Care Medicine, Leonard M. Miller School of Medicine, RMSB, Room 7058 (R-47), 1600 NW 10th Avenue, Miami, Florida, 33136. At that time we will ask your permission to continue using all existing samples and information about you that has already been collected as part of the study prior to your withdrawal. If you want us to stop using existing sample(s) or to destroy them we ask that you let us know in writing, as well. However, research information that has already been generated cannot be removed from the study.

If you are an employee or student at the University of Miami, your desire not to participate in this study or request to withdraw will not adversely affect your status as an employee or grades at the University of Miami.

CONTACT INFORMATION
If at any time you have any questions about the study, you may contact Dr. Adam Wanner, or a participant coordinator by telephone at 305-243-2568 or 24 hours phone: (305) 839-0549 or by mail at University Miami, Division of Pulmonary and Critical Care Medicine, Leonard M. Miller School of Medicine, RMSB, Room 7058 (R-47), 1600 NW 10th Avenue, Miami, Florida, 33136.

In case of study-related injury, please contact your health care provider. Please also notify Dr. Adam Wanner at 305-243-2568 during regular business hours or 24 hours phone: (305) 839-0549.
AGREEMENT OF DECISION TO PARTICIPATE

You will receive a copy of this signed informed consent form.
I have read this consent, which is printed in English (a language that I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study procedures, risks and discomforts, and side effects have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to take part in this study.

Mary Coombs
Signature of Participant

Mary Coombs
Printed Name of Participant

Signature of Person Obtaining Consent

Michael Campos
Printed Name of Person Obtaining Consent

1/13/11
Date

1/13/11
Date
HIPAA Research Authorization Template – Form B

AUTHORIZED TO USE AND DISCLOSE HEALTH INFORMATION

I agree to permit the ☒ University of Miami ☐ Jackson Health System ☐ both, and any of my doctors or other health care providers (together "Providers"), Principal Investigator and [his/her/their/tis] collaborators and staff (together "Researchers"), to obtain, use and disclose health information about me as described below.

1. The health information that may be used and disclosed may include:
   ☒ All information collected during the research and procedures described in the Informed consent Form for the Research as described in the accompanying Informed Consent Form ("the Research"); and
   ☒ Health information in my medical records that is relevant to the Research, includes my past medical history including medical information from my primary care physician and other medical information relating to my participation in the study; and

[The following checked boxes must be separately initialed by you in order to permit access to these records]

☐ HIV / AIDS status.
  HIV-related information, which includes any information indicating that I have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that I have been potentially exposed to HIV.

☐ Sexually transmitted diseases (STD’s).

☐ Mental health treatment records governed under state law (including mental health records relating to involuntary or voluntary mental health treatment).
  Mental health records may include substance abuse information.

☐ Substance abuse (drug and alcohol) treatment records.
  Substance abuse information may be part of the mental health records.

☐ Sexual assault information.

2. The Providers may disclose health information in my medical records to:
   • the Researchers;
   • representatives of government agencies, any applicable Cooperative Groups, review boards, and other persons who watch over the safety, effectiveness, and conduct of research; and
   • the sponsor of the Research, Adam Wanner, MD,
     (Print Sponsor Name)
     and its agents and contractors (together "Sponsor").

3. The Researchers may use and share my health information:
   • among themselves, with the Sponsor, with any applicable Cooperative Groups, and with other participating Researchers to conduct the Research; and
   • as permitted by the Informed Consent Form.

4. The Sponsor and any applicable Cooperative Groups may use and share my health information for purposes of the Research and as permitted by the consent form.

5. Once my health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

Required Information: Please Complete.

NAME:_____________________

MRN:_______________________  IDX  SMS

SS #:  DL #  PASSPORT #  OTHER_____________________

ID#:_______________________

AGE:_______________________  DOB:__/__/____

DATE OF SERVICE:__/__/____
6. I hereby authorize the Sponsor to observe any medical procedures I undergo as part of the Research.

7. Please note that:
   You do not have to sign this Authorization, but if you do not, you may not participate in the Research. If you do not sign this authorization, your right to other medical treatment will not be affected.
   You may change your mind and revoke (take back) this Authorization at any time and for any reason.
   To revoke this Authorization, you must write to either of the following:

   *Research Study Personnel Name: Adam Wanner, MD
   Address: 1600 NW 10th Ave, Miami, FL 33136
   Tel. No: (305) 243-3045
   Human Subjects Research Office
   Address: 1500 NW 12th AVE, Suite 1002 Miami, FL 33136
   Tel. No: (305) 243-3195

   However, if you revoke this Authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this Authorization, the Providers, Researchers, any applicable Cooperative Groups and the Sponsor may continue to use and disclose the information they have already collected to protect the integrity of the research or as permitted by the Informed Consent Form.

   While the Research is in progress, you may not be allowed to see your health information that is created or collected by the University of Miami, Jackson Health System, both, in the course of the Research. After the Research is finished, however, you may see this information as described in the University of Miami, Jackson Health System, both, Notice of Privacy Practices.

   *Study personnel must send copies of participant revocations to:
   Office of HIPAA Privacy and Security AND the Human Subjects Research Office.

8. This Authorization does not have an expiration (ending) date.

9. You will be given a copy of this Authorization after you have signed it.

   Mary Coombs
   Signature of participant or participant’s legal representative
   1/13/11
   Date

   Mary Coombs
   Printed name of legal representative (if applicable)

   Representative’s relationship to participant

   Study personnel must send copy with signature to the Office of HIPAA Privacy and Security
   For questions, contact the Human Subjects Research Office at 305-243-3195.

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University of Miami - Office of HIPAA Privacy and Security
PO BOX 019132 (M879)
Miami, FL 33101

Required Information: Swipe Keyplate if available and leave the box blank.

NAME: ___________________________  IDX: __________

MRN: ___________________________  SHS: __________

SS: ___________________________  DOB: ______/____/____

DATE OF SERVICE: __________/____/____

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