

**Northwestern University
Department of medicine
Division of Allergy-Immunology
ALLERGY, ASTHMA, IMMUNOLOGY CLINICAL RESEARCH UNIT**

CONSENT FORM AND AUTHORIZATION FOR RESEARCH

Project Title: Characterization of Research Participants

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SUPPORTED BY DIVISION OF ALLERGY-IMMUNOLOGY.

INTRODUCTION/PURPOSE:

You are being asked to participate in this research visit so we can better characterize your present health status. You will fill out questionnaires and have some tests to confirm your medical history, particularly related to allergic conditions and asthma. We will also collect samples for current and future research.

We will use the information collected in this visit to create a database of people interested in participating in clinical studies in this research unit. This database will help us match more efficiently participants with current and future research studies.

Contact for future research studies: We will keep your contact information and we may contact you in the future regarding new research studies. You may request at any point to be removed from our list of subjects who are interested in being contacted for additional studies.

PROCEDURES:

If you agree to participate, you will be asked to come to the Northwestern University - Allergy, Asthma and Immunology Clinical Research Unit for a single visit. During this visit, you will undergo the procedures selected below. The research staff will indicate as "Yes" or "No" the study procedures we would like you to consent to undergo during the visit. The visit will take up to 4 hours. Read the risks related to each procedure in the "Risks" Section. Read the whole Consent in all other sections.

Yes **Questionnaire:** First, you will complete a questionnaire on your medical history. It has a series of questions about medical conditions and treatments you may have had. This questionnaire will be kept confidential. It takes 15 minutes to complete it.
 No

Yes **History and physical examination:** A physician or a nurse will review your medical history and do a physical examination. These assessments will help us understand better your current and past medical history. This usually takes 30 minutes.
 No

Yes **Urine Pregnancy Test:** If you are a woman and will have the methacholine test, we will do a pregnancy test in your urine sample and tell you the result. Because the effects of methacholine on the unborn fetus are unknown, we will not proceed if you are pregnant. This test takes 5-10 minutes.
 No

- Yes **Exhaled Nitric Oxide:** In this test you will take a breath in and breathe out through a mouthpiece connected to a machine that will measure the nitric oxide gas produced by your lungs. This test takes 5-10 minutes.
- No
- Yes **Exhaled Breath Condensate:** In this test you will breathe in and out for 15 minutes through a mouthpiece connected to a tube that collects the water vapor from your breath. This test takes 20 minutes.
- No
- Yes **Spirometry** (Lung function test): The function of your lungs will be measured by having you breathe in deeply and then out forcefully through a mouthpiece into a recording device. We will perform this maneuver several times in a row to obtain the best 3 maneuvers. This test takes 10 minutes.
- No
- Yes **Bronchodilator response:** To measure how much better your spirometry gets after inhaling Albuterol (an asthma inhaler medication), we will perform spirometry 15 minutes after you inhale 4 puffs of Albuterol. Depending on the response, we may repeat this dose again and repeat spirometry 15 minutes later. This test takes 20 to 40 minutes.
- No
- Yes **Skin Allergy Test:** This is a common test for allergy to identify triggers of hay fever and asthma symptoms. We will apply 16 tests on the skin of your arm. For each test, we prick the skin with a small plastic needle that is wet with one of 14 common allergy triggers such as house dust, pet hairs, pollens, and molds. In addition, we will test for 2 control tests to ensure that your skin reacts properly. Fifteen minutes after the prick tests, we inspect the skin for local redness and swelling. This test takes 20 minutes.
- No
- Yes **Methacholine Test:** To test how sensitive your airways (bronchial tubes) are to methacholine, we will measure how much they narrow after you breathe in increasing doses of methacholine aerosol. Methacholine is very similar to the acetylcholine produced in our bodies, which tightens muscles around the airways. About 3 minutes after each dose, we will repeat the spirometry to measure how much narrower the airways get. The test will continue until the last dose is given, or until your spirometry reaches a target value. This test is also used in the clinical practice to evaluate asthma. It may take up to 45 minutes to complete.
- No
- Yes **Nasal Lavages** (rinse): This procedure involves gently placing into each of your nostrils a teaspoonful of warmed salt solution (normal saline), which you will hold for 20 seconds before expelling (blowing) the fluid from your nose into a plastic container. This test takes 5 minutes.
- No
- Yes **Nasal Cell Sampling:** To collect the cells lining the inside of your nasal cavities, we will first do 4 nasal lavages to clean the mucus inside your nose. Then, we apply 4 to 6 sprays per nostril of a mixture containing 1:1 of a non-prescription nasal decongestant (Phenylephrine or Oxymetazoline) with a local anesthetic like those used by dentists (Tetracaine 2%). The decongestant opens the nasal cavities making it easier to see inside the nose, and the anesthetic numbs the lining inside your nose. After a few minutes, we will gently rub a small (1/8 inch or less) plastic
- No

or metallic spoon against the lining inside your nose to collect nasal lining cells. We repeat this procedure until we have collected enough cells, usually 4-6 times in each nostril. We may use a rhinoscope (1/8 inch thick), a tube with a light at the end, to help us see better where to sample the lining cells. This test takes 15 minutes.

Yes **Blood draw:** After applying a tourniquet in your arm, we will clean the skin with alcohol and insert a needle to draw up to 4 ounces (120 ml) of blood. This is about a third of the amount of blood that is drawn in a blood donation. This test takes 10 minutes.
 No
Blood typing: We may use your blood sample to determine your blood type. We may also need a saliva sample to test if it contains blood type substances.

Yes **Sputum induction:** To avoid chest tightness during this test, we will first give you 4 puffs of albuterol, an inhaler used to open up lung airways in people with asthma. Then, 15 minutes later, you will inhale a mist of concentrated salt solution for up to 20 minutes. Every 2 minutes we will ask you to spit saliva into one cup, to forcefully cough up phlegm (mucus from the lungs) into another plastic cup, and to perform a peak flow measure (blow into a plastic device) to make sure you are not having excessive tightening of your airways. This procedure takes 40 minutes.
 No

Medication Hold: Some medications and foods may interfere with study tests. We may ask you to temporarily hold some medications or avoid having some foods before the study visit. After the visit, you will no longer need to hold any medication or avoid any food.

Storage of samples: Samples not completely used will be stored indefinitely in the Allergy-Immunology Division Laboratories for future studies also related to allergies and asthma. The samples will be coded and will not contain any of your identifying information. You may request that we discard your samples at any time in the future by contacting this Research Unit.

We use the collected samples to study in the laboratory their contents of chemicals and cells related to allergies (e.g. hay fever), asthma, and those related to airway response to environmental factors such as pollutants and respiratory infections. In addition, we study how the cells behave under different conditions in the laboratory.

Risks:

Your involvement in this study may involve the following risks:

Questionnaire, History and Physical Examination: You may feel that these procedures are repetitive and boring.

Urine Pregnancy Test: You may find out that you are pregnant. If so, you may not be able to complete all procedures.

Exhaled Nitric Oxide, Exhaled Breath Condensate and Spirometry: Breathing in and out deeply and/or repeatedly may cause lightheadedness or cough. These symptoms disappear after a few minutes of normal breathing.

Albuterol Inhaler: In some individuals, it may cause slight shakiness and an increase in heart rate (palpitations) for 15-30 minutes.

Skin Allergy Test: This is a common test done by Allergists to find out what sets off one's allergy symptoms. You may feel mild discomfort or pain when we prick your skin. The test may cause a local itchy red patch similar to a mosquito bite. This patch disappears in 1 to 2 hours, but if large, it may last a couple of days. In rare cases some people who are extremely allergic may develop anaphylaxis to the skin test. Anaphylaxis is a severe reaction to an allergen. These are very rare reactions (1 in 5,000 people tested) such as shortness of breath, swelling of the tongue or skin, hives and itching all over the body, or a fall in blood pressure. These rare reactions happen within 30 minutes. We have the medications to promptly treat them in the research unit.

Methacholine Test: Breathing in methacholine may cause chest tightness, coughing, or shortness of breath. These symptoms can be reversed quickly by treatment with an Albuterol or Atrovent inhalers, both of which are commonly used medications to relieve breathing problems in people with asthma or bronchitis. These medications work within a few minutes.

Nasal Lavage: The warmed salt solution in your nose may feel slightly uncomfortable. It may cause coughing, sneezing, or tearing for a couple of minutes.

Nasal Cell Sampling: It may cause mild nasal discomfort, tearing, and sneezing for a couple of minutes. The numbing of the nasal lining and decreased sense of smell and taste may last 2 to 4 hours. It may rarely (<1%) cause mild runny or stuffy nose for a few days. It may cause slightly blood-tinged mucus for 1 day.

Blood draw: The tourniquet may cause discomfort in the arm. The needle stick will cause mild pain, and rarely causes bruising (<1%). Some people may experience lightheadedness or fainting during the blood draw. Care will be taken to avoid these complications.

Sputum induction: Despite giving you Albuterol, you may still experience chest tightness. This procedure also causes runny nose, coughing and phlegm production which may last for 10-20 minutes afterwards.

Medication Hold: While holding medications for the study visit, your symptoms may worsen and become bothersome. In this case, you should resume your medications immediately and call us to reschedule the visit (phone 312-695-6518).

READ ALL SECTIONS BELOW. THEY APPLY TO ANY PROCEDURE

REPRODUCTIVE HEALTH:

Because the effects of some study medications on the unborn fetus are unknown, we will perform a pregnancy test and will not proceed if you are pregnant. All medications you may get in this study are short acting and will be out of your system within 12-24 hours.

BENEFITS:

You may not benefit from this research study. The study may aid in our understanding of the mechanism of asthma and allergic diseases, which may benefit people with these conditions in the future.

ALTERNATIVES:

You do not have to take part in this study. Your decision not to participate will not affect any rights to which you are entitled.

WHAT ABOUT MY CONFIDENTIALITY AND PRIVACY RIGHTS?

We are committed to respect your privacy and to keep your personal information confidential.

By signing this document you are **NOT** permitting your doctors and other health care providers to disclose personal health information they have collected about you to Northwestern University and the researcher listed above for purposes of the Study.

You are allowing Northwestern University and the researcher to disclose the personal health information to outside organizations or people involved with the processing of this Study, as described in the separate informed consent form.

This authorization for research section gives more detailed information about the following:

- What personal health information about you will be collected in this Study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access your personal health information during the Study
- Your right to withdraw your authorization (approval) for any future use of your personal health information

What personal information is collected and used in this Study, and might also be shared (disclosed)?

The following personal contact and personal health information will be collected, used for this research Study and may be disclosed or released during your involvement with this research Study:

- Name, Address, and Telephone number
- Medical history and Allergies
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature

Other tests and procedures that will be performed in the Study include:

- Questionnaires
- Urine pregnancy test, exhaled nitric oxide, exhaled breath condensate, spirometry, allergy skin test, methacholine test, nasal lavage, nasal cell sampling, blood tests, sputum induction, and laboratory tests related to allergy and asthma that will be performed in the collected samples.

Why is your personal information being used?

Your personal contact information is important for Northwestern University research team to contact you during the Study. Your personal health information (including the results of tests and procedures) is being collected during this research Study for purposes of the Study. The Principal Investigator may also use the results of these tests and procedures to treat you.

Who within Northwestern University may use or disclose your personal health information?

The following individuals and organizations within Northwestern University may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's Study team (other University staff associated with the Study)
- The Northwestern University Institutional Review Board (its committees are charged

- with overseeing research on human subjects)
- The Northwestern University Office for the Protection of Research Subjects (the office which monitors research studies)
 - Authorized members of the Northwestern University workforce who may need to access your information in the performance of their duties (for example: to make sure the research is being done correctly).

Who outside of Northwestern University might receive your personal health information?

As part of the Study the Principal Investigator, Study team and others listed above, may disclose your personal health information, including the results of the research Study tests and procedures to the following:

- Government agencies that oversee clinical research in the United States such as the Food and Drug Administration.

In all disclosures outside of Northwestern University, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

- The results of this study may also be used for reports, presentations at scientific meetings, and publications. Results will be discussed without the identity of the study participants.

How long will Northwestern University be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific Study does not expire. This information may be maintained in a research repository (database). However, Northwestern University may not re-use or re-disclose your personal health information collected in this Study for another purpose other than the research Study described in this document unless it obtains permission to do so from the Northwestern University Institutional Review Board.

Will you be able to access your records?

Results of all tests and procedures done solely for this research Study and not as part of your regular care will not be included in your medical record.

Can you change your mind?

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and “take back” (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to:
 - **If you withdraw your permission to use any blood or tissue obtained for the Study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.**
-

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- Unless you revoke your consent, it will not expire.

RESEARCH-RELATED INJURY:

You should promptly notify the study doctor in the event of any illness or injury (see below) that you think is related to this study.

In the event of injury or illness as a result of study medications, devices, or procedures, you may need to seek medical treatment through your physician or treatment center of choice. Payment for this treatment will be your responsibility.

The Office for the Protection of Research Subjects of Northwestern University, at telephone number (312) 503-9338, can provide further information about your rights as a research subject and is where any research related injury should be reported. Further information regarding this study may be obtained by contacting the principal investigator Dr. Pedro Avila, MD at telephone number 312-695-4000. For problems arising evenings or weekends, you may page this doctor at 312-695-7228.

FINANCIAL INFORMATION:

Your involvement in this study will involve no cost to you. Neither you, nor your health insurance carrier will be responsible for payment of any procedure involved in this study. If you inadvertently receive a charge, please let us know promptly so we can cancel it.

Results from this study and from research in the samples obtained during this study may lead to new discoveries. These new discoveries may lead to patents and commercial applications which will be solely owned by the investigators and by Northwestern University. You will not be entitled to any financial benefits from new discoveries made as a result of this study or study samples.

REIMBURSEMENT:

You will be reimbursed depending on the duration of your study visit in the Research Unit. For the first hour, you will receive \$30 even if you stay for less than one hour. Thereafter, you will receive \$15 per 30 min for a maximum of \$120 for the visit procedures. Your check will be mailed to you within 4-6 weeks after the visit.

Depending on the type of transportation you take, you will receive reimbursement for your travel expenses. Transportation reimbursement will be provided in the form of two \$1.75 CTA tickets (Bus or El-Train) or two Northwestern Intercampus Shuttle tickets. Transportation tickets will be equivalent to one roundtrip ride of commuter transit. If you choose to drive, a Northwestern Memorial Hospital parking ticket good for 6 hours will be provided. CTA and Shuttle tickets can be mailed to you prior to your visit, and a parking lot ticket will be issued after you finish your visit.

SUBJECT'S RIGHTS:

Your participation in this study is voluntary and you are free to withdraw at any time. Choosing not to participate or withdrawing from this study will not affect your present or future medical treatment; will not incur on any penalty or loss of benefit; will not affect your student status; will not affect your class/rotation standing (if you are taking one of our classes or clinical rotations) and will not affect present or future employment to which you are otherwise entitled regardless of whether or not you are a student or employee at Northwestern University.

CONSENT:

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. If I have more questions, I have been told who to contact. I agree to be in the research study described above. A copy of this Consent Form and Authorization for Research will be provided to me after I sign it.

Subject's **[Printed]** Name

Subjects Signature

Date

Person obtaining consent
[Printed] Name

Person obtaining consent
Signature

Date