Research Subject Information and Consent Form  
University of Wisconsin School of Medicine and Public Health  
Department of Allergy & Immunology  
Madison, WI

**Study Title:** Screening Protocol for Eligibility for Clinical Trials in Asthma and Allergic Disorders

**Principal Investigator:** Mark Moss, M.D.

This consent form may contain words that you do not understand. Please ask the study physician or the study staff to explain any words or information that you do not clearly understand.

The purpose of this form is to give you information about the study and by signing it you will give your permission to be in the study. You should join in this study only if you want to do so. You may refuse to join or stop being in this study at any time. Your decision to join or not join this study will not affect your doctor-patient relationship, your medical treatment in any way, or the relationship that you have with the University of Wisconsin-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation). This study is voluntary.

**Invitation:**
You are invited to take part in a “Prestudy” visit. This Prestudy visit will be used to gather information about you to find out if you can join a research study with the Allergy, Asthma and Pulmonary Clinical Research Unit (known going forward as Research Unit). The procedures carried out at a Prestudy visit are common procedures done to assess for asthma and allergies. Your participation is voluntary. You do not have to participate in a Prestudy visit in order to receive medical care.

**What is the Purpose of a Prestudy Visit?**
The purpose of a Prestudy visit is to find out if you are able to join a research study with the Research Unit. You may be able to join a study that has already started or you might be asked to wait for a study that is being planned.

**What Will Happen to Me?**
This is a screening protocol. Information collected at this visit will be entered into a password protected, computerized, recruitment database that will be used in the future to determine if you might be eligible for a research study. Only study doctors, study coordinators, research assistants and recruiters with the Research Unit can access the recruitment database. When possible, screening data collected for eligibility determinations will be used to update your registry data. If there is a research study that you might qualify for, you will be contacted by a recruitment coordinator by letter, email, or phone call to see if you are interested. You may also be asked to answer questions over the phone. You may ask to have your information removed from the recruitment database at any time.
There is a chance that a researcher outside the Research Unit will conduct a study that you might qualify for. If so, you will be contacted by Research Unit staff to ask your permission to pass along your contact information to the other researcher and/or his/her staff. It will be entirely your choice as to whether you allow your contact information to be passed along to another researcher conducting a study. Your choice whether to allow your contact information to be passed along will not affect your participation in our Prestudy protocol.

Additionally, you may be contacted in the future to come back to the Research Unit to complete other Prestudy visits. These include methacholine challenge, antigen challenge, exercise challenge, a short update visit, screening for COPD or a Rhinovirus blood draw screen. These will be explained to you in detail over the phone and all except the short update visit will have a new consent form. The short update visit may be done to have you come in and repeat some of the procedures already described in this consent. If you are contacted, you may be asked to hold your asthma medications prior to arriving for this visit. Your asthma symptoms may get worse if you stop your rescue medication to prepare for spirometry. If your asthma symptoms worsen, you should take your rescue medication IMMEDIATELY and call the study center.

This visit could take up to 1 hour. You will be asked about your medical, asthma and allergy history. The study coordinator will ask about medication usage, which includes your use of prescription medications, over-the-counter medications, vitamins, herbal remedies and nutritional supplements. Based on the Research Unit’s present need, you might do one or all of these procedures:

- Vital signs (blood pressure, heart rate, temperature, height, weight)
-Spirometry
- Reversibility testing
- Allergy skin testing.
- Brief physical exam (a doctor or nurse might listen to heart and lungs)
- Exhaled Nitric Oxide (eNO)
- Blood Draw (up to 10mls)

**Spirometry:** You will wear nose clips and blow into a machine that measures how much air you can blow out (volume) and how fast it comes out (speed). You will blow as hard as you can for as long as you can. You may be asked to do this up to eight times. You may be asked to withhold the following for 6 hours before spirometry:

- Caffeinated food (like chocolate) and drinks (like coffee and cola)
- Rescue medication (like albuterol, Ventolin, Maxair)
- Alcohol

**Reversibility testing** calls for spirometry before and 15 minutes after albuterol. Albuterol is a bronchodilator, which works by relaxing and opening air passages to the lungs. The aim of this test is to see how much your breathing changes after the medication.
Allergy skin testing is a common test for allergies. You may be asked to not take antihistamines for 1-5 days in preparation for this test. Examples of antihistamines include Allegra, Claritan, Zyrtec and others. 8-24 separate drops of common allergens (dust mite, cat, pollens, molds, etc.) will be put on the underside of your forearm. Your skin will be lightly scratched or pricked. 10-15 minutes later the study coordinator will look for redness and swelling (like a mosquito bite) where each test was done.

Exhaled nitric oxide is a gas that is released from inflammatory cells in your lung. You will be asked to slowly blow air into a mouthpiece attached to the eNO machine. We will have you gently blow air out into a machine for a 10 second period of time.

Blood Draw is a common measurement for inclusion criteria. You will provide up to 10 milliliters or about one teaspoon of blood for analysis of CBC, PT, CRP, safety labs or other biomarkers. The specific blood draw analysis will be thoroughly explained by a research coordinator.

What are the Risks?
There is a chance that you will not qualify for any study performed by the Research Unit. Other risks include:

**Spirometry**
- Withholding beta-agonist medication to prepare for spirometry. Your asthma symptoms may get worse if you stop your rescue medication to prepare for spirometry. If your asthma symptoms worsen, you should take your rescue medication IMMEDIATELY and call the study center.
- **Spirometry** might make you feel lightheaded (dizzy) or cough.
- **Albuterol given for the reversibility testing**: Common side effects are headache, increased pulse rate, shakiness of hands. Uncommon side effects are awareness of heart pounding or racing, mouth and throat irritation and muscle cramps. Rare side effects are low blood potassium, irregular heartbeat or heart rhythm, hyperactivity and an immediate increase in wheeze after dosing. Very rare side effects include an allergic reaction (hives, swelling of the face, mouth, tongue, and breathing problems). These are the most common side effects of these medications, but there are other less common events that are not listed. There may be side effects or risks that are unknown at this time.

**Allergy skin testing**
- Withholding antihistamine medication to prepare for allergy skin testing. You may experience a worsening of allergy symptoms if you stop your antihistamine to prepare for allergy skin testing. If you feel like you must take your allergy medication, please do so and call the study center.
- **Allergy skin testing**. There may be brief mild pain from scratching or pricking your skin. You will likely get a mosquito bite-like reaction if you are allergic to the allergen contained in that drop. You could have many mosquito bite-like reactions on your forearm if you have many allergies. The itching usually goes away shortly after you wash your arm at the end of this test. The mosquito-bite bump usually lasts for about an hour but can last longer. In very rare cases, you might have anaphylaxis, which is a
whole-body allergic reaction that may cause shortness of breath, hives, swelling of the skin or tongue, itchy skin or a fall in blood pressure. Emergency care is available to treat you if needed.

**Exhaled nitric oxide**
eNO is a breathing test with no known risks.

**Blood Draw**
You might feel pain at the point of needle entry. There is a small chance you could get a bruise or rarely, an infection at the point of needle entry. Some people feel lightheaded, dizzy or faint when giving blood.

**Risk of breach of confidentiality**
- As with all research, there is a chance that we could accidentally disclose information that identifies you, however, we are taking precautions to minimize this risk. All data will be stored in a password protected, study specific database. There is a remote risk that your name may become known in association with this research study.

**Text Message Reminders:**
You have the option to allow text message appointment reminders. A text message appointment reminder will be sent prior to your scheduled appointment. Standard message and data rates may apply. You can opt out of text message reminders at any time.

Please indicate your preference by placing your initials by one of the following:

_______: Please send me text message appointment reminders

Preferred Number: ___ ___- ___ ___- ___ ___ ___

OR

_______: Please **DO NOT** send me text message appointment reminders

**What are the Benefits?**
You are not expected to benefit directly from participation in this Prestudy visit.

**Are there any Costs?**
The procedures are done at no cost to you.

**What are My Alternatives?**
You do not have to complete a Prestudy visit or join research studies.

**Will I get Paid?**
You will be given $30.00 for your time and effort to complete a full Prestudy visit and if asked to complete an update to the prestudy visit you will be given $15.00.
Will there be Compensation for Injury?
In the event that you are physically injured as a result of participating in this research, emergency care will be available. However, you will be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize that you have not released this institution from liability for negligence. Please contact the study investigator, Mark Moss, M.D. at 608-265-9575 if you are injured or for further information.

Can I Change My Mind?
Your participation is entirely voluntary. You are free to refuse any or all of the Prestudy visit procedures and may stop the visit at any time without any penalty or loss of benefits that you had prior to the Prestudy visit. Your decision of whether or not to do a Prestudy visit will not affect any relationship you might have with the UW or the quality of your medical care at this hospital.

How Will My Confidentiality be Protected?
Researchers with the Research Unit will use information gathered from your Prestudy visit to decide if you qualify for a research study. Information gathered in the Prestudy visit will be entered into a computerized recruitment database that only the Research Unit can access. Results of this visit may be published for scientific purposes or presented to scientific groups. However, your identity, medical records and data related to this study will remain confidential, except as required by the law, and except for inspections by Agencies which regulate experimental drug studies, auditors, members of Independent Review Boards or Ethics Committees. Paper copies are kept in a locked file cabinet in locked rooms, electronic data is password protected.

What if I have Questions?
Please feel free to ask questions at any time. You may take as long as you like to decide if you want to do a Prestudy visit. In addition, if you have questions about your rights as a research subject, you may contact the UWHC Patient Relations Representative at 608-263-8009. You will be kept informed of any important new findings that may affect your interest in participating in this study. In some cases you may be asked to sign a new consent form. If you have any questions about this research please contact: Dr. Mark Moss, at (608) 265-9575.

Authorization
I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in a Prestudy visit. I have received a copy of this consent form.

Printed Name of Subject

__________________________________________ ________________

Signature of Subject Date

__________________________________________ ________________

Signature of Person Obtaining Signature Date