University of Pittsburgh

School of Medicine
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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH REGISTRY

TITLE: **Volunteer for Asthma – AIR (A**sthma **I**nstitute **R**esearch Registry)

PRINCIPAL INVESTIGATOR: **Sally E. Wenzel, MD**
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Asthma Institute 24-hour pager: 412- 647-2345
(Press 2 to speak with the operator and say "Please page the Asthma Institute Physician on call. I am a research study participant")

CO-INVESTIGATORS: University of Pittsburgh Asthma Institute Physicians and Research Staff
(Names may be provided upon request)

SOURCE OF SUPPORT: University of Pittsburgh Asthma Institute

What is the purpose of this Research Registry?

Many advancements in medicine have resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Because you are being seen by the UPMC Comprehensive Lung Center, The University of Pittsburgh Asthma Institute, or The University of Pittsburgh Division of General Internal Medicine Oakland (GIMO) Practice, we are asking for your permission to allow us to place your past, current and future medical record information into an Asthma Institute Research Registry. By placing the medical record information of many patients such as you into a research registry, researchers will be able to conduct research studies directed at increasing our knowledge about asthma and allergies.

It is anticipated that the Research Registry will assist our investigators in two important ways.

First, it will allow researchers to review and study the medical records of many individuals to answer questions about your disease and its treatment.

Second, it will help researchers identify and recruit patients who are eligible for participation in future

research studies. For example, physicians and other researchers associated with the UPMC Comprehensive Lung Center and the University of Pittsburgh Asthma Institute are also frequently involved in research studies directed at evaluating the safety and effectiveness of drugs, devices or procedures for the treatment of asthma and allergies. If you agree to participate in this Research Registry, your medical record information will be reviewed by physicians and researchers to determine if you might qualify for various future research studies.

Who is being asked to participate in this Research Registry?

All individuals with asthma are being asked to participate in this Research Registry. In addition, individuals who are interested in ongoing research studies at the University of Pittsburgh Asthma Institute will be also be invited to participate in the registry.

What will my participation in this Research Registry involve?

If you agree to participate in the Research Registry your past, current and future medical record information will be placed into the Research Registry. This will permit research studies to be conducted on the medical record information contained within the registry.

You are being asked to allow us to collect approximately 2 Tablespoons of blood from a vein in your arm. Your samples will be stored without any identifiers (i.e. name, initials, social security number) in order for the investigators to perform future studies on the samples. Samples will be stored indefinitely and will be destroyed only by your written request. De-identified samples may be shared with other investigators not involved with this research study. These investigators will not have access to your name or any other personal identifying information. The shared de-identified samples will not include any coded medical data. You may be asked in the future to return for a repeat blood draw in the case that your sample was depleted or unusable.

A portion of your blood will be used to evaluate genes that may be related to the development of asthmatic or allergic inflammation. The samples will be collected and coded in such a way that only the primary investigators will be able to link your genes to you, the individual.

Results of this genetic testing will not be provided to you. Analysis and results of this testing will be experimental. We will not be looking at genes that have documented clinical implications (i.e. that affect your health or well-being).

Genetic testing is optional and you do not have to participate. You may continue in the main study even if you do not wish to participate in the genetic portion.

If you have not performed a spirometry test within the last 6 months, you are being asked to perform spirometry testing (routine breathing test). Prior to completing the spirometry, you will be asked to withhold some of your asthma medications. The following are examples of asthma medications that will need to be withheld for 24 hours: Serevent, Foradil, Advair, Dulera, Symbicort, and Breo. Spiriva will need to be withheld for 72 hours. Short acting beta agonists such as albuterol, ProAir, Proventil, Ventolin and Xopenex will need to be withheld for 4 hours prior to testing. If you are unable to withhold your medications please let us know and we may need to reschedule your visit. The spirometry will include measurement of your lung function at baseline as well as your lung function after the administration of a medication called albuterol. Albuterol is a medication used to relax your airway muscles and is administered in the form of an inhaler. You will be asked to blow into a machine (spirometer) at least 3 times in order to evaluate your baseline lung function. You will then be administered 4 puffs of albuterol and will have to wait 15-30 minutes. After waiting 15-30 minutes you will blow into a machine (spirometer) at least 3 times, this will measure your lung function after the

administration of the albuterol. You may be asked to return to the Asthma Institute to perform

spirometry again in order to update your pulmonary information.

You are also being asked to complete a questionnaire regarding your asthma and allergies. Information collected from this questionnaire will only be kept in your Research Registry records. You may be asked to return to the Asthma Institute to complete questionnaires again in order to update your information. If you are unable to come to the clinic, you are being asked permission for us to contact you by phone to complete the questionnaire.

After completing the above procedures, you may be asked to perform an additional breathing test called exhaled nitric oxide test. If it looks like you may qualify for a different Asthma Institute research study that requires a certain exhaled nitric oxide measurement for enrollment, then you will be asked to perform this procedure. This is a very simple breathing test and there are no risks. You may be asked to return to the Asthma Institute to perform the exhaled nitric oxide test again in order to update your pulmonary information.

The order of the testing may vary depending upon your individual situation and availability.

You are being asked to allow us to contact you if one of our researchers determines, through review of your medical record information contained in the Research Registry, you are eligible for participation in a future research study directed at the study of asthma and/or allergies. Please note that if you qualify for any future research studies, you will be asked to sign a separate consent form that outlines in detail the nature of this research study, including its potential risks and benefits.

What are the possible risks of my participation in the Research Registry?

There are very minimal risks of physical injury associated with your participation in Volunteer for Asthma – AIR (Asthma Institute Research Registry). Participation in this Research Registry does involve the possible risk that information about your health might become known to individuals outside of the University of Pittsburgh Asthma Institute, Comprehensive Lung Center or The General Internal Medicine Oakland Practice.

Risks of blood draw include pain at the site (occurring in 100% of people, 100 out of 100). Bruising at the site is common (20% of people; 20 out of 100). Infection at the site is rare (occurring in less than 1% of people; 1 out of 100).

Risks of spirometry include feeling lightheaded, short of breath, chest tightness, or wheezing. These are common (20% of people, 20 out of 100).

Risks of albuterol include feeling jittery or nervous, a fast heart rate and you may experience a headache. These are common (> 25% of people experience these things).

There are no known risks associated with the exhaled nitric oxide procedure.

You may feel uncomfortable and/or bored when completing the questionnaire.

We will attempt to preserve your medical record confidentiality by assigning a special research code number to your medical record information stored in the Research Registry, and by removing personal identifiers (for example, your name, social security number, medical record number) from information stored about you in the Research Registry. Information linking the research code number to your name and other personal identifiers will be stored in a separate secure location. Access to any identifiable information about you that is contained within the Research Registry will be limited to investigators associated with the University of Pittsburgh Asthma Institute and their research staffs.

What are the possible benefits of my participation in the Research Registry?

It is unlikely that you will receive any direct benefit as a result of your participation in Volunteer for Asthma – AIR (Asthma Institute Research Registry). However, medical record information contained within the Research Registry will be used for research studies directed at improving our knowledge and treatment of asthma and allergies and this knowledge may benefit patients with these diseases in the future.

Will I or my insurance provider be charged for my participation in the Research Registry?

You will not be charged for any of the services you receive during this study. If you think that you or your health insurance have been charged for services that are part of the study please contact the UPMC billing office that sent the bill and a member of the study team.

If you receive routine clinical services at UPMC that are not a part of this study you or your health insurance will be billed in the standard manner.

Will I be paid for my participation in the Research Registry?

Yes, you will receive up to $30.00 plus a free spacer for your completion of the study procedures. You will receive $10 for completion of pre/post spirometry if it is done at the Asthma Institute. If your pre/post spirometry is completed during your clinic visit or if you have had pre/post spirometry done within the previous three months, we will not be completing the research spirometry; therefore, no reimbursement will be given. You will also receive $10.00 for the completion of the Baseline Questionnaire, $5.00 for the completion of exhaled nitric oxide, and $5.00 for the completion of the blood draw. If you are asked to return to the Asthma Institute to repeat any procedure, you will receive additional compensation for that procedure. Parking and bus fares will be provided at no cost.

Who will know about my participation in this Research Registry?

Any information from your medical records that is placed into this Research Registry will be kept as confidential (private) as possible. In addition, you will not be identified by name in any publication of the results of research studies involving the use of your medical record information unless you sign a separate consent form (release) giving your permission.

What is the nature of my medical record information that will be placed into the Research Registry?

All of your past, current and future medical record information related to your asthma and/or allergies will be recorded into the Research Registry. Since medical conditions and treatments not related directly to your asthma and/or allergies may affect asthma and/or allergies and/or its treatment, it is likely that all of your existing and future medical record information may be reviewed and possibly placed (filed) in your Research Registry folder. This information will not be placed in any other electronic database.

This information will be collected from your Asthma Institute study records, Comprehensive Lung Center Clinic records, General Internal Medicine records, hospital records and, if applicable, private physician records.

Who will have access to my identifiable medical record information contained in the Research Registry?

Access to your identifiable medical record information contained within this Research Registry will be limited to investigators associated with the University of Pittsburgh Asthma Institute and their research staffs. A current, complete listing of these individuals will be provided to you upon your written

request.

In addition, the following individuals may have access to your identifiable medical record information contained within this Research Registry:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review information contained within the Asthma Institute's Research Registry to ensure that the Research Registry adequately protects your privacy.

In unusual cases, the researchers may be required to release your identifiable medical record information from the Research Registry in response to an order from a court of law.

For how long will my medical record information continue to be placed in the Research Registry and for how long will this information be used for research purposes?

We will continue to place your medical record information into Volunteer for Asthma – AIR (Asthma Institute Research Registry) until 1) you are no longer living; or 2) you withdraw your permission for participation in the Research Registry.

Your medical record information contained within Volunteer for Asthma – AIR (Asthma Institute Research Registry) will be used for research purposes for an indefinite period of time.

Is my participation in the Research Registry voluntary?

Your participation in Volunteer for Asthma – AIR (Asthma Institute Research Registry), to include the use of your medical record information for the research purposes described above, is completely voluntary. Whether or not you provide your permission for participation in this Research Registry will have no affect on your current or future medical care at UPMC, affiliated health care provider, or your current or future relationship with a health care insurance provider. Whether or not you provide your permission for participation in this Research Registry will have no affect on your current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my consent for participation in this Research Registry?

You may withdraw, at any time, your consent for participation in Volunteer for Asthma – AIR (Asthma Institute Research Registry), to include the additional collection of your medical record information and its further use for the research purposes described above. However, any research use of your medical record information and blood analysis performed prior to the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation Volunteer for Asthma – AIR (Asthma Institute Research Registry) you should provide a written and dated notice of this decision to the principal investigator of the Research Registry at the address listed on the first page of this consent form. You must also specify if you choose to have any remaining blood samples destroyed at this time.

Electronic Signature (Only applicable if you are signing this consent form electronically)

After you have finished signing these documents a copy of the signed documents will be emailed to you and the study team. Although every reasonable effort will be taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that information may be captured and used by others not associated with this study.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of my participation in the Research Registry at any time, and that such future questions will be answered by the physicians associated with the University of Pittsburgh Asthma Institute or their research staffs. I understand that a copy of this consent form will be given to me.

I understand that any questions, which I have about my rights as a participant in the Research Registry, will be answered by the Human Subject Protections Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

I accept that a blood sample will be kept and my genes will be analyzed for research purposes.

YES _____ NO _____ (please initial)

By signing below, I agree to participate in Volunteer for Asthma – AIR (Asthma Institute Research Registry).

_____ _____
Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of Volunteer for Asthma – AIR (Asthma Institute Research Registry) to the above-named individual, and I have discussed the possible risks and potential benefits of participation in this Research Registry. Any questions the individual has about this Research Registry have been answered, and the physicians and research staff associated with the University of Pittsburgh Asthma Institute will be available to address future questions as they arise.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date