University of Wisconsin-Madison
Consent to Participate in Research and
Authorization to Use Protected Health Information for Research

Title of Study: Microglia Activation In Asthma (MAIA)

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Center for Healthy Minds
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Madison, Wisconsin 53703

Invitation
We invite you to take part in a research study about how asthma influences brain function, especially activation of a type of immune cell in the brain called microglia. We are inviting you because you are 18 to 50 years old and have allergies to house dust mite, ragweed or cat allergen with mild asthma.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study, for other research in the future and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

What is the Purpose of this Research Study?
The purpose of this study is to gain a better understanding of how asthma influences brain function as it relates to the activation of microglia, which are immune cells in the brain. One of the characteristics of asthma is airway inflammation. Airway inflammation in asthma may occur when an allergen is inhaled and causes an allergic reaction in the bronchial tubes. This reaction may lead to chest tightness, coughing and wheezing. We are doing this study to better understand the relationship between airway inflammation and its impact on the brain. We will also be looking at whether there are associations between inflammation and symptoms of depression and anxiety, as well as relationships between inflammation and different functions of the brain, such as memory or attention. The long-range goal of this research direction, of which this study is a first step, is to better understand asthma in relation to brain health and risk for dementia.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of up to 30 people will participate in this study.

Funding for this study is provided by the National Institutes of Health’s National Heart, Lung, and Blood Institute and the Departments of Radiology and Medical Physics at UW-Madison.

What will happen in this study?
If you decide to participate in the research study, the researchers may ask you to do the procedures listed in Table 1 attached at the end of this document. Please look at this table to help you better understand when certain procedures will occur.
You will be in the study for about one month and visit the research clinic up to 6 times. The visits are estimated to last from less than 1 hour up to 8.5 hours depending on which schedule you follow (see Tables 1a and 1b).

- **Medical history:** We will ask you detailed questions about your past and present medical, surgical and medication history, as well as the medical history of your family.

- **Vital signs:** We will measure your temperature, blood pressure, how fast your heart is beating, and how fast you are breathing. We will put a clip on your finger that will measure your oxygen level in your blood, called pulse oximetry. We will measure your height and weight.

- **Asthma and psychological questionnaires:** There will be several questionnaires that you will complete. One of these questionnaires will have to do with your asthma symptoms and the rest of the questionnaires will have to do with your experience of occurrences in your everyday life, both related and unrelated to asthma. Some of these questionnaires ask about personal information, such as your mood, your personal history, or the presence of different kinds of stressors in your life. You may skip any question on the questionnaires that you do not wish to answer.

- **Urine pregnancy test:** You will provide a small amount of urine for urine pregnancy testing if you are a female.

- **Allergy skin test:** Allergy skin testing is a common test to determine which allergies you may have. The skin on your forearm will be lightly scratched where the drops of extract are placed. After 10-15 minutes, we will look for redness and/or swelling (like a mosquito bite) where the tests were done. You may have localized itching at the site, and it may last for several hours. You will only have this procedure done if you haven't done this test with our research group within the last five years.

- **Physical exam:** The study doctor will listen to your heart and lungs, and look at your eyes, ears, nose and throat and do a general physical exam to ensure you are healthy.

- **Spirometry and reversibility:** This test measures how well your lungs are working. You will be asked to hold your albuterol for 6 hours, if possible, before each visit where spirometry will be measured. You will be asked to take a deep breath in and blow your breath out as hard and fast as you can into a machine for at least 6 seconds. This machine measures the amount of air you have in your lungs and how well you can blow the air out. We have you do this up to 8 times so we can get an accurate measure of your lung function. During the first screening visit spirometry with reversibility will be performed. In that case after spirometry, you may be given 2 – 4 puffs from an albuterol inhaler. We will wait 15-30 minutes and recheck your breathing to see how much it improves with medication. This is called reversibility.

- **Blood tests:** We will do routine blood tests to check your health. Blood will be drawn by venipuncture or indwelling venous catheter. We will measure your eosinophil level and do blood studies in the research laboratory. We will also determine which variant of a gene you have that makes translocator protein, which is increased when microglia are activated, as well as the variant of a gene, APOE4, you have that can inform your risk of developing Alzheimer’s disease. The purpose for an APOE4 genetic test is to potentially help researchers gain information about the genetics of Alzheimer’s disease and if genetics may affect the brain activation. We will draw approximately 7.5 tablespoons of blood over the course of the whole study.
• **Exhaled nitric oxide (ENO):** Nitric oxide is a gas that is released from inflammatory cells in the lung. We will have you gently blow air out into a machine for a 10-second period of time. ENO may be measured several times at each visit.

• **Sputum induction:** This is a procedure for obtaining some mucus or phlegm from your lower airways. Before the procedure, you will be given 2 – 4 puffs of albuterol to open your airways. You will inhale a mist of concentrated salt water through a mouthpiece for approximately 12 minutes. You will be asked to stop every 4 minutes to cough up some of the mucus from your lower airways and spit it into a collection cup. We will check your lung function after every 4 minutes to make sure it has not decreased. This is called spirometry (and is described above).

• **Whole Lung Allergen Challenge:** You will be asked to hold your albuterol for 6 hours if possible. We will measure your lung function. You will be asked to breathe in 5 puffs of allergen, starting at a very low concentration. This will be given through a mouthpiece on a nebulizer (a small machine that makes a mist you breathe in). Your lung function will be measured 10 minutes after each concentration of allergen. If your lung function has not decreased by 20% the concentration of the next dose increases. The challenge will end when your lung function measurements have decreased 20% or you receive the highest concentration we are using. This takes up to 2 hours. Your lung function will be measured at least every hour for up to 4 hours after the challenge is complete. You will be asked to measure your lung function after you leave the clinic with a hand-held peak flow meter, and record it on a diary form. You will be asked to do this every 2 hours until you go to bed, and again when you get up in the morning. You may be asked to record your lung function in the diary form on other days, as well. You may receive a follow-up safety phone call from the research team the next morning to check on how you are doing.

• **Complementary and Alternative Medicine (CAM):** Your tongue will be observed for characteristics such as shape, coating and grooves; and your pulse will be taken on both arms by a traditionally-trained physician in the Tibetan medical tradition. During the pulse analysis, the CAM physician will place her index, middle and ring fingers on your wrist pulses for 20-60 seconds per side. This assessment will take approximately 5 minutes total. Additionally, you will also be asked to provide a urine sample. However, if you are female and you provided a urine sample for pregnancy test you will not be asked to provide an additional urine sample. The urine will be assessed for characteristics such as color quality and sedimentation. Tibetan medicine has long recognized associations among the brain, lungs and gut regarding severity of asthma condition and long-term impact to the brain and nervous system. Currently, in the U.S. these Tibetan medical measures are considered part of Complementary and Alternative Medicine (CAM) practices. We are looking at associations between Complementary and conventional medicine understandings of these conditions. These will provide initial data to associate with established measures in conventional medical care, and potentially help us develop new ways to assess, prevent and treat asthma and related conditions.

• **Computer tasks:** You will complete tasks on a computer or tablet device, which will involve responding to pictures, shapes, or words by pressing a button on a keyboard or response box. These tasks will last between 30-90 minutes.

• **Neuroimaging:** We will use a PET/MR scanner to look at images of your brain. The MRI machine produces a magnetic field that passes through your body without disturbing any of its parts. Radio signals will be sent into your body. A small proportion of the water in your body will send back radio signals that the machine receives. The MRI machine uses a computer to determine where these radio signals came from to make a picture showing us what the inside of
your brain looks like. PET scans use very small amounts of radioactive compounds that allow researchers to image processes in the brain such as energy use and blood flow. In this study, a chemical (called a tracer) will be used to temporarily label portions of the brain where microglial cells are active. The tracer used in this study is $^{18}$F-FEPPA. Right before the PET scanning procedure, an IV will be inserted into each arm; one for administering the radioactive tracer and the other for collecting 2 blood samples. When you are ready for the scan, you will be placed in the scanner, lying on your back.

You will be able to use an MRI mock scanner during your screening visit. The mock scanner is very much like the actual scanner so you will be able to experience what a real scan will be like and make sure that you can be comfortable in it.

The scanning procedure for this study will include several different scans. Individual scans last from a few seconds to as long as 20 minutes to complete. You will have to lie still during the individual scans. To help you lie still, special pads will be placed around your head. We may also tape a capsule containing vitamin E to the side of your head. The capsule will show up on the MR image and will help us to know which side of your head is right vs. left. During some of the scans, you may perform tasks similar to the computer tasks described above, where you will be asked to respond to pictures, shapes, words or sounds by pressing a button. The entire scanning session will last 90 minutes. Support will be provided to keep you from becoming uncomfortable, and you will be able to stop at any time.

If you are absent from the study for a period of time, your health status changes (such as if you get a cold), or your need to wash out from or stabilize on a medication you are taking, you may be asked to repeat some procedures.

**Protected health information (PHI) used in this study**

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your diagnosis; lab test results, X-rays, MRIs, CTs or other kinds of medical imaging. We will get this information from your health care providers such as UW Health.

**How long will I be in this study?**

You will be part of the study for about one month. If you get sick during the study or change medications, we may ask you to repeat or delay certain procedures. This may mean that you are part of the study for more than one month. The estimated length of each visit is listed below in the payment section and also on the table at the end of this document.

The researchers may take you out of the study, even if you want to continue, if ...
Do I have to be in the study? What if I say “yes” now and change my mind later?
No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will not have an end date. However:
- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Dr. Melissa Rosenkranz, at 625 West Washington Avenue, Madison, WI 53703.

Participation in the Complementary and Alternative Medicine (CAM) measures is optional. Please indicate your preference placing your initials by one of the following choices:

- ______ I would like to participate in the Complementary and Alternative Medicine (CAM) measures.
- ______ I do not want to participate in the Complementary and Alternative Medicine (CAM) measures.

Will being in this study help me in any way?
Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about allergic disease and asthma and may also lead to new treatments.
Will I receive the results of research tests?
All of the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your doctors the results of these research tests (with the exception of pregnancy test results which will be told to you). Because the clinical utility of the APOE4 test is not established and because it will not be used as part of your clinical care, you will not be told the results of the test. The result of the test is not useful in treatment. The result will not go into your medical record and will remain confidential.

Will information from this study go in my medical record?
A medical record may be created for you if you do not already have one. None of the information we collect for this study will go in your medical record, but your medical record might say that you participated in this study. It might also indicate when you complete the whole lung antigen challenge(s). A copy of this consent and authorization form might go in your medical record.

Possible Discovery of Findings Related to Medical Imaging
Whenever imaging of the brain is done, there is the chance of finding something unexpected. Unexpected findings can have clear clinical significance, or uncertain clinical significance. Clear clinical significance means that the PET/MR shows a problem that may be treatable, and we generally know what the risks are of not treating the problem. Uncertain clinical significance means that the imaging shows something unusual in the brain, but we do not know if it might affect your health, and treatment may not be appropriate or possible. In this study, you will be informed of any findings of clear clinical significance that may be discovered during the imaging procedure, but you will not be informed if there are findings of uncertain clinical significance. The PET/MR image and report from this research study will not be placed in your medical record.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks also (such as problems with getting insurance or a job or feeling worried about a finding for which no treatment is required or appropriate). The neuroimaging we do in this research study is not the same quality that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.

You may also choose to have your physician informed of any findings of clear clinical significance that we report to you, by initialing below. Please note, however, that if you choose to have your physician informed of findings of clinical significance, that report will likely be placed in your medical record.
Please indicate your preference by placing your initials by one of the following choices:

_____ Please inform my doctor of findings of clinical significance – OR –

_____ Please do not inform my doctor of findings of clinical significance

Name of physician to contact
If you do wish us to report any findings to your physician, you must provide us with the name and location of your primary physician, prior to your [MRI, CT, X-ray, etc.].

Name of primary physician

City or clinic

What are the risks of the study?

- **Albuterol:** 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.

- **Holding asthma medication:** For some visits, the study staff may ask you to not take your asthma medication before the visit. If your asthma symptoms get worse and you feel that you need to take your medication, please take your asthma medicine and call the study staff to let them know.

- **Asthma and psychological questionnaires:** The questionnaires are not tests; there are no ‘right’ or ‘wrong’ answers. There are no known risks to answering the questionnaires. The questionnaires might be considered long with repeating questions. You can skip any question you feel uncomfortable answering.

- **Potentially identifying depressive symptoms:** There is a risk of identifying depressive symptoms during the psychological questionnaires. Should we identify moderate depression scores, you will receive a list of community resources for psychological support. Should we identify severe depression scores, you will receive a list of community resources for psychological support, in addition to a follow-up consultation with a licensed clinical psychologist within 3 days.

- **Computer tasks:** There are no ‘right’ or ‘wrong’ answers to the computer tests. There are no known risks to completing the tests. The tests might be considered long with repeating sections. You can skip any section that makes you uncomfortable completing or stop at any time.

- **Allergy skin test:** You may itch at the test site, and it may last for several hours. In very rare situations skin testing can cause a severe allergic reaction. Should this occur, you will be treated
with medication to reverse the reaction. You will need to remain in the office 20 minutes after the skin test is performed to make sure that no severe reaction is taking place.

- **Spirometry**: During spirometry you may feel short of breath during the 6-second exhalation measurement. If this occurs and does not go away on its own you may be given 2 puffs of albuterol.

- **FeNO**: There is no known risk associated with the exhaled nitric oxide procedure.

- **Sputum induction** is associated with chest tightness and a salty taste. You will be given albuterol before the sputum induction in order to prevent excessive chest tightness.

- **Blood draw and IV catheter placement**: You may experience some pain or bruising where the needle enters the skin. You may also feel faint or sick to your stomach while having your blood drawn or having a needle stick. There is a rare risk of infection where the needle enters the skin.

- **Whole Lung Allergen Challenge**: During the whole lung inhaled allergen challenge you are expected to have at least a 20% decrease in your lung function. You may experience asthma-like symptoms such as chest tightness, shortness of breath, wheezing, and cough. These symptoms should be tolerable at rest. They are expected to last 30 to 60 minutes and resolve on their own. If the response is significantly higher than expected, or you are reporting more symptoms than expected, we may give you inhaled albuterol to reverse the symptoms. You may have a second decrease in your lung function 4 hours after the challenge. This is called a late phase reaction. During a late phase reaction, you may have a return of the asthma-like symptoms. In rare cases, the symptoms during the late phase reaction don’t respond to the albuterol inhaler. If this happens, the study doctor will give you a dose of prednisone to take. Prednisone is a pill you swallow. The study doctor will talk to you about how much and how often to take the prednisone, usually only for a few days. The study doctor will also give you information on any side effects to expect at that time. The prednisone will be provided by the research clinic.

- **Prednisone**: You may experience side effects with the short-term use of prednisone. Those may include stomach irritation, headache, insomnia (not being able to sleep well), or mood changes such as irritability or aggression. These side effects are not expected to be severe with the short-term use of prednisone.

- **Worsening asthma**: Your asthma may become worse during the study. The study staff will be reviewing how well your symptoms are controlled at every visit. If you are using more than 8 puffs per day of the albuterol inhaler, or have an increase in breathlessness with your usual activities, or have new symptoms during the study please call the study staff at (608) 263-0524 to speak with the research nurse. If your asthma becomes worse during the study, you may require other medications. If this happens you may not be able to continue in the study.

- **Complementary and Alternative Medicine (CAM)**: There is no known risk associated with tongue observation, pulse analysis, and urine analysis.

- **Risk of disclosure**: There is a risk that your information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

- **Pregnancy risks**: The risks from the allergens used for the whole lung allergen challenge, as well as the radiation exposure, to an unborn child or nursing infant are unknown. If you are a woman of child-bearing potential, to be in this study you must agree not to become pregnant or
nurse a baby. If you do become pregnant, you must contact the study staff right away. You will be asked to provide information about your pregnancy, the delivery and the health of your baby.

- **PET:** Each PET scan is equivalent to two years of background radiation from living on the planet. The federal government has set regulations on the amount of radiation exposure that is considered safe, and these procedures are within those regulations. The PET tracer that will be used has not been approved by the FDA for this purpose and is considered investigational. There is a slight risk of discomfort, bruising, fainting or infection with the placement or removal of the needle used for injecting the solution. There is also a rare risk of developing hypersensitivity reactions with pruritus (itching), edema (swelling) and rash.

- **MRI:** Some subjects should not have MRI scans. These include persons with metallic implants, such as prostheses or aneurysm clips, or persons with electronic implants such as cardiac pacemakers. The magnetic field generated by the MRI machine can cause a displacement or malfunctioning of these devices. We know of no risks or adverse effects from the radio signals used in this study. Some subjects report some anxiety or claustrophobia in the MRI scanner since the head must be placed fully inside the scanner tube. If anxiety or claustrophobia occurs, you are free to stop the scan and will be brought out. Some people have also reported tingling or tapping sensations, or muscle twitches in different parts of their body during the imaging procedure. These sensations are not hazardous and should not cause you any discomfort. The MRI scanner produces loud tapping sounds during operation, which may reach somewhat uncomfortable levels. To minimize any discomfort, you will be provided with disposable earplugs or headphones to wear during the procedure. These earplugs will lessen the noise levels but do not entirely eliminate them, so that communication with the MRI technician is still possible. For those studies using headphones, care will be taken to properly position the headphones such that adequate hearing protection is ensured.

**Will being in this study cost me anything?**

There will be no cost to you for any of the study activities or procedures.

**Will I be paid for my participation in the study?**

We will pay you up to $500 if you complete all of the study visits and procedures (not including payments for COVID testing). Payment will be provided at the end of each visit (see chart). You will receive an additional $30 if you need to repeat procedures due to illness or medication changes. If you choose to leave or we take you off the study for any reason, you will receive payment for the visits you completed. The study activities will be performed according to schedule 1A or 1B. Study coordinators will inform you which time schedule you will be following. All the activities are the same, but they may occur at different visits.
Schedule 1A

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<tr>
<th>Visit</th>
<th>Schedule 1A</th>
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<td>Screening V0</td>
<td>$50</td>
<td>3 hours</td>
<td>$50</td>
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<td>Screening V0a</td>
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<td>6 hours</td>
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<tr>
<td>V1</td>
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<td>6 hours</td>
<td>$80 + up to $50 bonus*</td>
<td>6 hours</td>
</tr>
<tr>
<td>V2</td>
<td>$80</td>
<td>5.5 hours</td>
<td>$120 + up to $50 bonus*</td>
<td>8.5 hours</td>
</tr>
<tr>
<td>V3</td>
<td>$80 + up to $50 bonus*</td>
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<td>2 hours</td>
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<td>V4</td>
<td>$30</td>
<td>&lt;1 hour</td>
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*Bonus will be based on performance in a task done during brain imaging. The bonus will be paid in cash when the brain imaging is completed for that day.

**You will also receive an additional $15 each time you are asked to have a COVID test. Negative COVID test results may be required within 72 hours of certain study visits.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact the study team for instructions.
- Call the Lead Researcher, Dr. Melissa Rosenkranz at (608) 262-5050 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records.
may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health, it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?
- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?
- U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- The study sponsor, National Institute of Health (NIH)
- Collaborating researchers outside UW-Madison
- Companies or groups performing services for the research study

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent.

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

What will happen to my data and biospecimens after my participation ends?
We will use the samples collected in this study for the scientific investigations described above. Occasionally, the planned tests do not use the whole sample. We would like to keep your biospecimens (blood and lung cells) and associated data until they are gone. Data collected throughout this research study, including your health history, your family health history, medications, pulmonary function testing, allergy test response, and results of tests that were conducted during the study will be stored with the biospecimen samples. Keeping data or biospecimens for future research is called “banking”. The banked data and biospecimens will be kept in a secure location for use by researchers.

This is what will happen with your banked data and biospecimens:
- We will use the data and biospecimens in the future in research on allergies, asthma, pulmonary function, immunology, and neuroscience related questions. We may also use them for other types of research.
- The data and biospecimens may be shared with other researchers at the University of Wisconsin-Madison and outside the university. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data and biospecimens will be labeled with a code instead of your name.
- When we give your data and biospecimens to other investigators for research projects, they will not be able to use the code to figure out which data and biospecimens are yours.
- The research team will maintain a link between your data and biospecimens and your identifiable information kept by the study team. The key will be kept with the coordinator in a separate locked area not accessible to others.
- You can request to have your data and biospecimens removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data and biospecimens:
- Banked data and biospecimens will not be shared with your health care provider or used in your treatment outside this study.
- Your banked data and biospecimens will not be used for future genetic studies.

Let us know whether the study investigator, Dr. Melissa Rosenkranz, may use the residual biospecimen samples of your lung cells or blood along with data collected for this study for future research related to respiratory disease and inflammation.

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

- We **may** use your sample and the clinical study data associated with this sample for other research in our laboratory or share it with other investigators conducting approved research after removing all direct identifying information.

- We **may not** use your sample and the clinical study data associated with this sample for any future research in our laboratory or share it with other investigators conducting approved research.

**How will we communicate with you?**

We are requesting your email address so we can communicate with you about scheduling visits, reminding you about study visits, or promptly addressing questions that may arise. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact a nurse coordinator at (608) 263-0524. You do not have to provide your email address to participate in this study.
Please indicate your choice by writing your initials next to one option below:

_____ Yes, you may use email to contact me for this study.

_____ No, I do not want to be contacted by email.

If you do wish to be contacted by email, please write your email below.

Email address: __________________________

Future Contact
Occasionally we may want to contact subjects who did our studies in the past to see if they are interested in new projects. Your name and contact information will be kept in a database at the University of Wisconsin Asthma, Allergy and Pulmonary Research Unit. If you agree to be in this database, you may be contacted in the future to see if you are interested in participating in more studies. The results of your breathing tests will be included in this database, and this information may be used to see whether you qualify for future research studies. The database is password protected, and only research staff will have access to the information. There is a very small chance that your name, contact information and your screening information could, in error, be made public.

Please let us know whether you would like to be contacted or not by putting your initials in one of the spaces below:

_____ I would like to be contacted for future research studies.

_____ I do not want to be contacted for future research studies.

What if I have questions?
If you have questions about this research, please contact the Lead Researcher, Dr. Melissa Rosenkranz, at 608-262-5050. If you have any questions about your rights as a research subject, you may call one of the UW Hospital Patient Relations representatives at (608) 263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

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. Melissa Rosenkranz, at (608) 262-5050.
Agreement to participate in the research study
You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:
- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Printed Name of Research Participant

Signature of Research Participant Date

Signature of Person Obtaining Consent and Authorization Date

**You will receive a copy of this form**
Study coordinators will inform you which time schedule you will be following.

### Table 1a: Procedures and Time allocation per visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Screening Visit 0 (≈3 hrs)</th>
<th>Screening Visit 0a (≈6 hrs)</th>
<th>Visit 1 (~6 hrs)</th>
<th>Visit 2 (~5.5 hrs#)</th>
<th>Visit 3 (~6 hrs)</th>
<th>Visit 4 (&lt; 1 h)</th>
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### Table 1b: Procedures and Alternative time allocation per visit

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<th>Screening Visit 0a (≈6 hrs)</th>
<th>Visit 1 (~6 hrs)</th>
<th>Visit 2 (~8.5 hrs#)</th>
<th>Visit 3 (~2 hrs)</th>
<th>Visit 4 (&lt; 1 h)</th>
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</tbody>
</table>

* MRI simulation may happen on a different day after Visit 0 (but after informed consent) if needed due to scheduling.
# The ideal visit window is 4-6 weeks between consecutive administrations of antigens; however, the visits can go beyond 6 weeks due to illness, medication change, scheduling or at the discretion of the PI.
+ Spirometry with reversibility.
^ Pregnancy test may be needed if it has been >48 hours since the previous test or participant cannot confirm zero chance of pregnancy.
1 Allergy skin test will only be done during screening if historical data is not available.