



Version 9 May 16, 2005

University of Wisconsin – Madison

Subject CONSENT to Participate in Research and AUTHORIZATION to Use and/or Disclose Identifiable Health Information For Research

Title of Study: Cytokine Dysregulation, Virus Infection, And Asthma

PRINCIPAL INVESTIGATOR: Robert F. Lemanske, Jr., M.D.

CO-INVESTIGATORS: James Gern, M.D.,
Carole Ober, Ph.D.

Current Cooperative Studies:

Diet and Obesity as Environmental Risk Factors for Asthma and Energy Expenditure - (Principal Investigator HuiChuan Lai, PhD.)

T-Regulatory Cells and Childhood Asthma (Principal Investigator, James Gern, MD)

INVITATION

You are invited to participate in a research study about the origins of childhood asthma. You are eligible to participate in this study because you were enrolled in COAST (Childhood Origins of ASThma) prior to the birth of your child and are one of 281 families completing the first three years of COAST study. The study continues to be funded by the National Institutes of Health. Your participation is voluntary.

If you decide not to participate, the health care provided to you by the University of Wisconsin – Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

A. What is the purpose of this study?

The purpose of this research study is to follow enrolled children beyond the original three years (i.e. through age 7 years) so that we can continue to evaluate the development of childhood asthma. Research has shown that there are different patterns of wheezing and childhood asthma development. These patterns include 1) transient wheezers – these children wheeze in the first few years of life, but stop by age three; 2) persistent wheezers – these children begin to wheeze in the first year of life and continue to wheeze during childhood; or 3) late-onset wheezers - these children do not wheeze during the first few years of life, but wheezing begins by age 6. This study extension will investigate the development of these wheezing patterns and childhood asthma. We will be using study information gathered during the first “phase” of this study, and would like to build on what we have learned so far. We are interested in continuing to follow your child’s health and development and environmental factors, even if your child has not been ill or wheezed during the first 3 years of the study.

B. What will my participation in this study involve?

This study extension will be conducted over a four-year period (approximately). It will begin when your child becomes three years of age and will continue through age seven. Your child is eligible for this study if he/she participated in the COAST study during the first 3 years of his/her life. If your family decides to participate, there are six scheduled times to visit the study center (one time per year and ½ year visits at age 6 and 7). Your child may still participate if one or both parents decline involvement in study procedures. For families who move (or already reside) out of the greater Madison area during the course of the study, continued participation is encouraged. However, you may elect to withdraw from the study.

The annual visits will last about 2 hours and will include questionnaires, allergy skin testing (at age 5), breathing tests, a blood draw, a nasal sample, and a physician exam. EMLA[®] cream will be used to numb the skin prior to the blood being taken. Albuterol (a medicine that relaxes the airway) and methacholine (a drug that can cause airway tightening) are scheduled as part of the breathing tests and will be explained in a later section. The ½ year visits at age 6.5 and 7.5 will last approximately 30 minutes and are for the purpose of practicing/completing the breathing tests. We will also use this time to do the questionnaire that we otherwise do by phone.

Blood and Mucus samples will be stored in a very cold freezer (-80 degrees) so that samples can be kept and used for future studies. Your samples will be stored until they are all used or until you request withdrawal or destruction of your samples. However, the data collected up until the time of this request will continue to be used. Results of some tests will be available to you (e.g. viral testing of nasal samples, allergy skin test and RAST testing from blood samples) however, results of most tests will not be available to you because individual “normal” values are not yet known or understood.

Study Procedures

- Child allergy skin test (one time)
- Child pulmonary function tests (six times)
- Child post bronchodilator reversibility (1-5 times)
- Child Methacholine challenge (one time)
- Child blood draw (four times)
- Child physical exam (four times)
- Child questionnaire (four times)
- Parent pulmonary function tests (eNO, IOS, and spiro, one time for each parent)
- Parent questionnaire (four times for each parent)
- Phone questionnaire (twelve times)
- Nasal mucus sampling from child (yearly and with significant respiratory illness involving wheezing or diagnosed by a health care professional)

What will be done at each visit?

Please refer to the following table showing when procedures will be done:

Visit/ Age of Child	Visit 1 Age 4	Visit 2 Age 5	Visit 3 Age 6	Visit 4 age 6.5	Visit 5 Age 7	Visit 6 Age 7.5
Allergy Skin Testing - Child		X				
Pulmonary Function Testing Child	X	X	X	x	X	x
Post-bronchodilator Reversibility*		X	X		X	
Methacholine Challenge- Child*			X		or X	
Blood Draws – Child	X	X	X		X	
Physical Exam - Child	X	X	X		X	
Child and Parent Questionnaires	X	X	X	X	X	X
Pulmonary Function Testing – Parent			X		or X	
Nasal Mucus Sample**	X	X	X		X	
Phone Questionnaires***						

* The determination of which test will be conducted will be based on the child’s ability to complete spirometry and the status of your child’s pulmonary function at the time of the test.

** Nasal Mucus Samples will also be collected at the time of wheezing and/or lower respiratory infection.

*** A brief phone call will be made every 3-6 months to complete questionnaires assessing respiratory symptoms and updating personal data

Explanation of study procedures with risks

Allergy skin testing Your child will have allergy skin testing at the 5-year visit. Fourteen drops will be placed on the skin of your child’s back with a sterile instrument that will lightly prick the underlying skin and after 15 minutes, the skin will be looked at for localized redness and swelling. **RISKS:** Your child’s back might itch or burn where the test was done and there may be mild pain from the needle scratch. In very rare cases, a whole body allergic reaction may cause shortness of breath, hives, swelling of the skin or tongue, itchy skin or a fall in blood pressure and so we will observe your child for 20-30 minutes after the test. Emergency care is available to treat these rare reactions.

Pulmonary function testing: Your child will have Pulmonary Function testing (PFT) annually and at age 6.5 and 7.5. Parents will have tests performed (as specified in the following sections) during your child’s 5-year visit or at another time convenient for the family. There will be several types of tests completed at each visit. The tests can be stopped at any time if you or your child begins to feel uncomfortable. For families who move (or already reside) out of the greater Madison area during the course of the study and decide to continue in the study extension, these procedures will not be performed. Some medications, some foods and a recent respiratory infection can affect the results of these tests (and the next one described; methacholine challenge). We will talk to your family specifically if there is any need to wait to take a medication until after the test, or to wait to eat food until after the testing is completed or to reschedule if your child has had a recent cold or illness.

The first test is an **Exhaled Nitric Oxide (eNO)** determination test. This test will be performed to measure the amount of inflammation in your child’s lungs. The second test is called **Inhaled Oscillometry Study (IOS)**. Your child will be asked to breathe normally into a mouthpiece that is connected to a machine that measures sound waves generated during your child’s normal breathing.

The third test is **Spirometry**. This test includes asking your child to breathe forcefully into a device that measures the amount of air that he/she can blow out in one breath (like blowing out birthday candles). If your child is able to complete several spirometry tests with exactly the same effort, 2 puffs of albuterol would be given with a face mask, and the child would be asked to repeat the Spirometry. This is known as **Post-bronchodilator Reversibility**. This test is done to measure the improvement in lung function that your child experiences after taking medication to relax the muscles surrounding their airways. These first three tests will also be completed on the parents.

The half-year visits for pulmonary function testing are for the purpose of improving the child's skill with completing these tests just described. Since this will be the only procedure completed, the visit will take approximately ½ hour.

RISKS : There is no discomfort associated with the eNO, IOS, or Spirometry . In sensitive individuals, taking 2 puffs of albuterol may make your child's heart race, make them feel jittery or nervous, can increase blood pressure, and can cause nausea or headache. However, these feelings are only most likely to occur when taking more than two puffs of albuterol and these feelings usually go away in less than an hour. If your child has a cold or pneumonia, we will want to reschedule the breathing tests as the results will not be accurate for your child. Therefore, we will never ask you to hold medicines during a time that your child is sick. We will also never ask you to "skip" a breathing medication, but only to wait to give it until after the breathing test is completed. Specific instructions will be give for your child's situation.

Methacholine challenge. At age 6 or 7, if your child has been able to demonstrate reproducible spirometry and has been able to complete post-bronchodilator reversibility, your child would be eligible to complete the methacholine challenge. Methacholine is inhaled as a nebulized mist, beginning at very small concentrations, and slowly increasing over subsequent nebulizations. Methacholine may cause the airways of the lung to narrow by constricting the smooth muscles surrounding the airways. A breathing test (spirometry) will be done after each dose, so study personnel will know when the airways narrow. The purpose of this test is to determine if the airways will narrow by at least 20%. Your child may experience mild asthma symptoms during this challenge. These symptoms would go away on their own in about 15-45 minutes, however, we will give a dose of albuterol when the airways have "narrowed" by 20% so that the symptoms go away right away. This test will be performed by a trained professional. If your child is not able to perform the test one year, the COAST staff will perform the test again in the subsequent year in order to complete the test successfully.

RISKS: Methacholine challenge might cause coughing, chest tightness, shortness of breath, or wheezing. Some people might describe this as feeling like having a mild asthma attack. A medication to open the airways (albuterol) will be given. This test will only be completed within certain margins of lung function in order to assure safety.

Blood draws: Blood samples will be obtained annually from your child in order to evaluate for possible immunologic and genetic factors that influence the development of asthma. (Consent for genetic testing was obtained with a separate consent and your family may have decided not to participate in this test.) Approximately 25cc (approximately 1 ½ tablespoon) of blood will be obtained from your child. The blood samples will be obtained from a vein in the arm and will be tested for immunologic factors to help us learn more about the development allergies and asthma. Decisions about the types of tests being conducted are based upon our understanding of the importance of the factor in the development of allergies and asthma, the cost of the tests and the ability to perform the tests. More detailed information about the different tests that are

being completed is at the end of the consent form. EMLA[®] cream is used to reduce the pain your child may experience during the blood draw.

RISKS: Drawing blood from a vein may cause discomfort, possible bruising or swelling at the site of injection, and on rare occasions, a minor infection may result from this procedure. Possible side effects to the EMLA[®] cream include paleness, redness, mild swelling, itching, and rash at the application site. However, these effects are rare with the use of EMLA[®] cream due to the small dose absorbed.

For families who move (or already reside) out of the greater Madison area during the course of the study, continued participation in this part of the research study is encouraged. The re-location requires that a laboratory not otherwise associated with the research study obtain the blood sample. The COAST staff will complete the arrangements for the venipuncture procedure, including contacting a laboratory, providing the necessary equipment, and making all arrangements for billing. The family will go to the clinic for the blood draw procedure, receive the blood from the clinic and then take the pre-paid shipping box to the drop-off location for shipment to the UW.

Nasal mucus sampling You will be asked to call the study center when your child experiences symptoms of a respiratory infection, such as runny nose, cough, fever, and wheezing. We will continue to track all respiratory infection, including colds, but will only need to collect a sample when the child has a significant lower respiratory infection. Samples will be tested for immunologic factors (similar to the tests performed on the blood samples) to help us learn more about the development of allergies and asthma. More detailed information about the different tests that are being completed is at the end of the consent form. The samples will be obtained either by the modified bulb syringe method used since infancy or by using saline nasal spray being squirted into each nostril and asking the child to blow his/her nose into a plastic zip-loc baggie.

For families who move (or already reside) out of the greater Madison area during the course of the study, continued participation in this part of the research study is encouraged. In this case, we will ask families to perform the nasal washes. Families would be required to contact the on-call COAST staff when their child is ill (a toll-free number is provided). The COAST staff would verify the need to obtain a nasal sample. COAST will provide all required materials and a pre-paid mailer for sending the sample to UW. Instructions for the procedure will be in both oral and written form. Some families may elect not to perform this procedure. Options for continued participation will be discussed with the family.

Questionnaires

We also will collect the following health information about you for this research study in the form of questionnaires:

- Child health and medication history questionnaires
- Familial history of allergy and asthma and parental incidence of allergy and asthma
- Environmental overview relative to allergen exposure.

C. Are there any benefits to me?

You are not expected to benefit directly from participating in this study. Your participation in this research may benefit other people in the future by helping us learn more about allergies and asthma.

You may also consider that receiving knowledge about childhood asthma and allergies is a benefit. Information learned from this study will be shared with our families in two ways:

1. Information about your child such as the results of viral and/or RAST tests will be shared directly with you and with your primary care provider if you direct us to do so.
2. General study findings are shared using the following methods:
 - a.) published articles and abstracts (copies of these are available on our website <http://coast.medicine.wisc.edu>)
 - b.) newsletter published by COAST (2-4 times / year)
 - c.) presentations made by the principal Investigators.

Commercial Product Disclaimer

Although this is not the purpose of the research we are doing, it is possible that the work being done may contribute to research leading to new pharmacological or genetic treatment strategies. These research results may eventually be of commercial value, but you will not be able to share in any profit that may occur from the commercialization of products developed with information obtained from you or your child's samples.

D. Will I be paid for my participation?

Recognizing that this study will require extra time and effort, you and your child will be paid for participation in the study. *This amount will be prorated according to the procedures completed.* A list of compensation available per procedure is available upon request. The maximum amounts (assuming all procedures are completed) would be:

- Visit 1 - \$75
- Visit 2- \$100
- Visit 3- \$90
- Visit 4- \$20 gift card
- Visit 5 - \$75
- Visit 6- \$20 gift card

In addition, your child will be paid a total of \$15 for nasal mucus samples that are obtained at the time of illness. As part of the annual visit, families will be paid \$5.00 for the completion of each phone call questionnaire. Parents will be paid an additional \$20.00 for completing eNO, IOS, and spirometry.

Usable items that will also serve as study reminders (e.g. magnets, toys such as balls and bubbles) will be given after every study visit in appreciation of your commitment to helping us learn more about asthma and allergic disease. COAST will also schedule group gatherings for the purpose of child play and/or presentation of COAST findings.

E. Are there any side effects or risks to me?

The main risk of taking part in this study is that someone who is not involved in performing or monitoring this study could know your study information. A breach of confidentiality could result in damage to you or your reputation, but the chances that this will happen are very small. Risks for the individual procedures have been explained.

F. What protected health information will be used for this study?

How will my privacy be protected?

Who will use my health information?

We will gather the following protected health information for use in this study:

From you we will gather:

- Information about you and your child, such as birth dates, home address, home phone number, work phone number, email address

- Information about you and your child's health with comprehensive child questionnaires about factors related to allergies and asthma including environmental and dietary considerations.

From your child's medical records kept by his/her primary care physicians and any emergency or urgent treatment for any allergy/asthma related condition. We will work with you to learn the names of physicians, clinics and hospitals where your child is seen and have individual medical record release forms signed in order to acquire this information in order to include it in our COAST data.

Privacy Protection:

We will protect your confidentiality by assigning a subject number to all of the information that you provide. Any samples requiring an outside agency to perform the testing will be sent with an identifying number known only to the COAST staff. The particular identification system for the genetic testing with the COAST Co-Investigator has been described in that consent. All research records will be treated confidentially. Your name will not appear in any publication of the results of this study. Collaborative presentation of research findings is a possible outcome of this study through the use of shared group results (no individual results). This collaborative effort would be completed in order to achieve the aims of this study.

Who will use this information?

The information collected from you during this study and from your medical records will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. It may also be shared with others at the UW-Madison and outside the UW-Madison with the co-Investigator, Dr. Carole Ober of Chicago. General group information will be shared with specialty laboratory sites performing unique testing on environmental and blood samples (there will not be sharing of individual information). Whenever possible your health information will be kept confidential.

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison
- Research support services staff at the UW-Madison and its affiliates

Others outside of UW-Madison and its affiliates who may need to receive your health information in the course of this research:

- The National Heart Lung and Blood Institute of the National Institutes of Health (NIH)

People outside of UW- Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. However, when information is shared with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

We have received a **Certificate of Confidentiality** from the federal government, which will help us protect your privacy. The Certificate protects against the involuntary release of information about you collected during the course of the study to persons not connected with the study. The researchers involved in this project cannot be forced to disclose your identity or any information about you collected in this study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, you or the researcher may choose to voluntarily disclose the protected information under certain circumstances. The

Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if required by law (e.g. child abuse, reportable communicable disease, threat of harm to self or others) or as required by state or federal agencies who may review our records under limited circumstances, (e.g. such as a U.S. Department of Health and Human Services (DHHS) request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.) No study records or information will be released to insurance carriers unless you so request. The results of this study may be published in scientific journals or be presented at medical meetings, however the results will be presented as group results and neither you nor your child will be identified by name.

G. Is my permission voluntary and may I change my mind?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely withdraw from the study at any time. You also may choose to cease participation or skip any questions that you do not feel comfortable answering.

IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.

H. How long will my permission to use my health information last?

By signing this form you are giving permission for your health information to be used for this study and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed here:

Dr. Robert F. Lemanske, Jr.
 Professor of Pediatrics and Medicine
 University of Wisconsin Medical School.
 (608) 263-6180 (608) 263-8539.

Beginning on the date you withdraw your permission, no new health information will be used. Any health information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

Additional Principal Investigators conducting studies with the COAST children as the eligible participants include the following:

James Gern, MD Professor Department of Pediatrics University of Wisconsin 263-6201	Carole Ober, PhD The University of Chicago Department of Human Genetics c-ober@genetics.uchicago.edu,	Hui Chuan Lai, PhD RD Assistant Professor Nutritional Sciences University of Wisconsin 262-9972
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I. If I have additional questions, whom should I contact?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study, please contact Dr. Robert Lemanske, Jr., MD. For information on the rights of research subjects, you may contact the UW Hospital and Clinics Patient Relations Representative at (608) 263-8009.

Agreement to Participate in this Study

And

Permission to Use and/or Disclose My Health Information

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

Name of Child

Name of Parent

Signature of Parent:

Date:

****YOU SHOULD RECEIVE A COPY OF THIS FORM AFTER SIGNING IT****

Signature of person obtaining consent and authorization:

Date: _____



COAST Samples: Storage and Testing

January 2005

Storage of Samples: All samples of mucus, blood and “dust” that have been collected are stored frozen for future testing. These samples can be maintained for extended periods of time in these conditions, and at this time, COAST plans to maintain all samples for many years to assure availability for future testing based on new and relevant research findings.

Types of Tests There are now three types of samples on which the tests are conducted: the mucous samples, the blood samples, and the environmental samples. Decisions about the types of tests being conducted are based upon our understanding of their importance in the development of allergies and asthma, the cost of the tests and the ability to perform the tests. Each of these factors will be addressed throughout this document. The blood samples are the most complex group and will be discussed first.

Blood Testing: There are four major categories of blood testing that are currently being conducted on the COAST samples:

Cytokine testing = Cytokines include a large number of proteins made by cells that affect the behavior of other cells --- cytokines are being “discovered” or “recognized” by researchers all the time so the particular cytokine that COAST is studying is based upon previous research by ourselves and by reputable researchers throughout the world. Many of these proteins are classified into two groups --- the Th1 (those involved in antiviral responses) and the Th2 (cytokines that are associated with allergy). Additional protein substances made by specialized cells may also be studied as they relate to allergies and asthma. For example, leptin is a type of cytokine made by adipose cells. This hormone may amplify inflammation, and this effect could explain a relationship between obesity and asthma. There are multiple different types of proteins that could be studied so careful examination is given to the significance of the test and the funding that may be available to complete the test.

Another component of the blood that is being examined is “chitinase”. Chitinases are enzymes found in lower forms of life that are important in the regulation of cytoskeleton development (shells of insects and lobsters). In mammals, chitinase protein has been found to be important in the regulation of allergic airway inflammation. Importantly, chitinase has also been noted to be present in human asthma. Initial results in a landmark study by researchers at Yale University may lead to important information when examining the COAST samples. Yale will perform the test (samples will be sent de-identified) and we will assess whether chitinase protein can be detected, and if levels present correlate or track with the development of various wheezing phenotypes during infancy and early childhood. The results of these studies could provide unique and powerful insight into mechanisms that regulate the production of allergic inflammatory responses in the airway that ultimately lead to the development of childhood asthma.

RAST testing = (radio-allergo-sorbent test) is a test of the plasma that picks up the presence of antibodies that signal the possibility of allergy. In infancy examining antibodies to foods was important. As the COAST children get older, antibodies to airborne allergens such as ragweed become relevant to study. The specific tests completed will be age-appropriate and will be selected based on their significance in relationship to allergic and asthmatic symptoms in children.

Cell type testing = Since the COAST study was started, there have been a number of new discoveries related to allergy and asthma. For example, a type of cell called the T-regulatory cell has been identified that may be important in controlling inflammation and allergies. As a result, a new project was funded by the NIH to study this new area, and we will be asking your consent to allow your child to participate in these exciting new studies. This study involves additional tests on the COAST yearly blood samples (no extra blood needs to be drawn), and involved testing of a sample of dust from your home. More information about the dust sample is listed later in the newsletter.

Genetic testing = Genetic testing required a specific consent and families previously made a decision about participation (you may have decided to not participate). This testing is examining genes and particular locations and differences in DNA that demonstrate a relationship to the incidence of patterns of wheezing, allergy, or responses to environmental exposure that may confer risk for allergy and asthma. This testing is being performed by Dr. Carole Ober, who is a COAST researcher at the University of Chicago. COAST has decided that any change in genetic researcher or genetic testing center would require re-contact with the families.

Mucous Samples: Samples of nasal mucous were collected at well child visits and at the time of each significant respiratory infection. The Wisconsin State Laboratory of Hygiene examined the samples for viruses detectable by routine culture methods and a specialized test looking for RSV analyzed these samples. The samples are also stored for current and future examination to look for many of the same type of proteins (cytokines) and for leukotrienes (powerful inflammation mediators) that were discussed in the blood section. As many of you are aware, the virus testing measures did not always discover the virus causing the illness. In the past two years, COAST has developed an additional test that has been able to “magnify” the virus that is present in the sample and therefore, identify the virus found in the sample. Although this method is accurate, it is extremely time-consuming (only 18 samples can be examined for one virus only during an entire week--COAST has collected nearly 4000 samples). Therefore, we are currently working with a company to develop a system that would examine approximately 45 samples at a time for all of the known respiratory viruses (over 100 separate types of viruses). A major advantage of this new test is in the speed of the analysis – it can be completed in 1-2 days. If this work is successful, we will plan to use this new method to analyze samples that have not yet been tested, and to retest the old specimens to look for viruses that were missed the first time.

The original theory of COAST was that the RSV virus was most important in causing asthma. Although this virus is important, our studies have shown that rhinovirus, the common cold virus, is much more important than previously recognized. The fact that

there are more than 100 different strains of rhinovirus makes the further study of these new methods of detection crucial to understand how these viruses may lead to the development of childhood asthma.

Environmental Samples: Environmental samples were previously collected from homes of families who had remained in their same residence from birth to three years of age of the COAST child. There is now additional funding available to obtain environmental samples from the homes of all the COAST children (in the greater Madison, Wisconsin area). The initial samples were examined for the presence of allergens and certain bacteria in the home. These “dust” samples were analyzed by University of Colorado (Dr. Andy Liu), and Johns Hopkins University (Dr. Peyton Eggleston) – these are leading researchers in the area of dust analysis. In the future, we plan to work with another leading researcher (Dr. Don Milton at Harvard University) to look for other proteins from bacteria and fungi in the dust, and additional portions of the samples will be sent to Harvard for this purpose. The theory behind this is that exposure to some types of “harmless” bacteria and fungi in the environment may help the immune system to develop in a normal fashion, and help to prevent allergies and asthma. Once this work is completed, Dr. Ober (geneticist at U. of Chicago) will test this theory by comparing the environmental information to immune development and the presence of allergy or wheezing in the COAST children.