# National Institute of Allergy and Infectious Diseases (NIAID)
# Division of Allergy, Immunology and Transplantation (DAIT)
# Informed Consent Template (Adult - Maternal)

**TITLE OF CLINICAL RESEARCH STUDY**

Systems Biology of Early Atopy (SUNBEAM)

**Part 1**

This study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) through the Consortium for Food Allergy Research (CoFAR).

**Protocol Number:** CoFAR-12

**PRINCIPAL INVESTIGATOR:** Robert Wood, MD
**Johns Hopkins Institutional Review Board Protocol Number**: IRB00250006

You are being asked to take part in a research study. This is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

## YOUR PARTICIPATION IS VOLUNTARY

We will explain this research study to you. You may ask questions at any time.

- Your and your child's participation in this study is your decision.
- You may change your mind at any time.
- We will give you a signed copy of this consent form for your records.

**Key Information:**

The first few pages of this document include a summary of this study to help you decide whether to participate. Detailed information is provided after the summary.

### Why is this research being done?

We would like to learn more about factors that put very young children at higher risk for food allergies and eczema. This study will focus on risk factors that may be present before, during, and after birth and through the age of 3 years.

### How long will this research last and what will my child and I need to do?

Your participation in this study will last approximately 37 – 45 months, depending on when you enroll.

**Before the birth of your child**, you will have an enrollment visit at the study site that will include taking your height and weight, asking questions about yourself and your medical history and collecting biological samples like blood, urine, hair, stool, skin swabs and skin tapes, nasal swabs,

and vaginal swabs. We will also ask you to collect environmental samples from your home such as dust and water.

At **delivery**, a blood sample will be collected from the child's umbilical cord after the cord is detached from your child. At **1 – 2 days after delivery,** before your child leaves the hospital, several biological samples (skin swabs, skin tapes, and stool) will be collected. If the skin swab and skin tape samples are not collected at the hospital, study staff may be able to collect them at your child's first visit to the pediatrician, an unscheduled study visit, or at a home visit during your child's first week of life.

When your child is **2-, 5-, 12-, 24- and 36-months old**, you will be asked to bring your child to the clinic. At these visits, the study team will collect biological samples (blood, urine, stool, hair, skin swabs, skin tapes, saliva, nasal secretion (fluid) and nasal swabs) from your child. Beginning at 5-months, the visits will also involve allergen skin testing to foods, and at 12-, 24-, and 36 months, environmental allergens. You will also be asked to collect home dust, water samples and stool samples between visits. Depending on your child's history of exposure to a food, past food allergy symptoms, and the results of the allergen skin test, **your child may have an oral food challenge** at one or more visits to confirm the diagnosis of an allergy to that specific food.

Throughout the study, you will complete questionnaires related to you and your child's health, diet, and environment. You will be asked to complete some questionnaires that you will access over the internet at home, on your smart phone, tablet, or personal computer. Other questions will be completed at the clinic during study visits.

**Is there any way being in this research can hurt me or my child?**

All of the study procedures that will be conducted on you have little to no risk.

Most of the procedures that will be completed on your child have little to no risk. Two exceptions are the allergen skin test, which very rarely can both cause life-threatening allergic reactions, and the oral food challenge done to diagnose food allergy. Oral food challenges can cause allergic reactions that range from mild to severe and **to life-threatening**.

The risks for you and your child from the study procedures are discussed in more detail in Section 3, "**RISKS AND/OR DISCOMFORTS**."

**Will being in this research study help me or my child in any way?**

There may or may not be a direct benefit to you and your child from being in the study.

Your child could also potentially benefit from early detection of allergy to specific foods. Where there is doubt of food allergy, the supervised introduction of foods can establish the diagnosis of food allergy and allow for appropriate education. Knowing what foods are safe to eat can improve quality of life and possibly prevent the future development of food allergy.

**What other choices do I or my child have besides taking part in this research?**

You and your child do not have to take part in this research study. You can still have your prenatal and postnatal care as planned with your Obstetrician.

**Detailed Information:**

The rest of this document includes detailed information about this study (in addition to the information listed above).

## 1. INTRODUCTION/BACKGROUND

Food allergy affects about 15 million people in the United States. This includes 6 million children, most of which are diagnosed by their first birthday. Currently, there is no reliable way to predict which children will suffer from food allergies. Eczema is a chronic skin disease that affects approximately 13% of U.S. children. Eczema is thought to be related to allergic conditions like food allergy and asthma. One in three children with eczema suffer from moderate to severe disease, having a major impact on the quality of life of the children and their families. Knowing when a child develops food allergy and eczema could be a first step to predicting allergic diseases.

The goal of this study is to recruit pregnant mothers, their infant and their infant's biological father to study risk factors for the development of food allergies, eczema, and other allergic conditions. Ultimately, this knowledge may help us identify children who are at risk for developing these diseases so that treatments may be started early to prevent or treat the diseases.

## 2. STUDY COMPONENTS

This study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The study will enroll at least 2500 pregnant women, 18 years of age or older, who agree to enroll their child at birth.

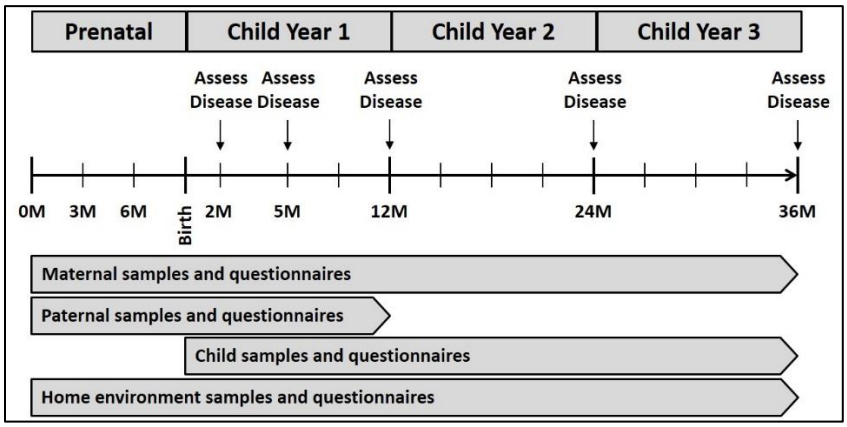
If you are pregnant with more than one child, only one child can be enrolled into the study. Infants that are delivered earlier than 34 weeks of gestation or are born with a major birth defect or medical condition will not be able to participate in this study. If you experience major medical complications during the pregnancy, you may not be able to continue participation in this study. It is also in the judgement of the investigator to exclude infants if participation is not in the infant's best interest.

Twelve clinical centers across the U.S. are participating in this study. Your child will be observed until he/she reaches 3 years of age.

### Summary of Procedures

During the study, biological and environmental samples and questionnaire information will be collected from the parents or legal guardian and the children. The children will be assessed for allergic diseases at clinic visits at ages 2-, 5-, 12-, 24-, and 36-months (Figure 1. Study Overview).

**Figure 1. Study Overview**




The following procedures will occur over the course of the study:

- **Consent:** You will read and sign the consent form before completing any study activities.
- **Questionnaires:** We may ask you questions about general health, environment, tobacco exposure, and quality of life. We will also ask you information about you and your child's medical history, vaccinations, medications, and diet. You may ask the study staff to explain any questions you do not understand. Some of the questionnaires you will answer yourself on a smart phone, tablet, or personal computer at your home or at the clinic.
- **Addendum Guidelines Counseling:** The study staff will counsel you at the 2-month visit on new guidelines that recommend the early feeding of peanuts to some infants to prevent peanut allergy.
- **Height and Weight:** We will measure your and your child's height and weight.
- **Immunoglobulin E (IgE) test:** We will take a blood sample from you and your child to measure antibodies in the blood to specific foods and other allergens.
- **Skin Assessments:** A doctor or nurse will examine your child's skin for eczema and other skin conditions.
- **Medication Review:** We will ask you about any medications your child is taking.
- **Sample Collections:** We will ask to collect biological samples from you and your child. We may collect samples during a study visit or we may give you instructions and supplies to collect the biological sample at home. Types of biological samples we will collect include:
    - **Blood:** Blood will be collected from you and your child. The largest amount of blood that we will collect on you during a visit is 1 tablespoon. The most amount of blood that we will collect on your child during a visit is 1.5 – 3 teaspoons, depending on his/her age. We will study the blood for immune components (cells and antibodies) and store it for future research.
    - **Breast Milk:** If breastfeeding, you will be asked to provide a breast milk sample up to 3 times during your child's first year of life. We will give you a kit to collect the breast milk along with instructions that include how to return the sample if

you choose to collect at home. The breast milk will be used to study immune responses and bacteria.

- **Cord Blood:** Blood from the umbilical cord will be collected after delivery of your child. Cord blood will be used to study immune responses.
- **Skin Tapes:** You and your child will have skin tape samples collected using sterile medical tape applied to specific areas of the skin. The skin is held tight and the tape strip is applied. Light pressure will be applied, and then the tape strip will be slowly removed. A maximum of 16 tapes may be applied to the same area of skin. However, when your child is 1 – 7 days old, a maximum of 8 tape strips may be used. We will study the tape strips for proteins, fats and gene expression, and store it for future research.
- **Skin Swabs:** You and your child will have skin swab samples collected. Skin bacteria is collected with a moistened sterile cotton swab which is rolled over the skin. The skin swab will be used to study immune responses.
- **Hair:** You and your child will have strands of hair collected from the back of the head and as close to the scalp as possible. The hair samples will be studied for environmental exposures that are potentially associated with allergic disease.
- **Nasal Secretion:** Your child will have nasal secretion (fluid) samples collected. Nasal bacteria will be collected on filter paper strips placed into a nostril and then removed. Nasal secretions will be used to study immune responses.
- **Nasal swab:** You and your child will have a nasal swab sample collected. An absorbent swab will be inserted into a nostril, rotated gently and then removed. The nasal swab will be used to study bacteria and immune responses.
- **Saliva (spit):** We will collect a small amount of saliva from your child by swabbing the inside of the child's cheeks. The saliva will be used to study immune response and bacteria.
- **Meconium and Stool:** Meconium is the first stool of a newborn infant. We will collect this from your child while in the hospital. We will give you a kit to collect you and your child's stool at home along with instructions that include how to return the sample. The meconium and stool will be used to study bacteria.
- **Urine:** A small amount of urine will be collected from you and your child while in the clinic. Your child's urine will be collected from a diaper placed on your child at the visit or a urine collection device placed on the toilet if your child is toilet trained. Urine will be used to study metabolic processes.
- **Vaginal Swabs:** You will be asked to swab your vagina. We will give you a kit and instructions for collecting this sample at home and returning it to the clinic. Alternatively, this sample can be collected at the enrollment visit. The swab will be used to study bacteria.

- **Home dust and water collection:** You will collect dust and water samples from the primary home of you and your child. The primary home is the home at which you and your child sleep most nights. You will receive the kits and instructions for collecting the samples and returning them to the clinic. Dust will be used to study allergens and water will be analyzed for calcium carbonate concentration.
- **Transepidermal Water Loss (TEWL):** A noninvasive measurement of water loss across you and your child's skin. A probe (a type of instrument) is applied to the exposed skin for about 15 seconds until the measurement is recorded.
- **Allergen Skin Prick Test:** Your child will be tested to foods and environmental allergens. Small drops of liquid will be placed on the arm. Each drop is lightly pricked under the

skin to see if there is a reaction. If there is a reaction, there will be a raised, red, itchy bump that may look like a mosquito bite. If your child is taking antihistamines like Benadryl or Zyrtec, the medications will need to be stopped for a short period of time before skin prick testing and oral food challenges so they do not interfere with the results of the tests. The test takes about 15 – 20 minutes.

- **Oral Food Challenge (OFC):** Depending on your child's history of exposure to a food, any allergic symptoms to the food, and the results of the allergen skin test, it may not be clear whether your child is allergic to that food or not. If it is not clear whether your child is allergic to a food, your child will be invited to have an oral food challenge to the food in the research clinic. We will ask you (or another parent/guardian of your child) to sign another consent form at that time for the oral food challenge. Oral food challenges, also called feeding tests, are used to find out if a person has a specific food allergy. During the OFC, the person is given gradually increasing amounts of the food they may be allergic to, to see if an allergic reaction happens. This is done under medical supervision and the person is closely watched while they are given the food and afterwards. Oral food challenges may be repeated at the next scheduled visits if the diagnosis of allergy to a specific food is still in question. Oral food challenges may be done for several different foods, which could require multiple clinic visits within a few weeks. This test takes about 2 – 4 hours.

The timeline for your assessments and procedures are outlined in the Figure below (Figure 2). See the Child's Sample and Procedures section below as well as Figure 3 for an overview of the child's schedule of events.

**Figure 2. Maternal Schedule of Events**

| | Prenatal | | | Year 1 | | | | Year 2 | Year 3 |
|---|---|---|---|---|---|---|---|---|---|
| **Maternal Events** | **Pre-Screen** | **Enroll Visit** | **Prenatal** | **1 m** | **2 m Visit(s)** | **5 m Visit(s)** | **12 m Visit(s)** | **24 m Visit(s)** | **36 m Visit(s)** |
| **Maternal Questionnaires and Forms** | | | | | | | | | |
| Verbal permission to prescreen and pre-screening questionnaire | X | | | | | | | | |
| Informed consent | | X | | | | | | | |
| Eligibility and enrollment checklist | | X | | | | | | | |
| Contact information | X | X | | | X | X | X | X | X |
| Sociodemographics (multiple forms) | | X | | | | | | | |
| Medical history of biological family | | X | | | X | X | X | | |
| Pre- and postnatal medications and vaccinations | | | | | X | | | | |
| Allergic and respiratory diseases | | X | | | | | X | | |
| Maternal Smoking | | X | | | X | X | X | | |
| Maternal exposure to secondhand smoke | | | | | X | | | | |

| Maternal Events | Prenatal | | | Year 1 | | | | Year 2 | Year 3 |
|---|---|---|---|---|---|---|---|---|---|
| | Pre-Screen | Enroll Visit | Prenatal | 1 m | 2 m Visit(s) | 5 m Visit(s) | 12 m Visit(s) | 24 m Visit(s) | 36 m Visit(s) |
| Maternal household chemical exposures | | | | | X | | | | |
| Perceived stress scale | | X | | | X | X | X | X | X |
| Depression scale | | X | | | X | X | X | X | X |
| Diet questionnaire (DHQ3) | | X | | | | | | | |
| Diet questionnaire (ASA24) | | | | | X | | | | |
| Maternal allergenic foods | | X | | X | | X | | | |
| **Maternal Clinical Procedures** | | | | | | | | | |
| Transepidermal water loss (TEWL) | | X | | | X | | | | |
| Height and weight measurements | | X | | | X | | X | | |
| **Maternal Sample Collections** | | | | | | | | | |
| Blood | | X | | | X | | | | |
| Skin tapes | | X | | | X | | | | |
| Skin swabs | | X | | | X | | | | |
| Vaginal swab | | X | | | | | | | |
| Urine | | X | | | X | | | | |
| Nasal swab | | X | | | | | | | |
| Hair | | X | | | | | | | |
| Stool | | | X | | X | | | | |
| Breast milk | | | | | X | X | X | | |
| Home dust collection | | | X | | | | | | |
| Home water sampling | | | | | | | | | |
| **Maternal Clinical Laboratory Tests** | | | | | | | | | |
| Total and specific IgE | | X | | | | | | | |

## Child's Samples and Procedures

After you agree for your child to continue study participation and provide informed consent, you will:

- Receive instructions on how to log into and enter information into the electronic questionnaires (also called ePRO)
- Receive instructions on how to collect and return your child's urine, stool, and environmental samples
- Receive kits for the self-collected samples

**Child's Study Procedures after Birth and before Discharge***

Prior to your child's discharge, the study staff will:

- Conduct Transepidermal Water Loss measurements
- Collect skin tape strips
- Collect skin swabs
- Collect a meconium and/or stool sample

*If the skin swab and skin tape strip samples are not collected at the hospital, study staff may be able to collect them at your child's first visit to the pediatrician, an unscheduled study visit, or at a home visit during your child's first week of life.

**Child's Clinic Visits and Visit Windows**

Your child will have clinic visits at age 2-, 5-, 12-, 24-, and 36-months. The 2-, 5-, and 12-month visits may occur 1 month before to 1 month after the target date. This window allows for one or more additional visits dependent on your child's requirements for testing.

The 5- and 12-month visit windows may be extended to 2 months before to 2 months after the target date if your child requires an oral food challenge to multiple foods.

The 24- and 36-month visits may occur 3 months before to 3 months after the target date. During this time window one or more visits may occur dependent on your child's requirements for testing.

If you have concerns about your child in between scheduled visits, such as a worrisome reaction following a study procedure, you will be instructed to contact the study team, and you may be asked to return to the clinic for an unscheduled visit.

If your child misses a regularly scheduled visit and has missed the window for the visit, the study team will try to bring your child in for an unscheduled visit. At this visit, all the procedures for the missed visit would be conducted. However, if the date being considered for an unscheduled visit is too close to the next scheduled visit, then your child will be brought in on the date of the next scheduled visit.

**Child's Clinical Procedures**

**Skin Assessments:** At every clinic visit starting at the 2-month visit.

**Transepidermal Water Loss (TEWL)**: At 1 – 2 days after birth (or possibly during the first 7 days at a home visit, an unscheduled visit, or pediatric office if not collected before the hospital discharge) and then at every clinic visit starting at the 2-month visit.

**Height and Weight Measurements:** At each clinic visit starting at the 2-month visit.

**Addendum Guidelines Counseling:** At the 2-month visit.

**Allergy Skin Prick Testing:** Allergy skin prick testing to food allergens will be conducted at the 5-, 12-, 24-, and 36-month visits and to aeroallergens (allergens carried in the air) at the 12-, 24-, and 36-month visits. The allergens tested at each visit are the following:

| | Visit | |
|---|---|---|
| **Allergen** | **5-Month** | **12- , 24- , 36 -Months** |
| Food | Milk<br>Egg<br>Peanut | Milk<br>Egg<br>Peanut<br>Wheat<br>Soy<br>Tree nuts (cashew, hazelnut, walnut)<br>Fish (cod)<br>Shellfish (shrimp)<br>Sesame |
| Aeroallergen (in the air) | | Alternaria<br>Cat<br>Cockroach<br>Dog<br>Dust mite<br>Mouse<br>Location-specific tree and grass pollens |

**Oral Food Challenge:** Starting at age 5 months, your child may have an oral food challenge to one or more foods. Your study doctor will explain what combinations of food exposure history, past allergic symptoms, or allergen skin prick testing or specific IgE concentration will require an oral food challenge. Oral food challenges may be conducted over several visits depending on how many foods have to be tested on your child. To reduce the possibility of a severe allergic reaction, children that show convincing signs of allergy to a specific food based on history and skin prick test will not have an oral food challenge to that specific food.

**Child's Samples Collected at the Clinic**

At clinic visits shown in the Child's Schedule of Events (Figure 3), we will collect the following samples:

- Blood
- Skin Tapes
- Skin Swabs
- Urine
- Saliva
- Nasal secretion (fluid)
- Nasal swab
- Hair

**Child's Samples Collected at Home**

Starting at the 1 – 2 week time point, you will collect stool samples from your child and environmental samples (dust and water) from your child's primary home. The primary home is the home at which your child sleeps most nights. Study staff will instruct you on sample collection procedures and provide you with sample collection kits. These samples will be either mailed or delivered to the study site at the next clinic visit.

**Child Questionnaires**

At study visits, you will answer questions about your child. Some of the questionnaires will be administered by study staff and some you will answer on a smart phone or other electronic device connected to the internet. Between visits, you will be asked to complete periodic questionnaires from home on your smart phone, tablet, or personal computer.

**Figure 3. Child's Schedule of Events**

| | Year 1 | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Events** | **Birth** | **1-2 d** | **1-2 w** | **1 m** | **2 m Visit(s)** | **3 m** | **4 m** | **5 m Visit(s)** | **6 m** | **7 m** | **8 m** | **9 m** | **10 m** | **11 m** | **12 m Visit(s)** | **24 m Visit(s)** | **36 m Visit(s)** |
| **Child's Questionnaires and Forms** | | | | | | | | | | | | | | | | | |
| Reaffirm child's participation with mother/eligibility and enrollment checklist | X | | | | | | | | | | | | | | | | |
| Birth record abstraction | X | | | | | | | | | | | | | | | | |
| Sociodemographics (multiple forms) | | | | | X | | | X | | | | | | | X | X | X |
| Medical History* | | | | | X | | | X | | | | X | | | X | X | X |
| Allergic and Respiratory Diseases* | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Child's Exposure to Secondhand Smoke | | | | | X | | | X | | | | | | | X | X | X |
| Child's Household Chemical Exposures | | | | | X | | | X | | | | | | | X | X | X |
| Allergenic Foods and Symptoms* | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Infant Feeding Practices | | | | X | | X | | X | | X | | X | | X | X | | |
| Block Food Questionnaire: Kids 2-7 Years | | | | | | | | | | | | | | | | X | X |
| Household Consumption of Allergenic Food | | | | | | X | | | | | | | | | | | |
| **Child's Clinical Procedures** | | | | | | | | | | | | | | | | | |
| Skin assessment, SCORAD, EASI | | | | | X | | | X | | | | | | | X | X | X |
| Transepidermal water loss | | X | | | X | | | X | | | | | | | X | X | X |
| Height (length) and weight measurements | | | | | X | | | X | | | | | | | X | X | X |
| Addendum Guidelines Counseling | | | | | X | | | | | | | | | | | | |
| Allergen Skin Prick Test | | | | | | | | X | | | | | | | X | X | X |
| Oral food challenge, when indicated | | | | | | | | X | | | | | | | X | X | X |
| **Child's Sample Collections** | | | | | | | | | | | | | | | | | |
| Cord blood | X | | | | | | | | | | | | | | | | |
| Blood | | | | | X | | | X | | | | | | | X | X | X |
| Skin tapes and swabs | | X | | | X | | | X | | | | | | | X | X | X |
| Urine, saliva, hair | | | | | X | | | X | | | | | | | X | X | X |
| Nasal secretion and nasal swab | | | | | X | | | X | | | | | | | X | X | X |

| Events | Year 1 | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Birth | 1-2 d | 1-2 w | 1 m | 2 m Visit(s) | 3 m | 4 m | 5 m Visit(s) | 6 m | 7 m | 8 m | 9 m | 10 m | 11 m | 12 m Visit(s) | 24 m Visit(s) | 36 m Visit(s) |
| Meconium or stool | | X | X | X | X | | | X | | | | X | | | X | X | X |
| Child's home dust collection | | | | | X | | | | | | | | | | X | X | X |
| Child's home water sampling | | | | | X | | | | | | | | | | | | |
| **Child's Clinical Laboratory Tests** | | | | | | | | | | | | | | | | | |
| Specific IgE | | | | | X | | | X | | | | | | | X | X | X |

*Medical History, Allergic and Respiratory Diseases, and Allergenic Foods and Symptoms questionnaires are also assessed between the 12-month, 24-month, and 36-month visits but are not shown on the schedule of events.

### 3. RISKS AND/OR DISCOMFORTS

Procedures in this research study may involve risks and/or discomforts that are not possible to predict. The most serious risks involve reactions to food challenges for your child. You will be informed of any new risks that may be identified during the course of the study. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

**Questionnaires:** You may find that some of the questions are too personal. You may refuse to answer any questions that make you feel uncomfortable. There is a possibility that your answers may be read by others outside of the study. We do not put your name on the questionnaires. We only write identification numbers on the questionnaires.

**Height & Weight:** There are no known risks for having your or your child's height and weight measured.

**Stopping Medications:** Stopping allergy medications before skin prick testing or food challenges may cause worsening of allergic symptoms. Your child will be able to take the medications right after the test is finished or during the test if needed for an allergic reaction.

**Allergen Skin Prick Testing:** The risks of allergen skin prick testing are small. Skin prick testing may result in a small, itchy hive where the test is placed. Usually, the hives stop within 1 – 2 hours, but the itch and swelling can occasionally last up to 24 hours. In approximately 1 out of 10,000 tests, the participant may experience other allergic symptoms including sneezing, itchy and watery eyes, and a runny nose. Very rarely, a serious, life threatening allergic reaction may occur, but no deaths from skin prick testing using standard dosing techniques have been reported in 50 years.

**Oral Food Challenges:** Oral food challenges may cause an allergic reaction that can range from mild to severe **and include life-threatening reactions and death.** However, the risk of a severe allergic reaction is reduced by starting the challenge with a very small amount of the food and increasing the amount slowly. The challenge is stopped at first sign of a reaction.

**Blood Draw:** The risks associated with drawing blood include discomfort, bleeding, bruising or swelling where the needle is inserted and in rare cases, lightheadedness, fainting, or infection. A numbing cream may be placed on the skin before the blood draw to reduce the pain of the needle. Side effects from this cream (mainly skin rash) are unlikely, but may occur.

**Hair, Saliva, Skin Swab, Stool, and Urine Sample Collections:** There are no significant risks associated with hair, saliva, skin swab, stool, and urine sample collections.

**Transepidermal Water Loss (TEWL):** There are no known risks associated with this non-invasive skin moisture measurement.

**Nasal Secretion:** The nasal filter paper used to collect the nasal fluidmay cause discomfort inside of your child's nose.

**Nasal Swab:** Nasal swabbing may cause localized discomfort inside of you and your child's nose.

**Skin Tapes:** Very mild redness may develop immediately after a series of tapes are applied on one area of skin. The redness is expected to last less than 12 hours without side effects. Very rarely people may experience lightheadedness, nausea, or fainting. Possible bleeding and/or bruising may occur at the area. It is unusual, but there is a small chance to have an allergic reaction to the tape or a skin infection. Since the tape is removed immediately after application, the risk of an allergic reaction is extremely low. To decrease the risk of an allergic reaction, skin tapes will not be collected from participants with a history of serious life-threatening reactions to tape or adhesives. The risk of skin infection is also extremely low because only superficial (outer) skin layers are removed.

**Identifiable Private Information:** Your and your child's privacy and the confidentiality of your data are very important to us. We will make every effort to protect them, but we cannot make guarantees. Confidentiality is described under Section 13, "**CONFIDENTIALITY.**"

## 4. POTENTIAL BENEFITS

There may or may not be a direct benefit to you and your child from being in the study.

This study may help us better understand the field of allergic diseases, which may make future clinical testing and treatment easier.

## 5. ALTERNATIVES TO PARTICIPATION

Before you decide to take part in this study, the study doctor from this site will talk with you about the standard of care available to you and your child. You may choose not to take part in this research study. If your child were to develop allergies in the future, he or she can still be treated by a pediatrician and/or allergist.

## 6. NEW FINDINGS

The study doctor will tell you any new information or significant findings that may affect your willingness for you and your child to continue in this study.

## 7. VOLUNTARY WITHDRAWAL FROM STUDY

- You may decide not to take part in this study.
- You can decide to stop your and your child's participation in this study at any time.
- If you decide to leave this study, there will not be any penalty or loss of benefits in your or your child's routine medical care or any other benefit(s) that you or your child are otherwise entitled to receive.

- If you decide to leave the study or give up legal guardianship of your child, your child's legal parent or guardian must sign a new consent which will replace the consent you signed for your child's study participation. Otherwise, your child will also be terminated from the study.
- In addition, you should talk to the study doctor from this site, who will discuss future treatment and procedures for your and your child's continued care.

## 8. REASONS WHY YOU OR YOUR CHILD MAY BE TAKEN OFF STUDY WITHOUT YOUR CONSENT

You or your child may be removed from the study without your consent at any time. Reasons why you or your child may be removed from the study include, but are not limited to, the following:

- You withdraw consent for your child's participation in the study.
- The study doctor from this site determines it is not in your or your child's best interest tocontinue in the study.
- You or your child are diagnosed with a serious illness or other condition that is not allowed for study participation.
- You are unable or unwilling to complete required study treatments and examinations.
- The study is stopped by the Institution, the Sponsor, or by the FDA or other health authorities.

If you are removed from the study, the study doctor from this site will contact you to discuss stopping procedures and your future care.

## 9. PREGNANCIES, BREASTFEEDING AND BIRTH CONTROL

Treatments and procedures involved in this research study are not expected to cause risks to an embryo/fetus or nursing child.

## 10. COSTS TO THE SUBJECT (YOU AND YOUR CHILD)

There will be no charge to you or your health insurance company for any costs which are directly related to this study.

The study does not provide routine care or any medications or treatments for you or your child's general health or allergic problems. You or your health insurance plan will be billed for some or all the costs of any routine medical care provided outside of the study. Physician visits outside of the study visits, emergency room, urgent care visits, or hospitalization during the course of the study will be billed to your health insurance plan.

## 11. CONFIDENTIALITY

Your and your child's medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your and your child's personal information private. However, we cannot guarantee complete confidentiality. You and your child will be each identified by a code, and personal information from your records will not be released without

your written permission. You and your child will not be identified in any publication or in the sharing of your data about this study.

When the study is finished, information and samples from the study will be entered in a central data repository sponsored by NIAID for scientific research use. Information will not be included that can identify you. Your and your child's privacy is protected whenever this information is used. We will keep your and your child's samples indefinitely, unless you tell us differently. The purpose is to make study data available to other researchers.

Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases.

Personal identifying information about you or your child (such as name, phone number, address) will NOT be included or shared with others.

Organizations that may look at and/or copy your or your child's medical records for research, quality assurance, and data analysis include:

- NIAID, the sponsor of the research
- NIAID representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring, or analyzing the study

Your and your child's study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your and your child's information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

## 12. FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

Your samples and your child's samples and study information may be shared with other researchers. This data would be coded so that other investigators would not have access to traditional identifiers (such as name, phone number, address).

We are asking your permission to store unused biological and environmental samples collected during this study to be used in the future for tests that are not yet planned. These tests may or may not be related to the study of food allergy or other allergic conditions.

Your samples and your child's stored samples will be used to obtain knowledge about genetic information in relation to you and your child's immune system. Genetic tests study an individual's

inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body.

In this study, we do not plan to use your samples for genetic cloning, paternity testing, or other personal identification. However, it is possible for genetic tests to detect non-paternity. The results of tests performed on stored samples or reports resulting from the analysis of your samples or your child's samples will not be given to you, your doctor, or your child's doctor. The results will not be put in your medical record.

There is no benefit to you or your child from the storage of samples and information. But, the use of your or your child's samples and information may help researchers learn more about the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research and to share what is stored with other researchers. Collecting, storing, sharing information and making it available for other studies may help people in the future. Information put into databases together with other stored information from many studies conducted in different places allow researchers to study the combined information and learn even more about health and many different diseases.

Samples will be stored at a SUNBEAM-designated biorepository. If you decide to allow storage, your and your child's samples and information may be stored for an unknown length of time.

Although your and your child's stored research samples will not be sold, the information obtained from the research performed on your and your child's samples may in the future lead to the development of commercial products. You will not receive any money from research using your/your child's stored samples and information.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing it is possible that it could be traced back to you or your child because your or your child's genes are specific to you or your child. We will make every attempt to protect your and your child's confidentiality and to make sure that your/your child's personal identity does not become known.

You can change your mind at any time and ask to have your and your child's samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your or your child's stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your or your child's samples will not affect your or your child's ability to participate in this study. The future use of your or your child's samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

**The Genetic Information Nondiscrimination Act (GINA)**

GINA is a federal law that helps reduce the risk of discrimination by health insurers or employers based on your genetic information. GINA does not protect you from discrimination if you apply for other types of insurance (such as life, disability or long-term care). GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

- Health insurance companies and group plans may not request genetic information from this research.
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your or your child's genetic information when deciding to hire, promote, or fire you when setting the terms of your employment.
- The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not protect you if you apply for other types of insurance (such as life, disability or long-term care).

## 13. WHAT OTHER THINGS SHOULD YOU KNOW ABOUT THIS RESEARCH STUDY?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

**What is the Institutional Review Board (IRB) and how does it protect you?**

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

**What should you do if you have questions about the study, or are injured or ill as a result of being in this study?**

Call the principal investigator for your study site, which is listed in the "**Site-specific Consent Information**" (Part 2 of this consent).

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department.

If you wish to contact the overall study principal investigator(s), use the contact information provided on page one of this consent form.

(NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the research subject. A copy should be placed in the research subject's medical record, if applicable.)

## SITE SPECIFIC CONSENT INFORMATION

**Site Name**: Vanderbilt University Medical Center
**Study Title**: Systems Biology of Early Atopy (SUNBEAM)
**JHM IRB Application Number**: IRB00250006
**Site Principal Investigator**: Leonard Bacharier, MD
**Site Principal Investigator Contact Information:** 615-322-2632
**Emergency Contact:** Leonard Bacharier, MD 615-322-2632
**Other Study Contact(s):** Janet Nicotera MSN, RN Research Nurse Specialist II 615-936-3097

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**Payments for your time spent taking part in this study or expenses:**
You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

| VISITS | PAYMENT AMOUNT |
|---|---|
| **MOTHER-CHILD** | |
| Prenatal | |
| Enrollment Visit | $ 50.00 |
| Prenatal Home Activities | $ 50.00 |
| Year 1 | |
| Birth | $ 30.00 |
| 2-Month Visit | $ 75.00 |
| 5-Month Visit | $ 75.00 |
| 12-Month Visit | $ 75.00 |
| Home Activities Month #1-12 | $ 100.00 |
| Year 2 | |
| 24-Month Visit | $ 75.00 |
| Home Activities Month #13 - 23 | $ 50.00 |
| Year 3 | |
| 36-Month Visit | $ 75.00 |
| Home Activities Month #25 - 35 | $ 50.00 |
| **BIOLOGICAL FATHER** | |
| Enrollment Visit/Clinic | $ 50.00 |
| **UNSCHEDULED** | |
| Unscheduled Visit | $ 25.00 |

**Research-Related Injury:**
If it is determined by Vanderbilt and the Investigator with Sponsor input that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the Sponsor to pay for the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury

**Problems or Questions**

| I can call … | At … | If I have questions or concerns about |
|---|---|---|
| ***Leonard Bacharier, MD*** **Site-Specific Principal Investigator** | **Phone: 615-322-2632** | ▪ **General study questions**<br>▪ **Research-related injuries or emergencies**<br>▪ **Any research-related concerns or complaints** |
| ***Theresa Rogers RN*** | **Phone: 615-936-5864** | ▪ **General study questions**<br>▪ **Research-related injuries or emergencies**<br>▪ **Any research-related concerns or complaints** |
| ***Vanderbilt University Medical Center IRB*** | **Phone: (615) 322-2918 or toll free at (866) 224-8273** | ▪ **Rights of a research subject**<br>▪ **Any research-related concerns or complaints**<br>▪ **If investigator/study contact cannot be reached**<br>▪ **If I want to speak with someone other than Investigator, Study Contact or research staff** |

**SITE SPECIFIC PRIVACY and HIPAA INFORMATION**

**Authorization to Use/Disclose Protected Health Information**

**What information is being collected, used, or shared?**
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

**Who will see, use or share the information?**
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

**Do you have to sign this Authorization?**
You do not have to sign this Authorization, but if you do not, you may not join the study.

**How long will your information be used or shared?**
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

**What if you change your mind?**
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

**Costs to you if you take part in this study:**
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

**FUTURE CONTACT**

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Vanderbilt University Medical Center from contacting you about other research.

**Please sign and date your choice below:**

**YES** ☐ _____ _____

**Signature of Participant** **Date**

**NO** ☐ _____ _____

**Signature of Participant** **Date**

**SIGNATURE PAGE**

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

_____

Signature of Parent/Legal Guardian/Court-Appointed Representative (Print Name) Date/Time

**FOR CHILD PARTICIPANT**

_____

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

_____

Signature of Parent #2 (Print Name) Date/Time
(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

_____

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED)**