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INFORMED CONSENT FORM FOR STUDY PARTICIPANT AND CARETAKER
URECA CONTINUATION TO AGE 17

TITLE:	Urban Environment and Childhood Asthma (URECA)
PROTOCOL NO.:	ICAC-07 WIRB® Protocol #20142570
SPONSOR:	The National Institute of Allergy and Infectious Diseases (NIAID)
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number

Note: In this consent form, "you" always refers to the study participant. If you are the parent or legal guardian, please remember that "you" refers to your child.

1. YOUR PARTICIPATION IS VOLUNTARY

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

- Taking part in this study is your decision.
- You may change your mind at any time.
- You will be given a copy of this consent form for your records.

2. PRINCIPAL INVESTIGATOR

[Name]

3. INTRODUCTION/BACKGROUND

We are extending the URECA study to follow all the participants into age 17 instead of stopping at age 16. At this time, we plan for the study to stop in the year 2024, which will allow all participants enough time to complete study activities until at least their 17th birthday. The study will be mostly the same, but there will be some new procedures that are explained below.

4. PURPOSE OF THE STUDY CONTINUATION

We want to keep following the URECA participants as they grow older to learn even more about which factors lead to allergies and asthma in children and to study lung growth in children with and without asthma.

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5. STUDY COMPONENTS

This continuation of study research is funded by the National Institutes of Allergy and Infectious Disease (NIAID). It will enroll as many subjects as possible from the participants previously enrolled and active in URECA.

If you agree to take part in this continuation, you will be asked to remain active in the study through your 17th birthday. This study continuation includes the following types of visits:

- Quarterly Phone Calls – You will be contacted to answer questions over the phone every 3 months, as long as there is not a clinic visit scheduled. These calls will be the same as the calls that you have received earlier in the URECA study, but some of the questions may change.
- Dust Sample Collection – You will be asked to collect a dust sample from your home yourself at ages 14 and 16. We will give you a vacuum cleaner and supplies to do this. You will need to return the sample by mailing it in an envelope that we will give you, or by bringing the sample to the clinic next time you have a visit. If there are problems, we can do the vacuuming at your home.
- Clinic Visits – You will be asked to come to the clinic at least once each year. These visits will include the procedures listed below and questionnaires that will give the study clinician information about the participant's health. If you miss any activities or can't be seen for a visit, some activities listed below can "roll over," or be done later at the next clinic visit. Prior to each visit, you will be asked to stop taking specific medications that could interfere with breathing tests, as long as it is safe to stop taking them. There are up to four clinic visits planned during this continuation, although you may be asked to come in for an unscheduled or additional visit if you are willing.

<u>Year 14 Clinic Visit</u>

This visit will occur when you are 14 years old, as close as possible to your 14th birthday. During this visit:

- You will answer some questions about your family, your allergies and asthma, your habits, and your general health. Questions about your stress and mental health will also be asked.
- The study clinician will examine your ears, nose, throat, chest, skin and lungs.
- Your height, weight, pulse, breathing rate, temperature, and blood pressure will be checked.
- You will be asked to give a urine sample. This is used to test your exposure to tobacco smoke and may be used for a pregnancy test, if applicable.
- An allergen skin test will be done. Drops of several common allergens, like pollen and grass, will be put on your arm with a device that pricks the skin. Fifteen minutes later, a member of the study staff will look for signs of an allergic reaction around the pricks, like redness and minor swelling. Any red or raised areas on your arm will be outlined with an ink pen. Tape will be placed over the ink pen mark. The tape will be removed and placed on a form. The test and measurements will help the staff member decide whether you have allergies. The skin test takes about 15 to 20 minutes. You will receive the results of this test.
- A blood sample (about 4 tablespoons of blood) will be collected from your arm.
- You will be asked to perform several breathing tests including:
    - Measurement of Exhaled Nitric Oxide (eNO) – where you will inhale through a mouthpiece and then steadily exhale into a special machine for about 10 seconds. This tells us how much of a certain kind of gas you exhale called nitric oxide, which can tell us about any irritation in your lungs.

  - Impulse Oscillometry (IOS) – where you will hold a mouthpiece of a machine in your mouth while it makes sounds. The way these sound waves move tells us more about how open your airways are and how well your lungs are working.
  - Spirometry - where you breathe deeply and then exhale as much air as you can into a mouthpiece as forcefully as possible. This tells us more about how much air your lungs can hold.
- You will be asked to do a methacholine challenge test. In this test, you will inhale a very low dose of medication called methacholine in the form of a mist. This medication can narrow your airways if you have asthma. Next, you will do Spirometry to check on your lungs and how they are functioning. This will be repeated several times and the amount of methacholine that you will inhale will increase a little bit each time. The test will stop if your lung function drops too far below your normal levels. You will be given albuterol at the end of the test to help you breathe more easily. The test will be done by a trained professional, with a doctor available at all times.
- You may be asked to repeat Spirometry and IOS after taking a medication (albuterol) to see if your results improve. This will only happen if you can't do the methacholine challenge test described above.
- You will rate your physical development using a form.

Year 15 Clinic Visit

This visit will occur when you are 15 years old, as close as possible to your 15th birthday. During this visit:

- If you did not do certain activities listed above, you may be asked to do them during this visit.
- You will answer some questions about your family, your allergies and asthma, your habits, and your general health.
- The study clinician will examine your ears, nose, throat, chest, skin and lungs.
- Your height, weight, pulse, breathing rate, temperature, and blood pressure will be checked.
- You will be asked to give a urine sample to be used for a pregnancy test, if applicable.
- Bioelectrical impedance analysis (BIA) will be done to measure body fat, lean tissue and total body water. BIA uses very small amounts of electrical current that you cannot feel and measures how they pass through your body.
- You will do a fitness test by walking up and down a hallway for six minutes. We will measure how far you walk and will measure your pulse.
- You will be asked to do IOS, where you will hold a mouthpiece of a machine in your mouth while it makes sounds. The way these sound waves move tells us more about how open your airways are and how well your lungs are working.
- You will be asked to provide nasal samples, including at least the following:
  - A small plastic brush will be used to collect cells from the inside of your nose.
  - An absorbent piece of paper will be used to collect mucus the inside of your nose.
- You will be asked to perform Spirometry, where you breathe deeply and then exhale as much air as you can into a mouthpiece as forcefully as possible. This tells us more about how much air your lungs can hold.

Year 16 Clinic Visit

This visit will occur when you are 16 years old, as close as possible to your 16th birthday. During this visit:

- If you did not do certain activities listed above, you may be asked to do them during this visit.
- You will answer some questions about your family, your allergies and asthma, your mental and physical health, and your habits.
- The study clinician will examine your ears, nose, throat, chest, skin and lungs.
- Your height, weight, pulse, breathing rate, temperature, and blood pressure will be checked.
- You will be asked to give a urine sample. This is used to test your exposure to tobacco smoke and may be used for a pregnancy test, if applicable.
- A blood sample (about 4 tablespoons of blood) will be collected from your arm.
- Sputum induction will be done. This is a procedure where you inhale a salt-water mist through a machine for 12 minutes. During this time, you will be asked to try vigorously coughing up mucus every two minutes. Your breathing will be monitored and if you are having too much trouble breathing, the procedure will be stopped and you will be given medication (albuterol) to help you breathe. This will help us see cells from your lungs.
- You will be asked to perform Spirometry, where you breathe deeply and then exhale as much air as you can into a mouthpiece as forcefully as possible. This tells us more about how much air your lungs can hold.

Year 17 Clinic Visit

This visit will occur when you are 17 years old, as close as possible to your 17th birthday. During this visit:

- If you did not do certain activities listed above, you may be asked to do them during this visit.
- You will answer some questions about your family, your allergies and asthma, your mental and physical health, and your habits. Questions about your stress and mental health will also be asked.
- The study clinician will examine your ears, nose, throat, chest, skin and lungs.
- Your height, weight, pulse, breathing rate, temperature, and blood pressure will be checked.
- You will be asked to give a urine sample to be used for a pregnancy test, if applicable.
- BIA will be done to measure body fat, lean tissue and total body water. BIA uses very small amounts of electrical current that you cannot feel and measures how they pass through your body.
- You will be asked to perform several breathing tests including:
    - eNO – where you will inhale through a mouthpiece and then steadily exhale into a special machine for about 10 seconds. This tells us how much of a certain kind of gas you exhale called nitric oxide, which can tell us about any irritation in your lungs.
    - IOS – where you will hold a mouthpiece of a machine in your mouth while it makes sounds. The way these sound waves move tells us more about how open your airways are and how well your lungs are working.
    - Spirometry - where you breathe deeply and then exhale as much air as you can into a mouthpiece as forcefully as possible. This tells us more about how much air your lungs can hold.
- You will be asked to repeat Spirometry and IOS after taking a medication (albuterol) to see if your results improve.

Methacholine Challenge Visit

You will only be asked to come in for this visit if you did not complete a methacholine challenge at your Year 14 or Year 15 visit. If you are asked to come in, this visit may occur any time after your Year 15

clinic visit. It may be repeated if you are unable to conduct a methacholine challenge during the visit. During this visit:

- If you did not do certain activities planned for you before this visit, you may be asked to do them here.
- You will be asked to give a urine sample to be used for a pregnancy test, if applicable.
- You will answer some questions about your physical health and current medications.
- The study clinician will examine your ears, nose, throat, chest, skin and lungs.
- You will be asked to perform breathing tests including:
    - IOS – where you will hold a mouthpiece of a machine in your mouth while it makes sounds. The way these sound waves move tells us more about how open your airways are and how well your lungs are working.
    - Spirometry - where you breathe deeply and then exhale as much air as you can into a mouthpiece as forcefully as possible. This tells us more about how much air your lungs can hold.
- You will be asked to do a methacholine challenge test. In this test, you will inhale a very low dose of medication called methacholine in the form of a mist. This medication can narrow your airways if you have asthma. Next, you will do Spirometry to check on your lungs and how they are functioning. This will be repeated several times and the amount of methacholine that you will inhale will increase a little bit each time. The test will stop if your lung function drops too far below your normal levels. You will be given albuterol at the end of the test to help you breathe more easily. The test will be done by a trained professional, with a doctor available at all times.
- You may be asked to repeat Spirometry and IOS after taking a medication (albuterol) to see if your results improve. This will only happen if you can't do the methacholine challenge test described above.

6. RISKS/DISCOMFORTS

Treatment and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during the study. Please ask your study clinician or the study staff to explain any procedures or risks that you do not understand.

Activity	Scheduled At	Risks/Discomforts
Allergen Skin Test	Year 14	<u>Likely</u> There may be redness, swelling, and itching of the skin at the site of the test. This may last for 1 to 2 hours. <u>Less Likely</u> Redness, swelling, and itching of the skin at the site of the test could occur up to 1 or 2 days after the skin test. The study clinician may prescribe a cream to treat these symptoms. There is a very small chance that you could have hives, congestion, asthma symptoms or fainting during the test. A study clinician will always be available to treat these rare symptoms, if they occur. <u>Rare, but Serious</u> While it is very rare, anaphylactic shock can occur with allergy skin testing. Anaphylactic shock is a dangerous allergic reaction. Although very rare, anaphylactic shock may include: Swelling of the

Activity	Scheduled At	Risks/Discomforts
		throat or other parts of the body, drop in blood pressure, difficulty breathing or swallowing, not being able to stay awake or alert, or death
Bioelectrical Impedance Analysis (BIA)	Year 15; Year 17	There are no known risks associated with the BIA (bioelectrical impedance analysis) test. BIA should not cause any pain, but if you have a lot of hair where the electrodes are placed, it may hurt when they are removed.
Blood Collection	Year 14; Year 16	Likely The risk of having blood taken may include pain, bleeding, or bruising. Lightheadedness and fainting may occur during fasting blood draws. Less Likely Lightheadedness and fainting rarely occur for non-fasting blood draws.
Exhaled Nitric Oxide (eNO)	Year 14; Year 17	There are no known risks for the exhaled nitric oxide testing.
Fitness Test	Year 15	There are no known risks for the fitness testing.
Impulse Oscillometry (IOS)	Year 14; Year 15; Year 17; Methacholine Challenge	Likely This breathing test can cause coughing or lightheadedness, which will go away soon after the test is finished. During the test, some puffs of air will come from the mouthpiece. This will not hurt, but may be startling, so the test will be introduced slowly for you to get used to it.
Induced Sputum	Year 16	Likely This procedure may result in wheezing, coughing or chest tightness and salty taste. We will give you albuterol before the procedure to lessen the risk. If albuterol is given, it can cause increased heart rate and blood pressure, nausea, headache, and a jittery or nervous feeling. These symptoms usually go away in less than an hour.
Methacholine Challenge	Year 14; Methacholine Challenge	Likely The methacholine challenge test might cause coughing, chest tightness, shortness of breath, and wheezing. Some people might describe this as feeling like having mild asthma symptoms. A medication to open the airways (albuterol) will be given if needed. If albuterol is given, it can cause increased heart rate and blood pressure, nausea, headache, and a jittery or nervous feeling. These symptoms usually go away in less than an hour.
Nasal Cell Collection	Year 15	Likely Collection of nasal cells cause discomfort or pain. Less Likely The brush used to collect nasal cells may cause your eyes to water or cause a nosebleed, sneezing, runny nose, or mucus to run in the back of your throat.
Nasal Mucus Collection	Year 15	Likely If your nose is sensitive, collecting nasal mucus may cause sneezing.

Activity	Scheduled At	Risks/Discomforts
Physical Examination	All Clinic Visits	There are no known risks for the physical exam as it will be done in this study.
Post-Bronchodilator IOS and Spirometry	Year 15; Year 17	After performing IOS and Spirometry, you will receive albuterol and repeat these tests. Breathing tests have the same risks after albuterol; those risks are included in their own sections here. Likely If albuterol is given, it can cause increased heart rate and blood pressure, nausea, headache, and a jittery or nervous feeling. These symptoms usually go away in less than an hour.
Questionnaires	All Visits and Calls	Less Likely You may find some of the questions too personal. You may refuse to answer any questions that make you feel uncomfortable. There are no right or wrong answers to the questions. If you do not understand a question, you may ask the study staff members for more information. Rare There is also a chance that your answers may be read by others outside of the study. Your name is not put on the questionnaires.
Spirometry	All Clinic Visits	Likely This breathing test can cause coughing or lightheadedness, which will go away soon after the test is finished. Less Likely The participant may get a headache or feel sick at the stomach. These symptoms usually go away in less than an hour.
Urine Collection	All Clinic Visits	There are no known risks for urine collection to test exposure to tobacco smoke or to test for pregnancy, as applicable.
Stopping Antihistamines	Year 14	If the participant takes antihistamines, we will ask you to stop some of those medicines 5 days before the allergen skin test. Likely If you take antihistamines, you may have allergy symptoms (but not asthma symptoms) from stopping your medicine. If you need to use your allergy medications, please use them, but we may need to reschedule your appointment. We can be reached at [site contact number].
Stopping Asthma Medications	All Clinic Visits	If you take asthma medicines, we will ask you to stop some of those medicines from 8 to 24 hours before the methacholine challenge and spirometry. We will tell you what medicines not to take before the test. Less Likely Stopping asthma medicines may make your asthma symptoms worse. If you feel bad or have asthma symptoms, you should not stop taking the medicine. If you start to have asthma symptoms (like coughing, wheezing, or shortness of breath) after stopping the

Activity	Scheduled At	Risks/Discomforts
		medicine, start the medicines as prescribed by your doctor. If you start to have severe asthma symptoms or an asthma attack, call your doctor.
COVID-19 Testing	All Clinic Visits	You may be asked to have a COVID-19 test before a visit or procedure. There are many different types of COVID-19 testing. The study team will let you know what type of COVID-19 test is done at your institution. • Nasal Swabs: It is likely that you will feel discomfort during the procedure. You may have a runny nose, headache, or earache. It is less likely, but possible that the swab will cause mild nose bleeding. • Throat Swabs: It is likely that you will feel discomfort during the procedure. You may have an itchy throat. It is less likely, but possible that the throat swab will cause mild bleeding. • Saliva Tests: There are no known risks for the saliva test. If requested, the COVID-19 test will need to be negative before you will be allowed to do certain procedures, like the breathing tests. You will receive the results of the COVID-19 test. Results from any COVID-19 tests are not anonymous and are not considered confidential. These results may be reported according to institutional guidelines to local/state health departments in the interest of public safety. You do <u>not</u> need to agree to the COVID-19 test to remain in the study. If you refuse the COVID-19 test, you may still be contacted by phone or come into clinic for procedures and sample collections that do not require a negative COVID-19 test, like the allergen skin test.

There may be some risks that are currently not known. There is a potential risk of loss of confidentiality. All efforts will be made to keep your personal information private and confidential. You will be identified in the study by a code. Personal information from your records will not be released without your written permission.

7. POTENTIAL BENEFITS

The results of the medical tests listed above will be shared with you. There will be no additional direct benefits to you as a result of these continuing study activities. The results of the study might be helpful in treating people with asthma in the future.

8. ALTERNATIVES TO PARTICIPATION

The study clinician and/or study staff will talk with you about this study and other options available to you. You may choose not to be in this research study. Your routine medical care will not be affected in any way should you choose not to continue to participate in this study or to withdraw from the study at any time.

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9. NEW FINDINGS

The study doctor will tell you about any new information that may affect your willingness to continue in this study.

10. VOLUNTARY WITHDRAWAL FROM STUDY

Your agreement to continue with the URECA study is entirely voluntary. You may decide not to take part or withdraw from the study at any time. The participant's routine medical care will not be affected in any way, and there will be no penalty nor a loss of benefits should you choose not to continue to participate in this study or to withdraw from the study at any time.

11. REASONS WHY YOU MAY BE TAKEN OFF STUDY WITHOUT YOUR CONSENT

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- If the study doctor feels it is not in your best interest to continue in this study.
- If the study is stopped by the Institution, the Sponsor(s), or by the Food and Drug Administration (FDA) or other health authorities.

12. PREGNANCIES, BREASTFEEDING, AND BIRTH CONTROL

You may continue participation in the study if you are or become pregnant, but will not be able to do some procedures. If you become pregnant while participating in the study, please inform your study team.

If you are a female who has had her period, you will be asked to have a pregnancy test at each in-person visit in this study. Results of the pregnancy test will be reported [Insert site specific language regarding who results of the pregnancy test will be shared with].

13. COSTS TO THE SUBJECT (YOU)

All study visits, study procedures, and required tests are provided to you without charge. There will be no charge to you or your health insurance company.

14. PAYMENTS (REIMBURSEMENT)

You will be reimbursed for your time and effort in completing all of the study visits and phone calls. You will only be reimbursed for the visits and calls that you complete.

Activity	Reimbursement	Actual Travel Cost Up To
Quarterly Phone Call	$25	N/A
Year 14 Clinic Visit	$200	$50
Year 15 Clinic Visit	$250	$50
Year 16 Clinic Visit	$250	$50
Year 17 Clinic Visit	$200	$50
Questionnaires Only*	$60	N/A
Methacholine Challenge Visit	$150	$50
Incomplete Methacholine Challenge Visit *(without Methacholine Challenge)*	$25	$50
Dust Sample Collection	$45	N/A
Unscheduled/Additional Visits	$25	$50

Activity	Reimbursement	Actual Travel Cost Up To
COVID-19 Testing Ahead of Visit *(when applicable)*	$20	$50

* If you are unable to come in for your clinic visit, but complete the questionnaire portion of the visit via phone and/or mail.

If your visit overlaps with one or more meal times, meal vouchers may be provided for families participating, not to exceed $30 per family for breakfast, lunch or dinner. If you have moved away from the clinic and significant travel is required to attend the yearly clinic visits you will be reimbursed for your travel costs up to $200. If $200 does not cover your travel expenses, additional reimbursement will be considered on a case-by-case basis. In addition, we will continue to reimburse you for cell phone minutes if you use your cell phone to answer questionnaires.

15. RESEARCH-RELATED INJURY

If you are injured or become ill because of taking part in this study, it is important to tell your study clinician, [investigator's name]. [Insert site-specific information.]

Emergency medical treatment will be available to you. If you have health insurance, your health insurance provider will be billed for the payment of any treatment or hospitalization you require as the result of study-related injury. It is up to you to check with your insurer before you start this study to find out whether these charges would be covered. If you do not have health insurance, you will be billed for these payments. No other form of reimbursement is available. The study does not offer compensation or payment for injuries due to participation in this study.

If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system. In case of injury resulting from this study, you will not lose any legal rights by signing this form.

You may contact [name of Human Research Protection Program Office] at [contact number] for more information or to report study-related injuries.

16. CONFIDENTIALITY

Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality.

You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. 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. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

Your privacy is important to us and we will use safety measures to protect it. In spite of all the safety measures that we use, we cannot guarantee that the participant's identity will never become known.

Although the participant's genetic information is unique to him/her, he/she shares some genetic information with his/her parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify the participant. Similarly, it may be possible that genetic information from the participant could be used to help identify them.

While we will not use information that is traditionally used to identify the participant, people may develop ways in the future that would allow someone to link the participant's genetic or medical information in our databases back to him/her. For example, someone could compare information in our databases with information from the participant (or a blood relative) in another database and be able to identify the participant (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking the participant's genetic and medical information to him/her. There may also be other privacy risks that we have not foreseen.

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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of suspected or actual child abuse and/or neglect and to prevent you/the participant from carrying out any threats to do serious harm to yourself or others.

<u>What information may be used and given to others?</u>
The study staff will get your personal and medical information. For example: research records, records about phone calls made as part of this research, records about your study visits.

<u>Who may use and give out information about you?</u>
The study clinician and the study staff.

<u>Who might get this information?</u>
The sponsor of this research (DAIT NIAID, NIH). "Sponsor" includes any persons or companies that are working for or with the sponsor.

Your information may be given to:

- Rho, Inc., an organization that provides research support services
- University of Wisconsin
- The U.S. Food and Drug Administration (FDA)
- Other Department of Health and Human Services (DHHS) agencies
- Other State and Local health authorities
- [Site name, if applicable]
- Other participating sites
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research
- to study the results
- to see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until the end of the study. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the registry staff. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. However, your information is given to others in a coded fashion unless you give us permission to send information otherwise, such as to your clinician.

17. PROBLEMS OR QUESTIONS

If you have questions, concerns or complaints about the study or you believe that the participant has been harmed, contact the study doctor(s) at [Number].

If you have questions about your rights as a research subject, if you have questions, concerns or complaints about the research or if you believe your rights have been violated, contact the IRB at:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

18. FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

You have the option to allow samples/data to be stored for use in future research studies. Stored material may be used indefinitely for tests not currently planned and new scientific discoveries may lead to new tests. Samples may be shared with other researchers; this data would be coded so that other investigators would not have access to traditional identifiers (like name, phone number, address). Making sure that information about you remains private is important to us.

We are asking your permission to store unused samples of biological specimens (e.g., blood, urine, and nasal secretions) collected during the course of this study to be used in the future for tests that aren't yet planned. These tests may or may not be related to the study of asthma.

Among the possible future uses, your stored samples may be used to obtain knowledge about genetic information in relation to your 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.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. You will not receive any financial gain from studies done using the participant's stored samples. However, the use of your samples and information may help researchers learn more about your disease or 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 and making information available for other studies may help people in the future. Coded information put into databases along with information from many studies conducted in different places allows researchers to study the combined information and learn even more about health and many different diseases.

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 because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

Samples will be stored at a central repository. If you decide to allow storage, your samples and information may be stored for an unknown length of time.

You can refuse to allow the participant's samples to be used for genetic testing. You can change your mind at any time and have the participant's samples destroyed. This request should be made in writing to the study clinician. If you make this request, all remaining stored samples will be destroyed. However,

the results of any previous tests using the participant's stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

Please read and mark your choice for the three statements below.

I agree to the storage and sharing of the participant's samples for **genetic** tests as a part of URECA.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

I agree to the storage and sharing of participant's samples for **genetic** tests not currently planned.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

I agree to the storage and sharing of participant's samples, and information resulting from the analysis of those samples, for **other** tests not currently planned.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

19. OTHER SUBJECT AUTHORIZATIONS
Please read and mark your choice for the statements below.

COVID-19 Testing: I voluntarily give permission for COVID-19 testing to occur for the participant before clinic visits. This applies only to the child participant. Giving general permission here does not negate your right to refuse COVID-19 testing in an individual instance.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

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Additional Visits: I agree to be contacted for additional and/or unscheduled visits within URECA.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

PCP Communication: I agree that information from the URECA research study may be sent to the participant's Primary Care Physician while the participant is in the study. I understand that information will be sent to the Physician or Group Practice indicated on the study contact information forms.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

Future Contact Related to URECA: I give my permission to be contacted by staff at [site name] in the future related to and/or as a follow-up to the URECA study.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

Future Contact Not Related to URECA: I give my permission to be contacted by staff at [site name] in the future with so that the participant may be invited to take part in other research studies.

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #1

☐ Yes ☐ No _____
Initials of Parent/Legal Guardian #2

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20. SIGNATURE PAGE

Consent and Assent Instructions

Consent: The parent or guardian must provide the consent. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child under applicable state law.

Assent: Written assent is required for participants from age 10 through 17 years old using the age-appropriate Assent form.

Please sign below if you agree to take part in this study.

Your signature indicates that:

- you have read the informed consent and/or had it explained to you
- you were given the opportunity to ask questions about the information, and
- you voluntarily agree to take part in the study

Parent/Legal Guardian #1 Name *(Typed or Printed)*	Parent/Legal Guardian #1 Signature	Date
Parent/Legal Guardian #2 Name *(Typed or Printed)*	Parent/Legal Guardian #2 Signature	Date

Signature of person explaining and obtaining the consent

Consent Administrator Name *(Typed or printed)*	Consent Administrator Title *(Typed or printed)*
Consent Administrator Signature	Date

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.