

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient
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INSTITUTE: National Institute of Environmental Health Sciences

STUDY NUMBER: 15-E-0058

PRINCIPAL INVESTIGATOR: Stavros Garantziotis, M.D.

STUDY TITLE: NHALES (Natural History of Asthma with Longitudinal Environmental Sampling)

Continuing Review Approved by the IRB on 09/03/2015

Amendment Approved by the IRB on 10/30/2015 (E)

Date Posted to Web:

Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH). This study is called the NHALES study, which stands for Natural History of Asthma with Longitudinal Environmental Sampling.

First, we want you to know that:

- Taking part in NIH research is entirely voluntary.
- You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.
- You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive. If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

1. Why is the NHALES study being done?

The main purpose of the NHALES study is to collect samples and medical information from people who have moderate to severe asthma, as well as from people who do not have asthma for comparison. The samples and medical information will be used in the future to help scientists understand how bacteria and other things in the environment can affect asthma in people. Another purpose of the NHALES study is to set up an asthma clinic at the NIH's National Institute of Environmental Health Sciences (NIEHS) Clinical Research Unit (CRU). This clinic will provide free doctor visits and asthma medications to people who do not currently have a good way to get treatment for their asthma.

2. Why are you being invited to participate?

You are being asked to take part in the NHALES study because you are a non-smoking adult (age 18-60), who has moderate to severe asthma, and who is not pregnant or breastfeeding (if you are female). Before knowing for sure if you can participate, the study doctor will check your asthma symptoms and general health, and will check that you do not have any medical conditions that would make you ineligible to participate in the NHALES study.

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

- Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (07-09)

P.A.: 09-25-0099

Protocol # 15-E-0058

OPS Concurrence Date: 11/3/2015

File in Section 4: Protocol Consent (1)

STUDY NUMBER: 15-E-0058

CONTINUATION: page 2 of 11 pages

3. How many people will take part in this research study?

About 200 people will take part in this study, and about 20 of these people will be invited to also participate in an additional study, called the bronchoscopy sub-study. (We will let you know if you may be eligible to participate in the bronchoscopy sub-study, and will give you a separate form that explains the sub-study.)

4. How long will you take part in this research study?

You will have regular clinic visits scheduled every 6 months, over 5 years. There are a total of at least 12 visits. The first visit (Visit #1, also called the Screening Visit) will last approximately 2.5-4 hours; the second visit (Visit #2, also called the Baseline visit) will last about 2.5-5 hours and the remaining visits (Visits #3-12; called Semi-Annual Visits) will also last approximately 2-3 hours each.

Additionally, if you experience any non-severe issues with your asthma between these regular visits, then we ask you to come to the clinic for a Sick Visit. Sick Visits are expected to last approximately 2-3 hours each.

If the doctor would like for you to participate in the bronchoscopy sub-study we may ask you to come in for an additional blood draw to confirm your eligibility. You are under no obligation to complete this or any other visit if you do not wish to. If you do return for the additional visit, you will be compensated for the visit.

If you experience an acute, severe episode of asthma, please visit your closest emergency department. We ask that you please contact us after a visit to the emergency department so that we can schedule a Sick Visit with you at the CRU.

5. What do we do to decide if you are eligible for this research study?

To see if you qualify for the NHALES study, we use information that you provide and that we get through a doctor's exam and lab tests. More specifically, to determine whether you are eligible, we will:

- Confirm that you have decided you would like to participate (indicated by you signing this form)
- Confirm that you are 18-60 years old
- Confirm that you have moderate to severe asthma
- Have you do breathing tests
- Confirm that you will be able to travel to the CRU for visits every 6 months
- Confirm that you will be able to receive asthma medications by mail
- Confirm that you agree to not eat certain foods and can withhold certain medications prior to the first visit
- Check that you are not pregnant or breastfeeding (if you are female)
- Confirm that you are not a current smoker, do not breathe in a lot of second-hand smoke, and did not smoke more than the equivalent of a pack a day for the past five years
- Check for any allergies or medical conditions that could interfere with the study or make it too risky for you

6. What procedures, drugs, or other treatments are involved in this research study?

All visits occur at the NIEHS Clinical Research Unit (CRU) in Research Triangle Park (RTP), North Carolina for all participants. The procedures for the various visits are described below.

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 3 of 11 pages

Please note: When you come to your appointments, you will need to bring a valid state or federal photo identification (such as a driver's license or passport) with you. You will have to show your photo identification at two checkpoints—at the gate when you first enter the NIEHS campus and again when you enter the building where the CRU is located.

Prior to Visit #1

We will mail you a medical history form to fill out on paper or online through a secure website. If you do not complete the medical history form before your first visit, you may fill it out when you come to the CRU, which may make your visit last longer.

We will send you written instructions and give you a call before the visit to remind you about the date and time of your visit and what to do beforehand.

Visit #1 (Screening Visit)

Visit #1 will last approximately 2.5-4 hours.

First, the study will be thoroughly explained to you. You may have as much time as you need to decide whether to participate and are encouraged to ask any questions that you have. If you choose to participate in this study, we will ask you to sign and date this consent form and will give you a copy for your records.

After you have signed this form, you will be asked to provide general information about yourself, such as your age, gender, race, and ethnicity. Your age and the results from the following procedures will be evaluated to determine if you are eligible for the NHALES study:

- **Vital signs:** We will take your temperature, pulse, breathing rate, and blood pressure, and will record your height and weight.
- **Urine sample collection:** We will collect a urine sample from you. This will be used to test for exposure to tobacco smoke and for a pregnancy test for all women. If you are eligible for the study, the sample will also be used for standard lab tests and some of the sample will be stored for future research.
- **Smoking Test:** You will be asked to confirm when you smoked your last cigarette (or if you are a non-smoker). You will be asked to hold your breath for 15 seconds then blow slowly into a mouthpiece, aiming to empty your lungs completely. If you cannot comfortably hold your breath for the full 15 seconds, you will be asked to hold your breath to a comfortable point, but breathe out completely. Carbon monoxide will be measured to confirm that you are a non-smoker.
- **Pregnancy test and question about breastfeeding:** If you are female, a urine pregnancy test will be performed and you will be asked if you are currently breastfeeding. Pregnant and breastfeeding women cannot enroll in the study. (You can rescreen for the study later once you are no longer pregnant or breastfeeding, and you can stay in the study if you become pregnant or start breastfeeding after you have joined the study.)
- **Medical history and medication history:** You will be asked about your medical history (including asthma and allergies), any drugs or medications you are taking, and any other chronic illnesses. You will be asked about your smoking history. If the doctor decides that any of the medications you are taking or that any of your current or past medical conditions may interfere with the study or put you at risk, you will not be able to take part in the study.
- **Physical examination:** The doctor will listen to your heart, lungs, and abdomen, and will feel your abdomen.

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Protocol # 15-E-0058

OPS Concurrence Date: 11/3/2015

File in Section 4: Protocol Consent (1)

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 4 of 11 pages

If the doctor finds anything that is outside of a normal range for this study (for example, if you have a fever, or a low or high pulse or blood pressure), you will not be able to take part in this study.

- **Spirometry test:** Spirometry measures the biggest amount of air your lungs can hold and how hard you can breathe in or out. A machine called a "spirometer" is used to do the test. It has a mouthpiece attached to a tube that is connected to a computer, which records the results. To do the test, you inhale deeply, close your mouth tightly around the mouthpiece, and then exhale through the tubing while measurements are taken. For some parts of the test, you will be asked to breathe normally. For other parts of the test, you will be asked to breathe in or out as hard as you can. The amount of air inhaled or exhaled, and the length of time each breath takes are recorded and analyzed. Nose clips are usually used to make sure air is only coming out of your mouth. Depending on the results of the spirometry test, you will either do the methacholine challenge test or the bronchodilator challenge test (both are explained below).
- **Sputum sample collection:** You will be asked to inhale a saline solution (mixture of salt and water) for 7 minutes through a nebulizer. After 7 minutes, you will be asked to rinse your mouth and cough up a sample of sputum into a cup. You will repeat this process two more times with higher concentrations of salt in the saline solution each time. The three different saline solutions will be given with two-minute breaks in between.
- **Bronchodilator challenge test:** This test is done if the spirometry test shows you have abnormal lung function (this is common in asthmatic patients). This test is done to see if the narrowing of your airways is at least partly reversed by giving you albuterol to help open up your airway passages. You will take the spirometry test (until 3 attempts give close to the same reading) and then breathe in albuterol using a nebulizer. Ten minutes after the albuterol treatment is finished you will a take the spirometry test again (until 3 attempts give close to the same reading).
- **Blood sample collection:** We will collect about 4 tablespoons of blood from you by needle stick, for standard lab tests and to be stored for future research. Part of that blood sample will be used to test for certain allergies you may have.

After these initial procedures, we will determine whether you are eligible to participate. If you are not eligible, you will be told the reasons why you are not eligible. If you are eligible, then we will contact you to return for the Baseline visit.

Visit #2 (Baseline Visit)

Visit #2 will last approximately 2.5-5 hours, depending on procedures performed. Before your visit, you will have to stop taking certain asthma medications for up to 2 days before the visit, depending on the asthma medication. Also, there are certain beverages we will ask you not to consume prior to your visit. This is because certain asthma medications and chemicals in beverages can interfere with some of the tests done during the visit. The following procedures will be done at the baseline visit:

- **Urine sample collection:** We will collect a urine sample from you. This will be used to test for exposure to tobacco smoke and to test for pregnancy in women who will complete the methacholine challenge test.
- **Pregnancy test and question about breastfeeding:** If you are female, a urine pregnancy test will be performed. If you are pregnant, you will no longer be eligible to continue with the study visits and will be withdrawn from the study. (You can rescreen for the study later once you are no longer pregnant or breastfeeding, and you can stay in the study if you become pregnant or start breastfeeding after you have joined the study.)

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Protocol # 15-E-0058

OPS Concurrence Date: 11/3/2015

File in Section 4: Protocol Consent (1)

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 5 of 11 pages

- **Methacholine challenge test:** You may or may not complete this procedure during this study visit. It will depend on the procedures you completed during your Screening Visit, and if you have recently done a Methacholine challenge test. If you have recently completed a Methacholine challenge test, we may not ask you to complete another in order to protect your safety. Depending on your spirometry test results, we may give you a Bronchodilator treatment instead.
- The methacholine challenge test is used to test how sensitive your air passages are to constriction (narrowing). To do the test you will blow into a machine to measure your lung function. Then you will use a device called a nebulizer to breathe in increasing doses of a drug called methacholine. We will test how hard you can exhale between each dose you are given. Once the force you can exhale gets 20% weaker than when you started, no more methacholine will be given. At the end of the test, you will be given inhaled albuterol to reverse any symptoms caused by the methacholine. This is a very common test to measure lung function, and most people do not have any problems with it. However, before you leave the clinic, we will make sure your lung function is close to what it was at the start of the test. We will do this by having you do another lung function test, like you did at the start. This test cannot be done if you have taken certain medicines before the test. You will be given information before the visit about what medicines not to take before you start the test.
- **Exhaled nitric oxide test:** This test measures airway inflammation. You will be asked to breathe into a device that will collect a sample of the air exhaled from your lungs. This sample will be tested for a gas called nitric oxide. This test cannot be done if you have taken certain medicines or eaten certain foods before the test, or if you had a cold in the past 4 weeks. You will be given information before the visit about what medications and foods to avoid before the test. The test takes approximately 5 minutes or less to complete.
- **Collection of other samples:** We will collect samples of DNA from your saliva to store for future research. We will use the DNA to conduct genetic analyses. We will also give you kits (with instructions) to collect a stool sample and to collect a dust sample from your house, which we will store for future research. If you are able to provide a stool sample while at the CRU, then you do not have to collect one at home.
- **Surveys:** You will fill out 6 different short surveys about your asthma symptoms.
- **Asthma medications:** The doctor will prescribe any asthma medications needed to treat your asthma. These asthma medications prescribed by the doctor will be provided to you free of charge. These medications should only be taken by you. They should not be shared with anyone.

Visits #3-12 and Sick Visits

Visits #3-12 (Semi-Annual visits scheduled every 6 months) and Sick Visits (visit whenever you need to see a doctor about your asthma) are expected to last approximately 2-3 hours each. The purpose of the Sick Visits is for you to receive asthma evaluation and treatment at no cost when you are experiencing an asthmatic episode. The Study Doctor will meet with you and discuss treatment for your asthma, but the Study Doctor does not conduct visits for other health issues. If you are experiencing a different health issue and do not have a regular doctor, we will provide you with contact information for the local health department.

During the Semi-Annual and Sick Visits, you will have a check-up on your asthma and provide samples and health information. The following procedures occur at these visits:

- **Vital signs** (same as described above for Visit #1)
- **Review medical history and medication history:** We will collect information about any drugs or medications you are taking, and about any symptoms related to your asthma that you have had since your last visit.

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NIH-2514-1 (07-09)

P.A.: 09-25-0099

Protocol # 15-E-0058

OPS Concurrence Date: 11/3/2015

File in Section 4: Protocol Consent (1)

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 6 of 11 pages

- **Physical examination:** The doctor will listen to your heart, lungs, and abdomen, and will feel your abdomen. The doctor will discuss your asthma with you and adjust your asthma medications if needed.
- **Spirometry test** (same as described above for Visit #1)
- **Exhaled nitric oxide test** (same as described above for Visit #2)
- **Urine sample collection** (same as described above for Visit #1, except no urine pregnancy test will be done)
- **Blood sample collection** (same as described above for Visit #1)
- **Sputum sample collection** (same as described above for Visit #1; this will not be done at the Sick Visits)
- **Collection of other samples** (same as described above for Visit #2)
- **Surveys** (same as described above for Visit #2)

Monthly Follow Up Calls

We will contact you monthly between visits 2-12 to ask you two to three questions about your asthma episodes and whether you have been to see a doctor since your last study visit. We will also confirm your address and remind you of upcoming study visits.

7. What are the risks and discomforts of this research study?

The risks and discomforts for the procedures in the NHALES study are about the same as when someone does these procedures at their regular doctor's office. The risks we know about for the procedures are described below. However, some risks might not be known yet.

- **Risks of withholding asthma medications prior to the Baseline Visit:** Withholding asthma medications prior to the Baseline Visit may present some risks to you. The NIEHS study doctor will talk to you about the risks of withholding medications during your Screening Visit.
- **Risks for blood draw:** You may feel some pain when the needle is inserted in your arm, and there is a small risk of getting a bruise and/or infection at the place where the needle entered your arm. Some people may feel lightheaded, or a little sick to their stomach, or may faint when having their blood drawn.
- **Risks for spirometry test:** This test has very few side effects and is a very low risk test. Some people may feel dizzy or light-headed, or have chest pain.
- **Risks for methacholine challenge test:** Some people may feel tightness in their chest, or have shortness of breath, wheezing, headache, dizziness, or severe coughing.
- **Risks for bronchodilator challenge test:** This test uses albuterol, which may cause similar side effects as the methacholine challenge test, and some people may also experience fast or irregular heart beat.
- **Risks for collection of DNA:** Even though we will do our best to keep your information confidential, there is a possibility that DNA test results could accidentally be obtained by a third party. This information could affect your ability to obtain health insurance as well as discrimination in employment.
- **Risks for induced sputum test:** Use of a nebulizer may cause difficulty breathing, wheezing, coughing, and shortness of breath. Excessive coughing may cause vomiting in some people.

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NIH-2514-1 (07-09)

P.A.: 09-25-0099

Protocol # 15-E-0058

OPS Concurrence Date: 11/3/2015

File in Section 4: Protocol Consent (1)

STUDY NUMBER: 15-E-0058

CONTINUATION: page 7 of 11 pages

- **Risks for nitric oxide test:** There are no known risks of this test.
- **Risks for household dust collection:** Any small parts that come with the dust collection kit may be a choking hazard to small children. Please keep dust collection kits out of the reach of small children.

8. Are there any benefits to you if you take part in this research study?

You will receive the benefit of regular care and medications for your asthma, including medical examinations with laboratory tests and lung function tests at no charge. The medical examinations, laboratory results, and lung function tests will be used to guide medications that are prescribed to you during your clinic visit. The medical staff will explain to you any health findings from the clinical assessments. We will provide you with a copy of your clinical results and you will have the opportunity to speak with a pulmonologist (doctor who specializes in lungs) to discuss any concerns. We will alert you to any study findings that require immediate medical attention.

Finally, although not a direct benefit to you, the samples and information you provide may help researchers better understand how factors in the environment affect asthma in people.

9. What other choices do you have?

You can choose not to participate in this study. Also, if you decide to participate now and change your mind later, you can stop participating in the study at any time. If you decide not to participate now, or if you stop participating later, there will not be any penalties to you or loss of benefits to which you are otherwise entitled.

10. Are there reasons that your research participation may end early?

You can stop participating any time that you want. If there are any significant new findings (either good or bad) during the study, such as changes in the risks or benefits to participating, you will be informed of this so you can decide whether you want to continue. If such new information is provided to you, your consent to continue participating in this study will be re-obtained. Also, the investigator may withdraw you from the study if there are any concerns about you participating further, especially to protect your health and safety, or if the study is stopped early. For example, if you have health issues that interfere with asthma care, or continue to have symptoms that the investigators feel cannot be appropriately treated at the CRU, the investigators may elect to withdraw you and refer you to another source of care in order to protect your health.

We will make every effort to stay in touch with you between visits. We will ask you during today's visit for the names and contact information for two people who will know how to reach you in the event that your contact information changes during the study period. However, participants who miss 2 visits or do not regularly complete all study procedures, including providing specimens, will be withdrawn from the study.

11. What will happen when the research study is over?

We ask that you call the CRU if you experience any symptoms within 2 days of your last study visit. After that, there is nothing else you need to do for the study.

When the study is over, you will no longer receive free care and medications for your asthma from the clinic at the CRU. Thus, you will need to find a doctor or local health department to provide care for your asthma and to prescribe your asthma medications once the study is over.

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 8 of 11 pages

12. Will your clinical and test results be shared with you?

We will mail you a copy of the allergy test results and your clinical laboratory test results after you have completed your screening visit.

By agreeing to participate in this study, you do not waive any rights that you have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Stavros Garantziotis at 919-541-9859.

13. Will the results of this research study be shared with you?

The results of the research study will not be shared with you.

14. Will any of your blood, tissue or other samples be stored and used for research in the future?

One of the main purposes of this study is to collect samples for use by future researchers. Thus, all samples collected from you (blood, urine, sputum, DNA, saliva, stool, and household dust) will be stored until they are no longer needed for research. Other investigators may also want to study your stored samples and request information such as your gender, age, diagnosis, health history, or ethnicity. An Institutional Review Board (IRB) will review all research protocols that wish to use your samples. The IRB is a committee that oversees medical research studies to protect volunteers' rights and welfare. You have the right to decide whether your samples and information will be shared with researchers other than members of this research team.

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File in Section 4: Protocol Consent (1)

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NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 9 of 11 pages

Please initial by the line indicating your wishes.

_____YES, I give permission to use my (blood or other fluids, tissues) samples in future research studies under the following conditions:

_____These samples may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine

_____These samples may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

_____MAYBE, I wish to be re-contacted if further studies with my samples are considered. After the study has been explained, I will then decide if I want my samples to be included.

_____NO under no circumstances shall my samples be used for any future studies. My samples should be discarded once the present study is complete or if I elect to withdraw from the study at a later time.

15. Will I be contacted in the future once this study is over?

Future studies that use the samples or information collected during this study may require knowing about you (such as your present health status). In addition, there may be new studies that you are eligible to participate in. If so, the study team may wish to contact you to ask for new information or to tell you about a new study.

Please read each statement below and think about your choice. Then check "Yes" or "No." You may still participate in the NHALES study or join other studies at NIEHS no matter what you decide about each statement below. If you have any questions, please talk with the study staff or Dr. Stavros Garantziotis.

- Future studies might need information from me that the study team does not already have. I understand that I do not have to provide any information I feel uncomfortable giving, but I agree that the study team may contact me again to ask for new information about me.

Yes [] No []

- There may be future studies that I might be eligible for. I understand that I do not have to participate in any future studies if I do not want to, but I agree that the study team may contact me again to tell me about new studies.

Yes [] No []

16. Will you receive any compensation (money or other) for taking part in this research study?

You will receive free care for your asthma for 5 years, which includes visits to the doctor and free asthma medication(s).

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NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 15-E-0058

CONTINUATION: page 10 of 11 pages

In addition, you will be compensated for the regularly-scheduled visits you attend at the CRU. You will not be compensated for any of your Sick Visits.

The total amount of compensation for completing all 12 regularly-scheduled study visits over the 5 years is \$3,035. There will be additional compensation of \$35 if you are asked to return to the CRU for the extra visit to confirm your eligibility for the bronchoscopy study.

If you arrive for a visit, but can't do every procedure, you will still be compensated for the procedures that you do finish during that visit according to the table below. If you are unable to complete any procedures or are ineligible to participate, you will receive \$25 for your time and travel.

Procedure	Amount Per Procedure	Occurrence	Total Amount
Medical/medication history and physical exam	\$25	Visit #1, 3 - 12	\$275
Spirometry	\$25	Visit #1, 3 - 12	\$275
Bronchodilator/ Methacholine challenge test, if conducted	\$50	Visit #1/Visit #2	\$50
Blood sample	\$35	Visit #1, 3 - 12	\$385
Urine sample	\$15	Visit #1- 12	\$180
Induced sputum sample	\$75	Visit #1, 3 - 12	\$825
Saliva sample	\$10	Visit #2 - 12	\$110
Stool sample	\$40	Visit #2 - 12	\$440
Household dust sample	\$20	Visit #2 - 12	\$220
Surveys	\$25	Visit #2 - 12	\$275
Total Amount Paid for Completion of All Procedures at All 12 Visits			\$3,035

If you have to travel more than 50 miles round trip to come to your regularly-scheduled visits, then travel costs will be reimbursed according to current government/NIH rates for mileage (you won't be reimbursed for travel costs for any Sick Visits). Parking will be provided free of charge for all visits (including Sick Visits). You will not be reimbursed for any meals or lodging costs you have.

A check will be mailed to you after each regularly-scheduled study visit at the address you provide the study staff.

17. Do any of the researchers or the NIH have a financial interest related to this research study?

None of the study staff involved in the NHALES study have reported a conflict of interest (including anything related to their finances) for this study. However, you should know that all researchers and institutions have an "intrinsic" conflict of interest, since professional advancement as doctors and scientists (such as getting promotions and reputation) depends in part on successfully enrolling volunteers into studies like this one. We hope to minimize this conflict by describing it to you here.

Also, the NIH reviews its staff researchers at least once a year for conflicts of interest (such as anything that could give personal benefit to study staff depending on how the research turns out). The following link contains details on this process: http://sourcebook.od.nih.gov/ethic-conduct/COI_Guide_121209.pdf. You may ask the study staff for additional information or a copy of the Protocol Review Guide.

PATIENT IDENTIFICATION**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

- Adult Patient or
- Parent, for Minor Patient

NIH-2514-1 (07-09)

P.A.: 09-25-0099

Protocol # 15-E-0058

OPS Concurrence Date: 11/3/2015

File in Section 4: Protocol Consent (1)

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. NIEHS will provide short-term medical care for any injury resulting from your participation in this research study. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIEHS, National Institutes of Health, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact Dr. Stavros Garantziotis, the Principal Investigator, CRU, Room 109, (919) 541-9859. You may also call the NIEHS Office of Human Research Compliance at (919) 541-4265.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

Adult Patient's Consent	
I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.	
_____ Signature of Adult Patient/Legal Representative	_____ Date
_____ Print Name	
_____ Signature of Investigator or Authorized Designee	_____ Date
_____ Print Name	
_____ Signature of Legally Authorized Representative/Witness (if applicable)	_____ Date
_____ Print Name	

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE
FROM 09-03-2015 THROUGH 09-02-2016.**