Division of Clinical Immunology and Allergy
UCLA School of Medicine

CONSENT FOR PARTICIPATION IN RESEARCH: Pollution-enhanced allergic inflammation & Phase II enzymes

You are asked to participate in a research study conducted by Dr. David Diaz-Sanchez and Adrian Casillas from the Division of Clinical Immunology and Allergy at the University of California, Los Angeles. This study is sponsored by the National Institutes of Health (NIH) and the Environmental Protection Agency. You have been asked to participate in this study because you are a person who can make responses to pollutants. Your participation in this study is entirely voluntary. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate. The number of subjects at UCLA that are expected to enroll in this study is approximately 60. The duration of your participation if you complete all the study should last approximately twelve weeks.

Disclosure: Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your physician.

PURPOSE OF THE STUDY

The purpose of this study is to compare the ability of adults and children in producing natural chemicals (antioxidants) that protect against pollution.

PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following:

1) **Nasal Challenge**
The nasal challenge, involves placing several small mists of fluid into the nasal cavity. Each challenge will consist of between one and five small samples (0.1cc, or about three drops) of fluid applied to the nasal cavity through a sprayer and will contain soot from a diesel truck (diesel exhaust particles).

   The diesel exhaust particles will be administered in small mists of fluid containing different amounts of particles. The highest amount of particles you may be given is equal to two day's average urban exposure in Los Angeles. This is less than you would receive from passing behind a diesel bus as it starts its engine. There have been no reported adverse reactions to this procedure, other than the possible uncomfortable feeling of fluid being sprayed into your nose.

2) **Nasal Lavage.** Samples of nasal lavage fluid will be obtained which involves tilting the head back, holding your breath for a short period of time, having one teaspoon of sterile salt water placed in one nostril, and then recovering the fluid by repositioning your head down and catching the fluid as it exits your nose.

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3. Overall. On day 1, you will do a nasal lavage and then be challenged with diesel exhaust particles. Next day you will do another nasal lavage. You will perform the same schedule after a period of four weeks, eight weeks or 12 weeks. Each time you will be challenged with a different amount of diesel exhaust particles.

POTENTIAL RISKS AND DISCOMFORTS

During the nasal lavage, there is a possibility of swallowing this fluid which has a salt water taste but contains no other substances. Additional potential complications of nasal lavage include aspiration (inhalation) of the fluid which is uncomfortable, but the amount of fluid is so small that there is no known possibility of any respiratory complication.

Diesel exhaust particles contain "polycidic aromatic hydrocarbons" which are known cancer-causing agents (called carcinogens) in laboratory animals and man when repeatedly exposed in high enough concentrations over years. Men regularly exposed to diesel exhaust at work for many years have shown slightly higher rates of cancer than similar men in "clean" jobs. For these reasons the State of California has classified diesel exhaust as a carcinogen. The excess cancer risk from one or a few diesel exposures like the one used on this study, if any, is very small. Certainly no more than the risk from spending a few days in a city like Los Angeles. You may experience some irritation (itchiness) in your nose for a few moments.

ANTICIPATED BENEFITS TO SUBJECTS

This study is not being done to improve your condition or health. You have the right to refuse to participate in this study. Your only benefit is that you may learn how well your body makes antioxidants in response to pollutants

ANTICIPATED BENEFITS TO SOCIETY

This study may benefit society by increasing our understanding of the mechanisms that induce allergic disease, and why children are more susceptible to pollution effects than adults.

ALTERNATIVES TO PARTICIPATION

The alternative to participation is not to participate.

PAYMENT FOR PARTICIPATION

You will be paid $20.00 per lab visit (total of 8 visits). This amount will be paid whether you complete the session or withdraw for any reason. After your participation you will not be required to return for a follow-up visit. The total payment for this study is $160. Parking will also be reimbursed ($7/visit) if applicable.

POSSIBLE COMMERCIAL PRODUCTS

All tissue and/or fluid samples are important to this research study. Your sample will be owned by the University of California or by a third party designated by the University (such as another university or a private company). If a commercial product is developed from this research project, the commercial product will be owned by the

University of California or its designee. You will not profit financially from such a product.

INFORMATION ABOUT YOUR SAMPLE
On the checklist below, you are asked to let us know if you would like to receive information about the results of this study. There are two types of information you may receive:

1. general information about what this study found (or conclusions of the study)
2. specific information about what the study found about your individual sample.

You may also choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years. Even if there is general information from a project, there may not be personal information for every participant.

FINANCIAL OBLIGATION
Neither you nor your insurance company will be billed for your participation in this research.

EMERGENCY CARE AND COMPENSATION FOR INJURY
If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not provide any other form of compensation for injury.

PRIVACY AND CONFIDENTIALITY
The only people who will know that you are a research subject are members of the research team and, if appropriate your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Authorized representatives of the National Institute of Allergy and Infectious Disease (NIAID) and the Public Health Service (PHS) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Your samples will be kept private and a code will be assigned to them, known only by the investigators.

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PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Dr. Andrew Saxon, will make the decision and let you know if it is possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to (rather than because you have decided on your own to withdraw), you will be paid the appropriate amount for completed procedures.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternative to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact David Diaz-Sanchez, Ph.D.. at 310-825-9261; 10833 Le Conte Avenue, Room 52-175, Center for Health Sciences, UCLA, Los Angeles, CA 90095-1680. Dr. Diaz-Sanchez can be reached 24 hours a day/7days a week by calling 310 709 1459. Additionally, you can reach the co-PI, Dr. Adrian Casillas at 310 825 1153.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Office for Protection of Research Subjects, 2107 Ueberroth Building, UCLA, Box 951694, Los Angeles, CA 90095-1694, (310) 825-8714.

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SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE
I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject

_____ _____
Signature of Subject Date

_____
Name of Parent or Legal Guardian (if applicable)

_____ _____
Signature of Parent or Legal Guardian Date

INFORMATION ABOUT MY SAMPLE
Please indicate by checking and initialing the category below what type of information you want to receive. It is your responsibility to let the investigator know if your address and/or telephone number changes. The contact information is in this informed consent form under "Identification of Investigators."

- ☐ ____General Information about what the study found
- ☐ ____Specific Information about what the study found about my sample
- ☐ ____I do not want any information about my sample

SIGNATURE OF INVESTIGATOR
I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subject's)

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