CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

GRANT RESEARCH: Risk of Asthma Among Children from in-Utero Exposure to Traffic Related Air Pollutants

SPONSORING AGENCY: South Coast Air Quality Management District

PRINCIPAL INVESTIGATOR: Christina Schwindt, M.D.

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27800 Medical Center Rd., Suite 240
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15785 Laguna Canyon Road #100
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675 Camino de los Mares #420
San Clemente, CA 92673

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form. You cannot take part in this research study until you sign this form.

This study asks questions about you and about your child. “You” may refer to you, or to your child

INTRODUCTION AND PURPOSE OF THE RESEARCH STUDY

You are being asked to take part in this research study because you have a child under the age of 18 years of age. The purpose of this research study is to study the amount of air pollution and allergens a woman was exposed to during pregnancy to see if there is an increased risk of a child developing asthma if the mother was exposed to higher levels of air pollution during pregnancy. It is proposed that women who are exposed to higher levels of pollution during their pregnancy give birth to children who have a higher incidence of asthma.

This research study is grant sponsored by South Coast Air Quality Management District. Christina Schwindt, MD is the principal investigator of this study.

Taking part in this study is entirely voluntary.
INFORMATION ABOUT THE STUDY

This study is a survey study that will survey 2,000 women, and their children. Participants will be separated into two groups of 1,000 participants; the groups will be separated by a known diagnosis of asthma in a child or absence of an asthma diagnosis in a child.

If you agree to participate in the study, you will be provided up to eight different surveys to complete, depending on the known presence of asthma. The surveys ask questions regarding you, your family history, where you lived and worked during your pregnancy, circumstances surrounding the birth of the child, and the child’s environment during certain periods of the child’s life (for example, birth through 12 months of age, one to three years of age).

There is an area on the survey form that asks you to provide authorization to be contacted in the future to provide additional information for the study if it is deemed necessary. It is entirely voluntary whether you agree to participate in the future as well as participate now. Declining to participate in the future does not affect your ability to participate now.

The information from the study will then be analyzed both at Southern California Research and at University of California Irvine with Dr. Ralph Delfino directing the data analysis at University of California Irvine. Therefore, in agreeing to take part in this survey study you are agreeing to share all information collected with the data analysis team at University of California Irvine. Information will be coded so that your name or other information that directly identifies you or your child is not associated with the information you provide.

YOUR ROLE IN THE STUDY

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

• Tell the truth about your and your child’s medical history and current conditions.
• Take time to complete the surveys accurately.
• Ask questions about anything you do not understand.

RISKS OF THE STUDY

As this is a survey study, there are no foreseeable risks related to participation in the study. Completing study surveys may be time-consuming. Answering personal questions may be uncomfortable to some. You may be at risk of loss of the privacy of your own or your child’s health data. This risk is minimized by protections described in the “Protecting the Privacy of Your Health Data” section below.

STUDY STAFF PAYMENT

South Coast Air Quality Management District and British Petroleum are paying the study doctor and study staff for their work in this study.

COSTS OF PARTICIPATION

There is no cost to you for your participation in this study.
COMPENSATION FOR YOUR TIME

For all participants who sign the consent form and complete all the surveys related to their participation, a $20 Target gift card will be provided to compensate for your time and commitment related to the study work. Gift cards will be provided upon completion and submission of the surveys to study center staff.

POTENTIAL BENEFITS OF BEING IN THE STUDY

As this is a survey study, there is no direct medical benefit to participation in this study. Your participation may benefit the community, scientists and doctors providing care to children with asthma.

ALTERNATIVE TO PARTICIPATION

There is no treatment involved in this survey study. Your only alternative is to not participate in this study.

PROTECTING THE PRIVACY OF YOUR HEALTH DATA

Certain people and organizations will need to see, copy, and use your health data so that they can do their part in the study. They are called ‘authorized users.’ Authorized users will be given access to and may make copies of your health data. This health data may or may not include your name. It may be traced back to you even if it does not include your name.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

Authorized users may include:

- Representatives of South Coast Air Quality Management District.
- Representatives of University of California, Irvine.
- Representatives of Chesapeake Research Review, Inc. (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Other authorized users.

Your health data needs to be shared for the research and other reasons. Therefore, complete privacy of your health data cannot be promised. However, sharing your health data will be guided by professional standards and the law.

Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.
GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study).

Contact the study doctor or study staff with any questions or concerns. Their telephone number is printed on the first page of this form. If you have any questions or complaints about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake Research Review, Inc.
  7063 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046

- or call **collect:** 410-884-2900
- or by **email:** adviser@irbinfo.com

Please reference the following number when contacting the Study Subject Adviser: CRRI Number Pro00006737.

BEING A STUDY VOLUNTEER

Entering a research study is voluntary.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.
STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

___________________________________
Signature of Research Subject

Date

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

___________________________________
Signature of Person Explaining Consent

Date

Printed Name of Person Explaining Consent
HIPAA Authorization Agreement
Permission to Review, Use and Release Information about You

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of South Coast Air Quality Control District.
- Representatives of University of California, Irvine.
- Representatives of Chesapeake Research Review, Inc. (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Other authorized users.

Once your health data has been shared with authorized users, it may no longer protected by federal privacy law.

Your permission to use and share health data about you will not end unless required by state law. If state law applies, your permission to use and share health data about you will end on December 31, 2062.
You may take back your permission to use and share health data about you at any time by writing to the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

**STATEMENT OF AUTHORIZATION**

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_________________________  ____/____/____
Signature of Research Subject  Date

_________________________
Printed Name of Research Subject

**STATEMENT OF PERSON EXPLAINING AUTHORIZATION**

I have carefully explained to the subject the nature and purpose of this form. I have been available to answer any questions that the subject has about this form.

_________________________  ____/____/____
Signature of Person Explaining Authorization  Date

_________________________
Printed Name of Person Explaining Authorization