

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AsthmaNet Ancillary GIS Consent
Research Participant Information and Consent Form

Study Title: Ancillary Geographic Information System (GIS) Protocol to Assess Environmental Effects on Drug Response for AsthmaNet Studies

This is a research study, and you do not have to take part. The researchers, Steven Lazarus, MD and Michael Cabana, MD, MPH or one of their research coordinators will explain this study to you. If you have any questions you may ask the research coordinator or contact Fernando Holguin 412-692-2817 or Jane E. Clougherty 412-624-7494.

Outdoor air pollution and neighborhood factors are associated with asthma. This study will help us understand if these factors also affect people's response to asthma treatments. We will use mapping methods to estimate air pollution and neighborhood factors near participant's homes. We are not focusing on any specific people or areas, but will study how the environment affects AsthmaNet participants as a group. Therefore, if your child joins in this study, you will not receive information from the study researchers on the environment near your home.

Our study is not designed to identify risk factors for any specific individuals or neighborhoods. Publications from this research may contain maps depicting air pollution or neighborhood factors across your city. It is possible that you could draw community-specific conclusions about associations between these factors and local asthma, but this is not what the research is designed to support.

You are being asked to take part in this portion of the SIENA study that involves providing your home address. This study uses computer software to look at how the local environment might relate to asthma. Joining this study is voluntary. You are invited to participate because your child is in the AsthmaNet SIENA trial.

Who is funding the study?

This study is funded by the United States National Institutes of Health (NIH), the National Heart, Lung, and Blood Institute (NHLBI).

How many people will be asked to be in this study?

Participants in every AsthmaNet study will be asked to join.

What will happen if my child takes part in this study?

If you agree to have your child be in this study, no additional measures are needed. We are only asking for your permission to use your home address to gather information about the local environment.

How long will my information be stored?

Home addresses will be destroyed by the University of Pittsburgh once their locations are found. The locations of addresses will be stored on a secure server for the duration of the study.

Are there any risks to me or my privacy?

The main risk is the release of your address as part of the AsthmaNet study. No other personal information could be released. We use secure data transfer and storage to make sure that this risk is very small, but we cannot make guarantees. Your privacy is very important to us.

- 1) Your address will be stored using the highest data security standards, and no attempt will be made to identify or contact any individuals.
- 2) Home addresses will be sent to the University of Pittsburgh through secure internet transfer software. The addresses will include a specific study number but not your name or other information.

We will do our best to protect the information we collect from you. If this study is published or presented at scientific meetings, names and other information that might identify you will not be used.

The following entities may have access to the data we collect for this ancillary study:

AsthmaNet Data Coordinating Center, Penn State University College of Medicine, Hershey, PA

AsthmaNet Data and Safety Monitoring Board (DSMB)

University of Pittsburgh, Ancillary GIS Team

Study sponsor and/or its agents: AsthmaNet (other facilities and investigators involved with this study), NIH/NHLBI

Are there benefits?

There are no direct health benefits from this research. The main reason you may want to take part in this study is to help AsthmaNet understand how the local environment may affect treatment response.

Can I say “No”?

Yes, you do not have to consent to this study in order to be in the SIENA study. If you choose not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from UCSF.

Are there any payments or costs?

There is no payment for participation in this study. There is no cost to you or your insurance for taking part in this study.

What if I change my mind?

If you decide not to participate in this study, your data can be permanently deleted at any time.

Who can answer my questions about the study?

You can talk with the study researcher and coordinators about any questions, concerns, or complaints you have about this study. If you have questions later, please contact the study investigator, Dr. Fernando Holguin at 412-692-2817.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY.

You have been given copies of this consent form to keep.

The project coordinator has explained to me the purpose of GIS, the procedures involved, and the risks and benefits. I have asked all the questions I have now, and I know whom to contact if I have more questions later.

Name of Participant (please print):

Please indicate your preference by initialing one of the statements below:
_____(initials) I agree to allow the use of my home address for analysis by researchers at the University of Pittsburgh.

Signature of Participant

Date (mm/dd/yyyy)

Signature of Person Obtaining Consent and Authorization Date (mm/dd/yyyy)