

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO DONATE SPECIMENS FOR FUTURE RESEARCH

Study Title: Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC)

You are invited to take part in a research study that involves contributing your biological samples, such as induced sputum, serum, plasma, and DNA, to a biobank. A biobank is a centralized collection of biological samples and health information that can be used by researchers for future studies in the areas of asthma and other diseases. The biobank in this study is called the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC). Joining this study is voluntary.

Medical research includes only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. The researchers Stephen Lazarus, M.D., and Michael Cabana, M.D., M.P.H., and their associates at UCSF will explain this research to you. If you have any questions, you may ask the researchers.

You are invited to participate because you are a participant in the AsthmaNet *Steroids In Eosinophil Negative Asthma (SIENA)* trial.

Who is sponsoring the study?

BioLINCC is funded by the United States National Institutes of Health (NIH), the National Heart, Lung, and Blood Institute (NHLBI). NHLBI is also the sponsor of AsthmaNet.

Why is this research being done?

As part of the SIENA study, you agreed to have induced sputum, serum, plasma, and possibly DNA collected for specific purposes related to the goals of the asthma study. After the planned analysis for the SIENA study is complete, there may be samples left over. We would like to contribute the left over samples to BioLINCC for long-term storage for future research. The plans for this future research are unknown as of today.

It is important for you to understand that scientific researchers outside AsthmaNet may apply to BioLINCC for use of biological samples and related datasets for any research purpose. These resources may be used for studies relating to asthma, the immune system, or cancer, for example, or any other medical subject area. Each application must be reviewed for its scientific value and given approval before samples and data are released.

Some future studies may be about how genes affect health, or how genes affect response to treatment. Your genes are made up of DNA and have the information needed to build and operate a human body. These studies would require genetic testing. It is up to you whether

or not you want to allow genetic testing on your samples by outside (non-AsthmaNet) researchers. You can agree to allow your samples to be sent to BioLINCC, but not agree to allow genetic testing on them by researchers outside of AsthmaNet, if you choose.

How many people will take part in this research?

All participants in every AsthmaNet study will be asked to participate. Network-wide, we expect to contribute samples from several thousand participants across multiple study sites and clinical trials.

What will happen if I agree to donate my specimens?

No additional procedures are required for participation in the biobank. We are only asking for your permission to allow us to send left over samples that were obtained as part of the AsthmaNet SIENA study to BioLINCC for storage and future research.

What risks are involved with donating specimens for research?

The main risk of participation in the biobank is accidental disclosure (discovery) of your medical information obtained from research which can result in loss of your privacy. If the released information suggests something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or health insurance. There are laws against this kind of misuse, but they may not give full protection.

There are additional privacy risks associated with genetic testing. Because your genetic information is unique to you, there is a chance that someone could trace it back to you even without having your name or other identifying information in the database. The risk of this happening is very small, but it may grow in the future. It is also possible for genetic tests to disclose family secrets involving paternity or adoption accidentally.

There may be other privacy risks that we do not know about. We believe the chance these things will happen is extremely small, but we cannot make guarantees. Your privacy and the confidentiality of your data and biological samples are very important to us, and we will make every effort to protect them, including:

- 1) New random identification numbers (codes) will be assigned to your clinical data and biological samples prior to their transfer to BioLINCC. This coding will prevent any linking of the samples with your personal identity or any information collected for the SIENA trial that was not submitted in the datasets required for the NHLBI. The AsthmaNet Data Coordinating Center in Hershey, PA will be responsible for preparing the BioLINCC datasets and coordinating the transfer of samples to the biobank. The Hershey site does not have access to any of your personal identifying information, such as your name, address, phone number, social security number, or e-mail address. No key linking the BioLINCC codes to your name or other personal information will exist. Through this process, the data and biological samples will be de-identified.
- 2) Biological samples and data are only available to qualified scientific researchers under specific terms and conditions consistent with this informed consent document and NHLBI policies. Each request is thoroughly reviewed. Researchers who are approved to receive biological samples and data are expected to take appropriate data security measures and to respect the privacy of research participants.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors, Michael Cabana, M.D., M.P.H., or Stephen Lazarus M.D. if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at 415-476-2091 (Adult participants) or 415-514-2660 (Pediatric participants).

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476- 1814.

What are the benefits of donating specimens for research?

You should not expect to get direct health benefits from this research. The main reason you may want to take part in the biobank is to help researchers find new ways to prevent, detect, and treat health problems in the future.

How long will my samples and information be stored?

Your biological samples will be stored for as long as they are useful to researchers. There is no limit on the length of time your information will be stored for research. Once the samples are sent to BioLINCC they cannot be retrieved as they are de-identified.

What financial issues should I consider before donating?

There is no payment for participation in BioLINCC. There is no cost to you or your insurance for taking part in BioLINCC. Although biosamples distributed through BioLINCC will not be used for commercial purposes (that is, they will not be sold or used for manufacturing of a product), the results from studies performed using these samples may lead to the development of a medical or genetic test, drug, or other commercial product. Neither you, nor your heirs, will be entitled to receive profits from the sales of any products developed directly or indirectly from such research.

What alternatives do I have?

Your participation in the biobank is voluntary. You can decide not to contribute any of your biological samples to BioLINCC and still participate in the SIENA study. This is not a treatment study. The alternative is not to participate.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. No matter what decision you make, there will be no penalty

to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

What if I change my mind?

Once samples have been submitted to BioLINCC, they cannot be withdrawn or destroyed because there will be no link to identify your samples from others in the repository.

Who can answer my questions about the study?

Please take as much time as you need to think over your participation in BioLINCC. Please ask questions about any part of this document that is unclear. You can talk with the study researcher about any questions, concerns or complaints you have about this study. Contact the study researchers, Michael Cabana, M.D., M.P.H., and Stephen Lazarus, M.D. at 415-514-2660 or 415-476-2091.

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/Assent Statement and Authorization

The project coordinator has explained to me the purpose of BioLINCC, 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 my left over biological samples from the AsthmaNet SIENA trial to be submitted to BioLINCC and used for future unspecified research, including genetic testing by researchers who were not part of AsthmaNet.

_____(initials) I agree to allow my left over biological samples from the AsthmaNet SIENA trial to be submitted to BioLINCC and used for future unspecified research, except for genetic testing by researchers who were not part of AsthmaNet.

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date

Parent or Legal Guardian

Date

Parent or Legal Guardian

YOU WILL RECEIVE A COPY OF THIS FORM AFTER YOU SIGN IT.