

**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 have your child take part in a research study that involves contributing his/her biological samples, such as nasal samples, 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).

Medical research includes only people who choose to take part. Take your time to make your decision about having your child participate. You may discuss your decision with your family and friends and with your child's health care team. The researcher Michael Cabana, M.D., M.P.H., or his research coordinator at UCSF will explain this research to you. If you have any questions, you may ask the researchers.

Joining this study is voluntary. You are invited to have your child participate because s/he is a participant in the AsthmaNet **ST**ep-up **Y**ellow **Z**one **I**nhaled **C**orticosteroid**S** to **P**revent **E**xacerbations (**STICS**) trial.

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

Why is this research being done?

As part of the STICS study, you agreed to have your child's nasal samples, serum, plasma, and, possibly, DNA collected for specific purposes related to the goals of the asthma study. After the planned analysis for the STICS 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 child's 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 child's 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 child's 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 STICS study to BioLINCC for storage and future research.

Your child's biological samples will be stored for as long as they are useful to researchers. There is no limit on the length of time your child's information will be stored for research.

What risks are involved with donating specimens for research?

The main risk of participation in the biobank is accidental disclosure (discovery) of your child's medical information obtained from research which can result in loss of your privacy. If the released information suggests something serious about your child's health, it could be misused. For example, it could be used to make it harder for him/her 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 child's genetic information is unique to them, there is a chance that someone could trace it back to your child even without having their 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 child's 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 the clinical data and biological samples prior to their transfer to BioLINCC. This coding will prevent any linking of the samples with your child's personal identity or any information collected for the STICS 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 child's personal identifying information, such as name, address, phone number, social security number, or e-mail address. No key linking the BioLINCC codes to your child's 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 doctor, Michael Cabana, M.D., M.P.H. if you feel that your child has been injured because of taking part in this study. You can tell the doctor in person or call him at 415-514-2660.

Treatment and Compensation for Injury: If your child is 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 that your child will 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 child's 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.

What financial issues should I consider before donating?

There is no payment for participation in BioLINCC. There is no cost to you or your child's 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 your child, nor his/her 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 child's participation in the biobank is voluntary. You can decide not to contribute any of your child's biological samples to BioLINCC and still participate in the STICS study. This is not a treatment study. The alternative is not to have your child 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 have your child take part or not to take part in the study. No matter what decision you make, there will be no penalty to you or your child and your child will not lose any of his/her regular benefits. Leaving the study will not affect your child's medical care. You child 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 child's 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 research coordinator about any questions, concerns or complaints you have about this study. You may also contact the study doctor, Michael Cabana, M.D., M.P.H. at 415-514-2660.

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 child's left over biological samples from the AsthmaNet STICS 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 child's left over biological samples from the AsthmaNet STICS trial to be submitted to BioLINCC and used for future unspecified research, except for genetic testing by researchers who were not part of AsthmaNet.

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

Date

Person Obtaining Consent

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