UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Trial of Infant Probiotic Supplementation to Prevent Asthma

This is a medical research study. A member of the study team, led by Michael Cabana, MD, MPH from the UCSF Department of Pediatrics will explain this study to you.

Medical research studies include 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. If you have any questions, you may ask your study doctor.

We are asking your permission to include both of you (both parents) in this study because you are about to have a child who will have at least one parent with a history of asthma. Children of one or more parents with asthma are at increased risk for developing asthma later in life.

Why is this study being done?

The overall purpose of this study is to find out if newborn babies who eat *Lactobacillus GG* supplements (*Lactobacillus GG* is a bacteria that is normally found in yogurt) once a day for the first 6-months of life have a decreased risk for developing early signs of asthma. Eczema is a skin condition often seen with asthma and is one of the early signs that researchers will be monitoring.

The study is being funded by the National Institutes of Health, via the National Heart, Lung and Blood Institute.

The purpose of this segment of the study is to survey the pregnant mothers and the biological father to (1) collect data about the baby's overall risk for developing asthma and to (2) ask for your permission to approach both of you again (after the baby is born) in the nursery to ask your permission to include your baby in the study.

How many people will take part in this study?

Approximately 276 children will take part in this study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

We will ask you questions about the mother, the father of the baby, your families and your household. The researcher will interview you for about 30 minutes before or after your obstetrics office visit.

- After the baby is born, we will ask you if you would like your baby to participate in the overall study.

- **Study location:** All these procedures will be done in the Pediatric Clinical Research Center or at your home at a convenient time.

How long will I be in the study?

Until the end of your pregnancy or upon completion of the baseline surveys.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- Some of the interview questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand/learn more about factors associated with the later development of asthma.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your research records for research quality assurance, and data analysis include:

- The National Institutes of Health
- The UCSF's Committee on Human Research

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

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. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions or concerns you have about this study. Contact the researcher, Dr. Michael Cabana at 415-514-2660.

If you have any questions, comments, or concerns about taking part in this study, first talk to the researcher (above). If for any reason you do not wish to do this, or you still have concerns after doing so, you may contact the office of the **Committee on Human Research**, UCSF's Institutional Review Board (a group of people who review the research to protect your rights).

You can reach the CHR office at **415-476-1814**, 8 am to 5 pm, Monday through Friday. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143.

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CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

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

Date	Participant's Signature for Consent (Biological Mother)
Date	Participant's Signature for Consent (Biological Father)
Date	Person Obtaining Consent

By signing this consent form you indicate an interest in having your infant participate in this research study upon birth. Once the infant is born research staff will visit you in the nursery and ask if you are still interested in the study and are willing to consent your infant.

If you are discharged from the hospital before study staff can meet with you or if you do not deliver at the University of California, San Francisco we would like to have a study nurse, doctor or trained research staff member visit you at your residence. The purpose of this home visit would be to consent your newborn into the study and provide study materials.

By signing below I am indicating that I would be willing to have a study nurse or doctor visit me at my residence.

Date	Participant's Signature for Consent (Biological Mother)
Date	Participant's Signature for Consent (Biological Father)

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told of the other choices I have and how they may be better or worse than being in the study,

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,

9) To receive a copy of the signed and dated consent form,

10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.