University of California, Santa Barbara
Santa Barbara Cottage Hospital

SALIVA COLLECTION CONSENT FORM

Immune Regulation, Microchimerism and Maternal-Fetal Health

Protocol No.: Version 3.0 Dated 04/06/2023

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IRB: Santa Barbara Cottage Hospital Institutional Review Board
P.O. Box 689
Santa Barbara, CA 93102

Name of Subject:_____

State of California

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 than what would be used in standard practice.

3. To be told about the frequent and/or important risks, side effects, or discomforts associated with 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 the other choices of procedures, drugs or devices I have and how they may be better or worse than being in the study, including risks and benefits.

6. To be allowed to ask any questions concerning the study and procedures 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 participating after the study has 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 or not participate.

If I have questions about the research study, I should ask the researcher or research assistant. In addition, I may contact the Institutional Review Board (IRB), which is concerned with protection of volunteers in research projects. I can reach the IRB office by calling 805-324-9255 during normal business hours, or by writing the Santa Barbara Cottage Hospital Institutional Review Board, Santa Barbara Cottage Hospital, P.O. Box 689, Santa Barbara, CA 93102.

By signing below, I state that I have read and have had the opportunity to ask questions about the rights which all subjects in a research study have.

_____ _____

Signature of Participant Date

What is the Purpose of this Consent Form?

You have been asked to participate in this specimen collection research study because you are a close relative of a pregnant person participating in our research study on genetically distinct cells that may be transferred during pregnancy (also known as microchimerism). It is possible that some of your cells may be present in people with whom you share a maternal lineage. Dr. Boddyis engaged in a study designed to discover the diversity of microchimeric cells that may be present in a pregnant person. DNA from your saliva sample will allow for detecting matching DNA in the blood of your pregnant relative.

What is Involved?
This project seeks a saliva donation from as many close relatives of pregnant participants as possible. If you agree to participate in this study, you will self-administer a saliva sample collection using the provided kit. You will then mail your sample to the researchers at University of California, Santa Barbara (UCSB) using the provided pre-paid envelope. You will also be asked to specify your relationship to your pregnant relative.

What are the Possible Risks and Discomforts?
Providing a saliva sample does not pose any physical risk.

How Will Information about You be Kept Private?
Your privacy is very important to us, and we will make every effort to protect it. Here are just a few of the steps we will take:

- We will remove your name and other identifiers from your sample and information and replace them with an identification code unique to this study. We will keep the list that links the code number to your name separate from your sample. Only a few of the staff will have access to the list and they sign an agreement to keep your identity a secret.
- Researchers who study your sample and information will not know who you are. If results of this study are published, they will be presented in aggregate, and you will not be identifiable in any way.

Genetic Information and Nondiscrimination Act (GINA)
Genetic testing looks at your genetic material (DNA), which is in your body's cells such as blood and/or tissue cells. Genetic material is inherited from your parents and carries instructions for the body to grow and develop. For example, some genetic material controls hair color and eye color. Differences in genetic material can affect the way a disease develops, the way drugs act on the body, or the way your body uses drugs.

The research will include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). Because you will be having genetic testing done on your saliva, it is important to know about a Federal law called the *Genetic Information Nondiscrimination Act* (GINA). This law generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- GINA prohibits discrimination in housing, education, public accommodations, mortgage lending, elections, and state-operated programs. Access to unlimited monetary damages (i.e. back pay, future lost earnings, emotional distress, punitive, attorney fees, etc.).

Be aware that this Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

What are the Potential Benefits?
You may not receive direct benefit from participating in this research project. The main reason you may want to take part is to help researchers better understand the immune system in relation to pregnancy and help people in the future.

Are There Any Costs or Payments?
There are no costs to you as a participant.

Specimen Donation and Use
Your saliva samples will be provided to Dr. Boddy and may be stored indefinitely. After private information that can identify you is removed from your stored samples, the samples may be used for future research studies or given to another researcher for future research studies without obtaining additional informed consent from you. Standards for specimen research oversight will be followed and the appropriate ethics and regulatory oversight will be provided for any/all subsequent studies.

Information collected by scientists on saliva samples sometimes results in the development of new tests or products which have the potential of significant financial gain for the researchers and/or their companies. However, even though you agreed to donate your saliva sample, you will not receive any money, recognition, or other personal gains from such discoveries. Donating your saliva releases your ownership over the samples and any rights to revenues it may produce now or in the future.

What are My Choices?
You are free to not participate or to change your mind about having your sample used for this research project at any time. There are no penalties, if you want to change your mind. If you no longer wish to participate in this research project or have your samples used for research, you may contact Dr. Boddy at 805-893-2456. Dr. Boddy or her research staff will have your remaining sample destroyed.

What Happens in Case of Research-Related Injury?
In the event that you believe participation in this research project has led to injury, you may contact the study coordinators, Amelia Jones (ajones1@sbch.org, (805) 569-7461) and Carmen Carbajal (ccarbaja@sbch.org, (805) 569-7461), to identify the medical resources that may be

available to you and to assist you in obtaining appropriate medical care. The hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. Your doctor, the investigators, their affiliated organizations and Cottage Health do not have any program to provide compensation for persons who may experience injury while participating in research projects.

What If I Have More Questions?

If you would like more information about this research project you may contact Dr. Boddy at (805) 893-2456, Ms. Jones at (805) 569-7461, or Ms. Carbajal at (805) 569-7461. If you would like more information regarding your rights as a research subject, you may contact the Institutional Review Board at (805) 324-9255.

OFFICIAL SIGNATURE OF RESEARCH SUBJECT

I have read this document (or someone has read it to me). I have been given an opportunity to ask questions concerning the details of the research. I wish to participate in this study. I shall receive a signed copy of this document, which includes the *State of California Experimental Subject's Bill of Rights, and the Consent for Saliva Collection*. My consent is valid for the duration of this study.

Participant Signature	Date	Time

SIGNATURE OF WITNESS OR INTERPRETER (if applicable)

I have witnessed the entire consent process. I believe the participant understands the information described in this document and freely consents to participate.

Witness or Interpreter Name, Identification Number (if applicable), Signature and Date (Cannot be a member of the Research Team. To be used with translated consent form, short form, or for participants unable to read the consent form [illiterate, visually impaired.])

SIGNATURE OF INVESTIGATOR (or investigator-designated member of the research team with sufficient knowledge of the protocol)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Investigator's Signature	Date	Time
Name & Signature of Designated Research Team Member Obtaining Consent (if other than Investigator)	Date	Time