University of California, Santa Barbara
Santa Barbara Cottage Hospital

SALIVA COLLECTION CONSENT FORM
LEGALLY AUTHORIZED REPRESENTATIVE

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 Legally Authorized Representative Date

What is the Purpose of this Consent Form?

The person I am representing has been asked to participate in this specimen collection research study because they are a close relative of a pregnant person participating in a research study on genetically distinct cells that may be transferred during pregnancy (also known as microchimerism). It is possible that some of their cells may be present in people with whom they 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 their saliva sample will allow for detecting matching DNA in the blood of their 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 allow the person you are representing to participate in this study, the participant will collect a saliva sample (either self-administered or assisted) using the provided kit. The sample will then be mailed to the researchers at University of California, Santa Barbara (UCSB) using the provided pre-paid envelope. The participant will also be asked to specify their relationship to their 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?
Participant 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 names and other identifiers from the participant's 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 the participant's name separate from their sample. Only a few of the staff will have access to the list and they sign an agreement to keep participant identity a secret.
- Researchers who study the samples and information will not know who the participants are. If results of this study are published, they will be presented in aggregate, and individual participants will not be identifiable in any way.

Genetic Information and Nondiscrimination Act (GINA)
Genetic testing looks at a person's genetic material (DNA), which is in their body's cells such as blood and/or tissue cells. Genetic material is inherited from 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 the 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 genetic testing will done on the participant's 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 someone based on their genetic information. This law generally will protect people in the following ways:

- Health insurance companies and group health plans may not request the genetic information that we get from this research.
- Health insurance companies and group health plans may not use genetic information when making decisions regarding eligibility or premiums.
- Employers with 15 or more employees may not use genetic information that we get from this research when making a decision to hire, promote, or fire people or when setting the terms of their 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 against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

What are the Potential Benefits?
Participants may not receive direct benefit from taking part in this research project. The main reason you may want to contribute 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 the participant.

Specimen Donation and Use
Saliva samples will be provided to Dr. Boddy and may be stored indefinitely. After private information that can identify participants 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 participants agreed to donate their saliva sample, they will not receive any money, recognition, or other personal gains from such discoveries. Donating their saliva releases their ownership over the samples and any rights to revenues it may produce now or in the future.

What are My Choices?
You are free, at any time, to disapprove of or to change your mind about having the sample provided by the person you are representing be used for this research project. There are no penalties, if you want to change your mind. If you no longer wish to allow participation in this research project or have their samples used for research, you may contact Dr. Boddy at 805-893-2456. Dr. Boddy or her research staff will have any remaining sample destroyed.

What Happens in Case of Research-Related Injury?

In the event that you or the person you are representing 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 and to assist 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. Medical expenses will be the participant's responsibility or that of their third-party payer, although they 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. Their 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 participant rights as a research subject, you may contact the Institutional Review Board at (805) 324-9255.

OFFICIAL SIGNATURE OF LEGAL REPRESENTATIVE

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 for the person I am signing on behalf of 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 for this individual is valid for the duration of this study.

Printed Name of LAR	Reason participant is unable to sign

I hereby attest that I am the official decision maker for this participant, as I have indicated in the circled category below, and I further attest that, to the best of my knowledge, no other surrogate exists with a higher priority than me:

1. Agent named in an advanced health care directive; 2. Conservator or Guardian; 3. Spouse; 4. Domestic Partner; 5. Adult son or daughter; 6. Custodial parent; 7. Adult brother or sister; 8. Adult grandchild; 9. Other adult, not listed above: _____

Legally Authorized Representative (LAR) Signature	Date	Time

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

I have explained the research to the legal representative 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