University of California, Santa Barbara
Santa Barbara Cottage Hospital

SPECIMEN COLLECTION AND TISSUE BANKING 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 Patient Date

What is the Purpose of this Consent Form?
You have been asked to participate in this specimen collection research study because you are pregnant. Dr. Boddy is engaged in a study designed to understand the how your immune system and the quantity of fetal cells circulating in your blood change throughout pregnancy.

What is Involved?
This research seeks participation from 1000 pregnant individuals. If you agree to participate in this study, you will be asked to do the following:

- Complete two surveys regarding your medical and reproductive history. You may also complete an optional follow-up phone interview.
- Allow a medical professional to obtain an additional blood sample for the purposes of this study. These samples will be collected in two tubes for a total volume of 12.5 mL (about 2.5 teaspoons) only during routine blood draws needed for your medical care during your pregnancy.
- Allow cord blood to be collected after your baby is born. A medical professional will collect blood from the cut umbilical cord.
- Allow researchers to access your confidential health information (medical records and other pertinent health information related to your pregnancy).

You may participate in some or all of the above components. Not all components are required for you to be included in this study.

What are the Possible Risks and Discomforts?
There is a small risk of infection with drawing blood. You may experience discomfort from pain during the blood draw. There is a potential risk that your private health-related information may be improperly released. The research team will protect against this risk by placing a code without any identifying information on your sample. All your private information will be stored in locked cabinets or password protected computers.

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 and information. 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.
- We will not give information that identifies you to anyone, except if required by law. Information that is shared with those who are not associated with this research project may no longer be protected by the federal privacy law called 'HIPAA'. But it will be protected as described in this form and may be covered by other privacy laws.
- Your consent to participate in this study includes consent for the investigators and their research staff to review your confidential health information (medical records and other pertinent health information) as may be necessary for purposes of this study. Your health

information may also be inspected by governmental agencies such as the United States Food and Drug Administration (FDA), and the Santa Barbara Cottage Hospital Institutional Review Board (SBCH IRB; a committee for the protection of research participants). Representatives from these groups may inspect your health information for study monitoring and/or auditing purposes, while maintaining your health information as confidential to the extent required by law.

- Members of the healthcare team involved in your medical care will have access to your confidential health information, which may include information about you that involves your participation in this research study. As a result, these individuals may be able to see your research-related information and/or procedure results. All members of the healthcare team are bound by confidentiality laws to keep information about you confidential.

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 blood or tissue, 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 changes in the immune system related to pregnancy and help people in the future.

Are There Any Costs or Payments?

Taking part in this study will not lead to added costs to you or your insurance company. A $25 gift card will be mailed or emailed to you following your first blood sample donation. Another $25 gift card will be compensated to individuals that complete the postpartum phone survey.
Your donated specimens will not be used for commercial profit.

Will I Find Out the Results of the Research?
Clinically relevant research results, including individual research results, will not be disclosed to you. However, significant new findings, if any, which may relate to your willingness to continue, will be provided to you.

Specimen Donation and Use
Your blood samples will be provided to Dr. Boddy. Your blood samples 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 tissue 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 tissue sample, you will not receive any money, recognition, or other personal gains from such discoveries. Donating your tissue releases your ownership over the tissue 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 samples and health information used for this research project at any time. There are no penalties if you want to change your mind. You may also opt out of any portion of the study without fully withdrawing. 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 and data deleted.

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.

Authorization for Use or Disclosure of Health Information
From A Cottage Health Facility

Immune Regulation, Microchimerism, and Maternal-Fetal Health

Completion of this document authorizes the disclosure and/or use of individually identifiable health information, as set forth below, consistent with California and Federal law concerning the privacy of such information.

A. ABOUT THE HEALTH INFORMATION:

State and Federal privacy laws protect the use and release of your health information, also known as *Protected Health Information* (PHI). Under these laws, your health care provider cannot release your PHI to the research team unless you give your permission. This form describes the different ways that the researcher and research team may use your health information for the research study. The HIPAA Privacy Rule designates PHI uses into two categories, *required* and *optional research activities*.

- Authorization for *required activities* refers to the *PHI which is needed* as part of the investigation. **You cannot participate in the research study if you do not authorize the use of your PHI for required purposes.**
- Authorization for *optional activities* refers to the *PHI which is not needed* as part of the investigation. **You do not have to authorize the use of your PHI for the optional research activity(ies) in order to participate in the study.** An example of an optional research activity includes a request for collecting and/or banking your tissue specimen or blood sample for future research.

The specific required and optional uses of PHI for which you are being asked to provide your authorization are listed in section B.

B. HEALTH INFORMATION TO BE RELEASED:

1. If you provide your authorization for the required research activities and sign this form, you are allowing the release and disclosure of medical information collected at a Cottage Health Facility (Santa Barbara Cottage Hospital, Goleta Valley Cottage Hospital, Santa Ynez Valley Cottage Hospital, and/or Pacific Diagnostic Laboratories) in association with the research study listed above. This includes clinical information about this pregnancy, including patient chart review, patient/infant demographics, any diagnoses related to this pregnancy including COVID-19, date of birth, date of delivery, birth weight of infant, and other relevant information related to this pregnancy. This health information will be used to characterize the crosstalk between the fetal and maternal environmental during pregnancy.

2. OPTIONAL RESEARCH ACTIVITIES

This research study does not include any optional requests for the use of your PHI.

C. TO WHOM INFORMATION MAY BE GIVEN:

This information will only be used, as necessary, as part of your consented enrollment in the research study described in the informed consent. By signing this form, you are authorizing that your health information collected at the facility(ies) listed in Section B(1) above, be made available to employees and/or designees of Cottage Health and University of California, Santa Barbara (UCSB) who are coordinating the study, the Santa Barbara Cottage Hospital Institutional Review Board overseeing the study, other authorized officials of Cottage Health and of its

facility(ies) engaged in the research, and other regulatory officials as needed in the task of study monitoring and/or auditing purposes.

If the recipient of your health information is not subject to the HIPAA Privacy Rule, the recipient is legally allowed to disclose your PHI to others without your written Authorization. However, California law requires that the information not be further disclosed by the recipient in any way that would disclose the identity of patients or violate the California's Confidentiality of Medical Information Act.

D. REVOKING AUTHORIZATION:
You may refer to the Cottage Health Notice of Privacy Practices and/or the Notice of Privacy Practices or ask the investigator regarding any special conditions regarding your right to revoke your authorization. However, if you do not provide your authorization or if you wish to revoke your authorization for the required research activities at any time, you may no longer participate in the study. A decision to participate in this research means that you agree to the use of your health information for the required research activities related to this study (conditioned authorization), and you agree not to see your research-related health information until the study is completed.

This authorization is valid until the completion of the research. If you wish to revoke your authorization, you may do so at any time, but it must be in writing.

You will be given a copy of this signed Authorization form.

E. SIGNATURE:
I give my permission to use and disclose my health information (PHI) for purposes of this research study. My signature below attests to this authorization:

_____ _____

Signature of Patient Date

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 Specimen Collection,* and *the Authorization for Use or Disclosure of Health Information*. My consent is valid for the duration of this study.

Patient Signature	Date	Time

SIGNATURE OF WITNESS OR INTERPRETER (if applicable)

I have witnessed the entire consent process. I believe the patient 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 patients 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 patient 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