RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Consent for First Time Mothers

Protocol Title: **Measuring Child Health Disparities: Health Literacy, Discrimination and Health Services (The Healthy Beginnings Study)**

Sponsor: **The National Institute of Child Health and Human Development Rockville, MD**

Principal Investigator: **Elizabeth McFarlane, PhD, MPH**
Adjunct Assistant Professor, Department of Pediatrics
University of Hawaii School of Medicine

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1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask a member of the study team to explain any words or information in this informed consent that you do not understand.

2. Why is this research being done?

This research is being done to better understand how the health and experiences of mothers affect the health, growth and development of their children. The goal is to improve the health and well being of children.

3. What will happen if you join this study?

If you agree to be in this study, the following things will occur:

- You will be asked to participate in an interview of questions about yourself including your pregnancy, your feelings, your behavior and your experiences. The interview will last about 1 hour. We will either come to your home, your health clinic, participating community program, or to a site you choose to conduct the interview. We also will contact you after 6 month time for a second interview.

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future.
Please initial your choice below:
_____ Yes, you may contact me in the future about other studies
_____ No, I do not want you to contact me about other studies

4. What are the risks or discomforts of the study?

There are no medical risks to this study. You might feel uncomfortable about some of the questions we ask. If so, you can refuse to answer any questions at any time. If you have concerns about any questions, we will be happy to discuss them with you.

5. Are there benefits to being in the study?

There is no direct benefit to you or your family for being in the study. However this research may help us understand how children's development before birth helps to explain how they develop after birth and benefit other children and families in the years to come.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your health care and the services you receive will not be affected.

7. Will it cost you anything to be in this study?

There is no cost for study participation.

8. Will you be paid if you join this study?

You will receive $25 cash or gift card for each completed interview.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, The University of Hawaii may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

10. How will your privacy be protected?

All research information about you will be held confidential to the extent allowed by state and federal law. Your personal information will not be given to anyone without your written permission. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form.

The people working on the study will collect information about you. This includes things learned from the interview. They may collect other information including your name, address, date of birth, and other details.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services at the National Institute of Health (NIH). With this certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in

any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances that include child abuse, elder abuse, and your intent to hurt yourself or others.

The research team will need to see your information. Sometimes other people at University of Hawaii School of Medicine may see or give out your information. These include people who review the research studies, their staff, lawyers, or other University of Hawaii School of Medicine staff.

People outside of University of Hawaii School of Medicine may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, and other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form. The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by calling the UH Committee on Human Studies at (808) 956-5007 or by calling the Study Principal Investigator, Dr. Elizabeth McFarlane at (808) 692-1913.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

11. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?
The University of Hawaii Committee on Human Subjects/IRB is made up of doctors, nurses, ethicist, non-scientist and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The UH Committee on Human Subjects number is (808) 956-5007.

b. What do you do if you have questions about the study?

Call the principal investigator (PI), Dr. Elizabeth McFarlane (808) 692-1913. You may also call the UH Committee on Human Subjects at (808) 956-5007.

c. What happens to Data that are collected in the study?

Data and saliva collected during this study are important to both this study and to future research.

If you join this study:

- You will not own the data given by you to the investigators for this research.
- Both University of Hawaii School of Medicine and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, University of Hawaii School of Medicine may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

12. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study
- You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Participant's First/Last Name (Printed)

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.**