Date Approved: February 10, 2011
Principal Investigator: Tina Cheng
Application No.: NA00042617

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

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

CONSENT FOR COGNITIVE INTERVIEW

Application No.: NA_00042617

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

Principal Investigator: Tina Cheng, MD, MPH
Director, Division of General Pediatrics and Adolescent Medicine
The Johns Hopkins University School of Medicine

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. If you join the study, you can change your mind later. 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. In this part of the study we will ask you questions about you, your health, and your thoughts on factors that affect health like stress, health communication, and discrimination, and see if the questions we are asking are clear.

Mothers can take part in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to participate in an interview which last from 1 to 1.5 hours and will take place at Johns Hopkins University Division of General Pediatrics and Adolescent Medicine.

Interviews will be taped.

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 able to discuss them with you.

5. Are there benefits to being in the study?

There may be no direct benefit to you or your family. However the study could help uncover important new medical knowledge that could benefit 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 care at Johns Hopkins University and or your primary health provider 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 $50 for a 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, Johns Hopkins 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?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. 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.

Generally, 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 procedures described in this consent form. They may collect other information including your name, address, age, and other details.

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

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, 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 and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

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 Johns Hopkins Privacy Officer at 410-735-6509 or by sending a letter to:

Johns Hopkins Privacy Officer
5801 Smith Avenue
McAuley Hall, Suite 310
Baltimore, MD 21209
Fax: 410 735-6521

Please be sure to include the name of the principal investigator, the study number and your contact information.

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 Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- 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 IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

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

Call the principal investigator, Dr. Tina Cheng at(410) 614-3862. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

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

Scientists at Johns Hopkins work to find the causes and cures of disease. The data collected from you 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 Johns Hopkins and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, Johns Hopkins may use them for future research only with your consent .
- 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.

d. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians
- Suburban Hospital
- Sibley Memorial Hospital

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

_____

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.**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO SHOULD BE USED TO CONSENT RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO CONSENT RESEARCH PARTICIPANTS.