Informed Consent to Participate in Research

Information to Consider Before Taking Part in this Research Study

IRB Study # _____

Researchers at the University of South Florida (USF) and the Florida Department of Public Health
WIC clinics study many topics. To do this, we need the help of people who agree to take part in a
research study. This form tells you about this research study.

We are asking you to take part in a research study that is called: Laboratory Testing of Breast milk
Samples

The people in charge of this research study are Dr. Kathleen O'Rourke and Dr. Wendy Nembhard.
They are called the Principal Investigators. However, other research staff may be involved and can act
on behalf of the persons in charge.

The person explaining the research to you may be someone other than the Principal Investigators, such
a research assistant. Other research personnel who you may be involved with include: Dr. Azliyati
Azizan, the Study Coordinator and other study personnel.

The research will be done at the University of South Florida and selected Florida Department of Health
WIC clinics.

This research is being paid for by the National Institute of Child Health and Development.

Purpose of the study

Breastfeeding is best for your baby and it is recommended that babies are breast fed for at least six
months. The purpose of this study is to:

- Find the best laboratory methods to test breast milk. This study is not designed to test the
safety of breastfeeding. Because this study will only test laboratory methods, we will not have
any results to share with you. The results from this study should not change anything about
your decision to breastfeed.

Study Procedures

If you take part in this study:

- You will be asked to take part in this study for about 4 months after your baby is born.

- You will be asked to take part in a total of 4 visits: at 1 month, 2 months, 3 months, and 4 months after
- your baby is born. Each visit will take about 20 minutes.
  At the first visit, we will schedule a time to drop off an electric breast pump we are giving you
- and teach you how to use it. The breast pump training can be done at your home and will take
  about 45 minutes.
  For the 1st, 2nd, 3rd , and 4th collection visits you will be asked to collect a breast milk sample at
  home, which should take about 30 minutes. We will schedule a time that we can pick up
- the
  sample, either at your home or another place that is convenient for you. We will also ask you to
  complete a 10-15 minute survey asking about your breastfeeding experience and any possible
  chemical exposures.
  The breast milk samples will be tested for chemicals and then sent to a study lab for testing.
  These samples may be kept for up to 2 years for repeat testing. These samples will be labeled
  with and ID number and your name will not be on them.
  You will be given $25 at each visit to thank you for your time.

Alternatives

You can choose not to participate in this research study now or at any time in the future.

Benefits

We don't know if you will get any benefits by taking part in this study. However, other mothers and
their babies will benefit from the information we learn about testing breast milk samples.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with being in this
study are the same as what you face every day. There are no known additional risks if you decide to
take part in this study. Since we are only testing laboratory methods for testing breastmilk samples, we
will not have any results to share with you. You can feel comfortable to continue breastfeeding your
baby.

Compensation

We will give you $25 for each time you provide a breast milk sample and complete the survey.

Confidentiality

We must keep your study records as private as possible. We will not put your name on any surveys or
breast milk samples. We will keep a separate list of your name and address and any contact
information in a locked file cabinet in a locked room at the University of Florida. We will only use this
list to contact you so we can schedule the next survey and sample collection. At the end of this study,
the list will be destroyed. Only individuals working on this study will be allowed to see the list of
names and addresses.

However, certain people may need to see your study records. By law, anyone who looks at your
records must keep them completely confidential. The only people who will be allowed to see these

records are:

- The research team, including the Principal Investigators, study coordinator, and approved other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.) These include:
  - The University of South Florida Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
  - The Department of Health and Human Services (DHHS).
  - The Florida Department of Health or people from the Food and Drug Administration (FDA).
  - People at the agency who paid for this study. The National Institute for Child Health and Human Development may look at the study records to make sure the study is done in the right way.

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study, to please the investigator or the research staff. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. Your decision to participate or not to participate will not affect your WIC benefits.

Questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, call Dr. Kathleen O'Rourke at 813-974-3240 or Dr. Wendy Nembhard at 813-974-6861.
If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.
If you experience an unanticipated problem related to the research call Dr. Kathleen O'Rourke at 813-974-3240.
If you have questions about your rights as a person taking part in this research study you may contact the Florida Department of Health Institutional Review Board (DOH IRB) at (866) 433-2775 (toll free in Florida), or 850-245-4585.

Consent to Take Part in this Research Study

It is up to you to decide whether you want to take part in this study. If you want to take part, please
sign the form, if the following statements are true.
I freely give my consent to take part in this study. I understand that by signing this form I am
agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____
Signature of Person Taking Part in Study Date

_____
Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she
understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.

Signature of Person Obtaining Informed Consent Date

Printed Name of Person Obtaining Informed Consent