

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:

PROTOCOL NO.

SPONSOR:

INVESTIGATOR:

SITE:

STUDY RELATED

PHONE NUMBERS: Dr. Ruby Natale
305-243-6624 (office hours)
xxx-xxx-xxxx (24-hours)

Introduction:

This consent form describes a research study and what you might expect if you decide to participate. You are asked to read this consent form carefully and ask the person who presents it any further questions you may have before making the decision whether or not to participate. This form describes the known possible risks and benefits and describes what other choices for care or services are available if you do not wish to be in the study. You are completely free to choose whether or not to participate in this study. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making a decision.

Purpose:

We would like you to take part in a study that will help us determine the best way to collect information about the diet of infants and young children.

Number of Subjects

Approximately 60 subjects will be enrolled in this study at the University of Miami and 216 subjects nationally.

Procedure:

If you participate in this research, you will be in the study for approximately 2 months. You will be asked questions about your infant's/child's eating habits. One of the questionnaires will be completed on the computer (using the Internet) and others will be completed using a paper and pencil. We will meet with you 2 times over no more than 2 months. The first visit will last approximately 1 hour and will consist of answering a few questions as well as receiving some instructions on how to complete the other questionnaires at home. The time involved in completing the questionnaires and food records (a diet log sheet to track your infant's/child's daily food consumption, including food portion and time) at home will generally be approximately 40-60 minutes each time. If your infant/child is in daycare, you can get help from the daycare teachers to record what your infant/child ate while s/he was in daycare. We

will also send you a brief questionnaire about how easy it was for you to complete the computer-based survey during this study. We will meet with you again at the end of the study so that you can turn in all of the questionnaires you completed at home. This meeting will take no more than 15 minutes. Because this study has parts of it that are web-based, you will need to have access to the Internet on a computer. Someone will be available to you should you have technical difficulties with completing with web-based measure.

Risks:

The risks to you for taking part in this study are minimal. As a result of being involved in this study you may potentially feel a bit of embarrassment about your infant's/child's eating habits at home if you feel they are not healthy.

Potential Benefits:

No direct benefit can be promised to you. However, as a result of being involved in this study you **may** learn something that could help you improve your infant's/child's eating habits. There may also be societal benefits as this national study will contribute to researchers' understanding of children's health and development.

Alternatives:

You have the alternative not to participate in this study.

Costs:

Neither you nor your family will be billed for the cost of any of the proposed procedures in this study.

Incentives:

To thank you for your time, may receive up to \$50 for completing all of the surveys.

Confidentiality:

If you decide to participate in the study, your infant's/child's information will be kept in a locked file cabinet in the office of the Principal Investigator and only the University of Miami investigators who work on this project will have access to your information. The investigators and their assistants will consider you and your infant's/child's records confidential to the extent permitted by law. Your infant's/child's records may also be reviewed for audit purposes by authorized University employees, the Department of Health and Human Services (DHHS), or other agents who must follow the same rules of confidentiality. The results of the study will be published as group data without revealing the identity of any participant.

Voluntary participation:

Your participation in this study is voluntary. You may choose not to participate in the study or withdraw consent at any time during the study by notifying one of the study staff in writing that you wish to withdraw from the study. Your decision will not result in any penalty or loss of benefits to which your infant/child is entitled. The investigator may remove you from the study without your consent at such time that she feels it is in the best interest for you medically or for administrative reasons.

Questions:

You will receive a copy of this consent form. You may ask and will receive answers to any questions related to this study. If you have any questions about this study, please feel free to contact Dr. Ruby Natale at 305-243-6624. If you have any questions about your rights as a research subject, you may contact the University of Miami Human Subjects Research Office at 305-243-3195.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Consent:

I have read the information in this consent form (or it has been read to me). I am familiar with the purposes, possible benefits and risks of the study. All my questions about the study and my participation in it have been answered. I agree to be in this research study.

CONSENT SIGNATURE:

Printed Name of Subject (if 18 years or older)

Signature of Subject (if 18 years or older)

Date

Signature of Person Obtaining Consent

Date