[STUDY CENTER]

CONSENT TO PARTICIPATE IN RESEARCH

NCS Dietary Research for Pregnant Women

You are asked to participate in a research study conducted by [PROJECT PRINCIPAL INVESTIGATOR] at [STUDY CENTER]. You were selected as a possible participant in this study.

Why is this study being done?

The purpose of this study is to evaluate the feasibility, burden and data quality of collecting data on the diet of pregnant women. This information will help to make recommendations for a large study about the relationship between diet and child health.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to do the following:

1. Come to our [STUDY CENTER] office (visit 1) where you will:
    a. Give your informed consent to participate in the research.
    b. Complete a short questionnaire with questions on acculturation.
    c. Practice an ASA-24 recall. This is an internet-based self-administered dietary recall which asks you to report all the foods and drinks you had in the last 24 hours. (You will be asked to repeat this three more times over a three-month period).
    d. Review the study packet with research staff (ASA24 Brochure, Food Portion Size Guide, 3 Food Diary Blank Forms, Food Diary Directions and Sample and Food Frequency Questionnaire)
    e. We will schedule the Visit 2
2. Task and questionnaires to be completed between visits:
    a. Month 1
        i. Day 1: Complete first food diary on the blank food record form
        ii. Day 2: The day after you complete your first food diary, do your first ASA24 Recall on a computer
        iii. After you finish the first ASA24 recall, fill out the acceptability Questionnaire
    b. Month 2
        i. Day 1; Complete second food diary on the blank food record form
        ii. Day 2: The day after you complete your second food diary, do your second ASA24 Recall on a computer
    c. Month 3
        i. Day 1: Complete third food diary on the blank food record form

ii. Day 2: The day after you complete your third food diary, do your third ASA24 Recall on a computer
iii. Complete the Food Frequency Questionnaire
iv. Fill out the second acceptability questionnaire

3. Come to our [STUDY CENTER] office (Visit 2) where you will:
    a. Bring: 3 completed Food Diaries, Completed Food Frequency Questionnaire and completed two Acceptability Questionnaires
    b. Review completed questionnaires and food diaries with research staff

How long will I be in the research study?

Participation in this study will last for three months. Estimated time for each step is listed below:
Visit 1: You will come to our [STUDY CENTER] Office to complete a questionnaire, practice the ASA24 recall, and receive the study packet. This visit will last about 60 minutes.
Between Visits: Month 1: You will be asked to fill out a food diary, do an ASA24 Recall on a computer and fill out an acceptability questionnaire. This will take about one hour to complete. Month 2: You will be asked to fill out a food diary, do an ASA-24 Recall on a computer. This will take about 45 minutes to complete. Month 3: You will be asked to fill out a food diary, do an ASA-24 Recall on a computer, complete the Food Frequency Questionnaire, and complete a second acceptability questionnaire. This will take about 1.5 hours to complete. You will receive reminder emails and phone calls to complete questionnaires, ASA24 recall and second visit.
Visit 2: After three months you will come to our [STUDY CENTER] office and return 3 completed food diaries, completed food frequency questionnaire and completed acceptability questionnaire. This will take about 15 minutes to complete.

Are there any potential risks or discomforts that I can expect from this study?

There are no anticipated risks or discomforts. The confidentiality of your data will be protected according to Federal law.

Are there any potential benefits if I participate?

You will not directly benefit from your participation in the research.
However, the study is designed to benefit the design of the National Children's Study and therefore offers a societal benefit as this national study will contribute to researchers' understanding of children's health and development.

Will I receive any payment if I participate in this study?

You will receive $25 for time spent learning about the study, receiving instructions, and completing the acculturation questionnaire during Visit 1. You will receive an additional $25 for completing each of the sets for the dietary assessment (food diary, ASA24 Recall, and Acceptability questionnaire). For the last assessment, you will receive $50 for completing the food diary, ASA24, acceptability questionnaire, and the additional NCS Food Frequency Questionnaire. The total possible for money compensation for

participation in this dietary research project is $125. A check will be mailed to you; it will take approximately 4-6 weeks. [STUDY CENTER] accounting policy requires that we collect your Social Security Number in order to issue payment for research purposes. Therefore, we will request that you provide us with your Social Security Number in order to process payment for your participation in the study. Your Social Security Number will only be used for this purpose. Records which contain your Social Security Number will be stored securely and separately from research records, will not be copied unnecessarily, and will be destroyed as soon as it is feasible. If you receive more than $600 from [STUDY CENTER] in the course of a year, [STUDY CENTER] must report this income to the Internal Revenue Service.

You will also receive a [STUDY CENTER] parking permit for your two visits to our [STUDY CENTER] office.

Will information about me and my participation be kept confidential?

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of using study ID numbers on questionnaires and food diaries. Hard copy questionnaires will be stored in a locked cabinet in our office. The ASA24 Recall will be entered directly by study ID number into a computer database maintained by the National Cancer Institute (NCI) but the NCI will not have any contact information or personally identifiable information. Forms that have your name and/or contact information on them will be kept in a locked cabinet in our office that is separate from where the questionnaires and food diaries are stored. Only the project coordinator will have access to the file with your personal identifying information and study ID number. This information will only be used to contact you. Security plans and data use agreements for this project have been approved by the NICHD CIO and the NCS Confidentiality Officer.

Withdrawal of participation by the investigator

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If the following events occur, you may have to drop out, even if you would like to continue:

- Failure to attend appointments
- Failure to complete ASA24 Recall (total of 3)
- Failure to completed questionnaires and food diaries

The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made to allow for the full completion of the research study.

What are my rights if I take part in this study?

You may withdraw your consent at any time and discontinue participation without penalty or loss of benefits to which you were otherwise entitled.

You can choose whether or not you want to be in this study. If you volunteer to be in this study, you may leave the study at any time without consequences of any kind. You are not waiving any of your legal rights if you choose to be in this research study. You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can answer questions I might have about this study?

In the event of a research related injury, please immediately contact one of the researchers listed below. If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact [PROJECT PRINCIPAL INVESTIGATOR] [CONTACT TELEPHONE NUMBER],

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please call the [LOCAL IRB CONTACT NUMBER FOR STUDY CENTER]. or write to [LOCAL IRB CONTACT FOR STUDY CENTER].

SIGNATURE OF STUDY PARTICIPANT

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

In my judgment the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date