

HEALTHY COMMUNITIES STUDY
FAMILY HOUSEHOLD VISIT PROTOCOL OVERVIEW
FOR SECOND PARENTS/CAREGIVERS PARTICIPANTS

This document provides an overview of the protocol for the family household visit for the second parent/caregiver. Protocol materials include the consent form and the anthropometric measurement recording form. These data collection materials will be used for the household visit in every community and for the repeat in-person household visit three years after the initial visit for the Repeat In Person Assessment (RIPA) communities.

Once a household has been enrolled in the study, and the home visit has been scheduled, an Examination Management Services, Inc. (EMSI) trained field interviewer will conduct the home visit to administer the interview with both the parent/caregiver and child, and collect anthropometric measurements of the child, and where available, the parents/caregivers. While the collection of anthropometrics for one parent/caregiver is included in the parent/caregiver participant protocol, it is estimated that only in 50% of the households will a second parent/caregiver be available and provide consent to have their height and weight measured.

During the visit, the EMSI field interviewer will explain the study to the parent/caregiver and child in their home, review the consent documents, and answer any questions the parent/caregiver may have. At this time, the parent/caregiver will be asked to sign the informed consent form, which will indicate their consent to participate. If other parents/caregivers are living in the home and available to have their height and weight measured, they will also be asked to sign the form indicating their agreement to be measured. The master adult consent form, provided below, includes language for both parents/caregivers agreement to being measured. The average time for consenting and measuring a second parent/caregiver is estimated at 7 minutes. EMSI field interviewers will be trained to explain the study thoroughly and answer questions fully. They will be instructed to proceed only if the participants have provided their voluntary, informed consent. EMSI field interviewers will be trained in Human Subjects Research, and will therefore know the guidelines regarding what qualifies as “informed” consent.

If either or both parents/caregivers do not consent to being measured, self-reported height and weight measurements will be requested; if either or both parents/caregivers are not available, proxy-reported height and weight measurements will be requested.

The measured height and weight (or self- or proxy-reported measurements) will be recorded onto a paper form and entered into the computer at the earliest opportunity before leaving the house. Measurements will be made according to the NHANES protocol, recorded in metric units (centimeters and kilograms), and measured to the nearest .1 cm and .1 kg. BMI will be calculated by dividing weight in kilograms by height in meters squared (kg/m^2).

**HEALTHY COMMUNITIES STUDY
MASTER ADULT CONSENT FORM¹**

Public reporting burden of this collection of information is estimated at 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to S. Sonia Arteaga, Ph.D., project officer at hcs@nhlbi.nih.gov

PURPOSE

The purpose of the Healthy Communities Study is to see what programs and policies in communities across the United States help children lead healthy lives. This study is being conducted by a research company, Battelle Centers for Public Health Research and Evaluation. It is funded by the National Institutes of Health (NIH).

PROCEDURES – STANDARD PROTOCOL

If you agree to have you and your child participate in this study, a trained interviewer will come to your home [one time/two times, now and again three years from now]. [He or she/Each time he or she] will ask you and your child questions about nutrition and physical activity. The interviewer will also ask questions about your home and your community and will record the precise location of your home. This information will allow researchers to look at the specific resources and environment around the homes of study participants to understand where community programs have an impact.

Your answers will be recorded on a computer and some answers will be entered into the computer directly by you and your child. If your child was aged 12 or older when we first asked you to join the study, we will ask him or her to answer many of the questions without your help.

The interviewer will take measurements of your child including your child's height, weight, and waist circumference. A cosmetic pencil will be used to place a small mark on your child's hip in order to accurately place the tape measure for the waist measurement. The interviewer will also record current height and weight measurements for the child's parents/caregivers. If you are a parent/caregiver, the interviewer will measure your height and weight today, and measure the height and weight of the other parent/caregiver, if he or she lives here, is available today, and consents to being measured. If you are not the parent/caregiver, the interviewer will measure the height and weight of the parents/caregivers if either/both live here, are available today, and consent to being measured. If any parent/caregiver is not available or willing to be measured, we will ask you to report their latest known height and weight, if you know that information. All measurements will be repeated for accuracy. Finally, the interviewer will ask you to sign a form to let us look at your child's past medical records on file at your child's doctor's office to collect information on how your child has been growing. The entire visit today by the interviewer should take about 75 minutes.

[One year/Two years] from now, we will contact you again and ask you to answer about 35 minutes worth of questions through a web or telephone survey. The questions will be similar to those you are answering during today's visit.

We may also contact you again in the future when similar studies take place in your community. At that time you will be given the choice to participate in that new study or not.

¹ This master version of the adult consent form contains shaded wording under Procedures and Compensation indicating where sentences or phrases will differ as appropriate according to the type of community and type of protocol.

PROCEDURES – ENHANCED PROTOCOL

If you agree to have you and your child participate in this study, a trained interviewer will come to your home [two times/four times, twice now and twice again three years from now]. During the first visit [each year], he or she will ask you and your child questions about nutrition and physical activity. The interviewer will also ask questions about your home and your community and will record the precise location of your home. This information will allow researchers to look at the specific resources and environment around the homes of study participants to understand where community programs have an impact.

Your answers will be recorded on a computer and some answers will be entered into the computer directly by you and your child. If your child was aged 12 or older when we first asked you to join the study, we will ask him or her to answer many of the questions without your help.

The interviewer will take measurements of your child including your child's height, weight, and waist circumference. A cosmetic pencil will be used to place a small mark on your child's hip in order to accurately place the tape measure for the waist measurement. The interviewer will also record current height and weight measurements for the child's parents/caregivers. If you are a parent/caregiver, the interviewer will measure your height and weight today, and measure the height and weight of the other parent/caregiver, if he or she lives here, is available today, and consents to being measured. If you are not the parent/caregiver, the interviewer will measure the height and weight of the parents/caregivers if either/both live here, are available today, and consent to being measured. If any parent/caregivers is not available or willing to be measured, we will ask you to report their latest known height and weight, if you know that information. All measurements will be repeated for accuracy.

Your child will be asked to wear an activity monitor for the next week. The monitor measures movement. It should be worn at all times except while sleeping or when in water, such as while bathing or swimming. The interviewer will show you how to put the monitor on (and take it off) your child.

You and your child will also be asked to recall what your child ate yesterday. We would like to audio record the discussions as this food recall is being completed so that we can check that we entered the correct information in the computer. Finally, the interviewer will ask you to sign a form to let us look at your child's past medical records on file at your child's doctor's office to collect information on how your child has been growing. The entire first visit by the interviewer should take about 95 minutes.

One week after the first visit [each year], the interviewer will come back to your house to collect the activity monitor and repeat the food recall and the measurements. At this time, they will also ask you questions about what activities your child did yesterday. This second visit will take approximately 50 minutes.

[One year/Two years] from now, we will contact you again and ask you to answer about 35 minutes worth of questions through a web or telephone survey. The questions will be similar to those you are answering during today's visit.

We may also contact you again in the future when similar studies take place in your community. At that time you will be given the choice to participate in that new study or not.

HOW YOU WERE SELECTED

You are eligible to be in the study because you have a child between 3 and 15 years old living in your household and your household is located within one of the 279 communities we are studying. Approximately 23,000 children and their parents will eventually participate in this study.

DATA SECURITY

The study team will do everything they can to make sure your information stays private and secure. All study staff members are required to complete trainings on keeping your information safe. Study laptops and equipment are password protected. They also have programs to protect your information. Your information will be stored in a locked building with access limited to authorized study team members only.

Any forms with your name (or your child's name) will be kept separate from any papers that might be used to collect information about your child. Study data forms will only have your study identification number on it.

The only reasons we would have to reveal your study participation, as required by law, are:

- 1) if a case of child abuse is discovered during the study, or
- 2) if the Institutional Review Board (IRB), the body which oversees the protection of study participants, needs to review records.

If you let us look at your child's medical records, your doctor will know that you are in the study, but he or she will not have access to the information we collect during this study.

Final study results will be published on groups only. No individual information will be included. No individual in this study will be able to be identified.

RISKS/DISCOMFORTS

There are few known risks to participation in this study. Some of the questions we ask may be sensitive. Because the study is voluntary, you do not need to answer any question you do not feel comfortable answering. There is also a risk of your data being revealed. Every effort will be made to keep your information safe and secure.

BENEFITS

This study has no known individual benefits for participation. However, it is important for you and your child to participate because it will help researchers understand what programs and policies in the community help children to stay healthy. The results of this study could help improve existing and future programs/policies for children across the United States.

COSTS AND COMPENSATION

There is no cost to you for being in this study. In appreciation of your participation, after [the/each] [first] home visit if your child was between 3 and 11 years old when we first invited you to join the study, you will get a gift worth \$25 and a small age-appropriate toy for your child. If your child was 12 or older when you agreed to join the study and today your child helps answer more of the study questions directly, you will each get a gift worth \$15.

At the end of [your/each] second home visit, when the interviewer collects the activity monitor, your family will get an additional \$50 money order.

If you complete the follow-up web or telephone questions in a few years, we will mail you another gift worth \$10. As an additional thank you for your participation in this study, at the end of the study, you will get a summary report of the study results for all participants as a group.

VOLUNTARY

Participation by you, your child, and any other parents/caregivers in this study is voluntary. You may ask questions at any time. You may refuse to answer any survey question. You may also drop out at any time without penalty to you or your child. If your child is aged 8 or older today, we will also ask your child to sign a form indicating his or her agreement to be in the study before we begin any data collection.

CONTACT INFORMATION

For questions about your rights as a study participant, contact:
Battelle Institutional Review Board
1-877-810-9530

For questions or concerns about the study:
Dr. Howard Fishbein
Battelle Centers for Public Health Research and Evaluation
703-248-1647

I have read this consent form and the study staff have answered my questions.

I, _____, parent/guardian of _____,
Printed Parent/Guardian Full Name Printed Child Full Name
agree for myself and my child to participate in the "HEALTHY COMMUNITIES STUDY."

PLEASE CHECK ONE OF THE FOLLOWING BOXES

- I agree to allow audio recording of the food recall part of the interview.
- I do NOT agree to allow audio recording of the food recall part of the interview.

Parent/Guardian Signature

Date

Witness Signature

COMPLETE THE FOLLOWING FOR ANY PARENT/CAREGIVER NOT PARTICIPATING IN THE INTERVIEW WHO CONSENTS TO HAVE THEIR MEASUREMENTS TAKEN.

I agree to have my height and weight measured for the "HEALTHY COMMUNITIES STUDY."

Parent/Caregiver Signature

Parent/Caregiver Signature

**HEALTHY COMMUNITIES STUDY
ANTHROPOMETRIC MEASUREMENT RECORDING FORM FOR PARENT/CAREGIVER**

Public reporting burden of this collection of information is 3.5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to S. Sonia Arteaga, Ph.D., project officer at hcs@nhlbi.nih.gov

To be completed by EMSI research staff: FOR ALL HEIGHT AND WAIST CIRCUMFERENCE MEASUREMENTS, RECORD MEASUREMENT IN CENTIMETERS TO THE NEAREST .01 CM. FOR ALL WEIGHT MEASUREMENTS, RECORD MEASUREMENT IN KILOGRAMS TO THE NEAREST .01 KG. IF PARENT/CAREGIVER REFUSES TO BE MEASURED OR IS NOT AVAILABLE, ASK FOR SELF-REPORTED OR PROXY-REPORT HEIGHT IN FEET AND INCHES AND WEIGHT IN POUNDS.

SECTION A: MOTHER/CAREGIVER MEASUREMENTS

- | | | | |
|-----|--|---|---|
| A1. | MOTHER/CAREGIVER ID NUMBER | ID..... <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | MOTHER/CAREGIVER UNKNOWN. (SKIP TO SECTION B).9 |
| | | | |
| A2. | MOTHER/CAREGIVER HEIGHT #1 | MEASURED CM..... <input type="text"/> <input type="text"/> <input type="text"/> | |
| | | OR | |
| | | SELF REPORT FT..... <input type="text"/> <input type="text"/> | |
| | | SELF REPORT INCHES..... <input type="text"/> <input type="text"/> | |
| | | OR | |
| | | PROXY REPORT FT..... <input type="text"/> <input type="text"/> | |
| | | PROXY REPORT INCHES..... <input type="text"/> <input type="text"/> | |
| | | OR | |
| | | RF..... | 9997 |
| | | DK..... | 9998 |
| | | | |
| A3. | MOTHER/CAREGIVER HEIGHT #2
(ONLY DO IF ENHANCED PROTOCOL) | MEASURED CM..... <input type="text"/> <input type="text"/> <input type="text"/> | |
| | | RF..... | 9997 |
| | | | |
| A4. | MOTHER/CAREGIVER WEIGHT #1 | MEASURED KG..... <input type="text"/> <input type="text"/> <input type="text"/> | |
| | | OR | |
| | | SELF REPORT LBS..... <input type="text"/> <input type="text"/> <input type="text"/> | |
| | | OR | |
| | | PROXY REPORT LBS..... <input type="text"/> <input type="text"/> <input type="text"/> | |
| | | OR | |
| | | RF..... | 9997 |
| | | DK..... | 9998 |
| | | | |
| A5. | MOTHER/CAREGIVER WEIGHT #2
(ONLY DO IF ENHANCED PROTOCOL) | MEASURED KG..... <input type="text"/> <input type="text"/> <input type="text"/> | |
| | | RF..... | 9997 |

SECTION B: FATHER/CAREGIVER MEASUREMENTS

B1. FATHER/CAREGIVER ID NUMBER ID.....
 FATHER/CAREGIVER UNKNOWN.. (SKIP TO SECTION C).9

B2. FATHER/CAREGIVER HEIGHT #1 MEASURED CM.....
 OR
 SELF REPORT FT.....
 SELF REPORT INCHES.....
 OR
 PROXY REPORT FT.....
 PROXY REPORT INCHES.....
 OR
 RF..... 9997
 DK..... 9998

B3. FATHER/CAREGIVER HEIGHT #2 (ONLY DO IF ENHANCED PROTOCOL)
 MEASURED CM.....
 RF..... 9997

B4. FATHER/CAREGIVER WEIGHT #1 MEASURED KG.....
 OR
 SELF REPORT LBS.....
 OR
 PROXY REPORT LBS.....
 OR
 RF..... 9997
 DK..... 9998

B5. FATHER/CAREGIVER WEIGHT #2 (ONLY DO IF ENHANCED PROTOCOL)
 MEASURED KG.....
 RF..... 9997