

Enhanced Protocol: Parental Permission to Participate in Research (Children Ages 3-17)



**Parental Permission to Participate in Research:
The Community Transformation Grants Enhanced Evaluation
(Children Ages 3-17)**

Title of Research: Youth and Adult Biometric Study

Introduction

Please read this form. It will explain what the study is about and what your child will be asked to do. It will also tell you who can be in the study, what are the risks and benefits of the study, how we will protect any personal data about your child, and who you can call if you have questions. If something isn't clear, please ask your interviewer to explain it.

Purpose

RTI International, a nonprofit research group, is conducting this study for the Centers for Disease Control and Prevention. We are trying to learn what your child believes and how your child behaves in regard to physical activity, the food he or she eats, his or her emotional health, his or her risks for obesity and illnesses, and the community or school programs that you're involved with to prevent obesity and tobacco use. About 500 adults and 300 children (ages 3 to 17) from your local area will take part in this study this year.

Procedures

If you agree to let your child take part in this study, the field interviewer who visits you in your home will ask your child some questions (ages 12-17), or ask you some questions about your child (ages 3-11), take some measures, and ask your child to give a sample of saliva.

Children will be asked different questions depending on their age.

- **Child age 12 to 17 years:** An interviewer will ask your child questions in your home and your child will give his or her own answers. Your child will be asked about his or her own physical activity, the food they eat, their tobacco use, what they know and think about school and community programs to prevent and reduce obesity and tobacco use; being exposed to secondhand tobacco smoke, recent weight loss or gain, and recent illness or medical diagnosis that could affect their physical measures. The interviewer will enter your child's answers into a computer. You will be with your child when we ask these questions. For sensitive questions about tobacco use and weight loss, we will show your child a card that has a letter for each answer, and your child can answer by giving us the letter that is next to his or her answer. This

Enhanced Protocol: Parental Permission to Participate in Research (Children Ages 3-17)

way, your child's privacy is protected because you will not know what your child's answer is. Once the 20-minute survey is finished, the interviewer will measure your child's height, weight, and waist circumference. The interviewer will also take a saliva sample to test how much secondhand smoke your child has been exposed to.

- **Child age 3 to 11 years:** An interviewer will ask you questions in your home and your answers will be based on what you've observed about your child's behavior. You will be asked about your child's eating and exercise behaviors, if he or she has been exposed to secondhand tobacco smoke, any recent weight loss or gain, or recent illness or medical diagnosis that could affect his or her physical measures. The interviewer will enter your answers into a computer. Once you finish this 20-minute survey, the interviewer will measure your child's height, weight, and waist circumference. The interviewer will also take a saliva sample from your child to test how much secondhand tobacco smoke he or she has been exposed to.

Quality Control (QC) Procedures: Through a random process, your child may be selected to participate in a QC procedure that only includes another interviewer observing height, weight, and waist circumference measurements being taken, and observing saliva samples being taken.

Biospecimen Collection

Your child will be asked to give a saliva sample to a trained interviewer who will ask your child to spit about three times into a funnel to collect the saliva.

Your child's saliva will be tested for the amount of a chemical in his or her body that will show how much secondhand tobacco smoke he or she has been exposed to. You will not get the results of this test. Also, we will not test your child's saliva sample for DNA, alcohol, cancer, HIV, illegal drugs, sexually transmitted diseases or to find out who is the father of the child.

Your child's saliva sample will be stored at a special facility at RTI until it's tested. Your child's sample will not be associated with his or her name. The saliva sample will be kept until it is no longer needed for the study. Your child's sample will be used only for this study and will not be sold.

Study Duration

It will take about 40 minutes to complete the survey, measurements and saliva collection.

Possible Risks or Discomforts

Some of the survey questions may make you or your child feel uneasy or upset. Your child doesn't have to answer any question he or she doesn't want to answer (or you don't have to answer any questions about your child that you don't want to), and you or your child can take a break at any time. You or your child can also stop the interview at any time. No one who takes part in the study will be identified in any report or publication of this study or its results. Taking your child's height, weight or waist circumference pose no risk, but may make your child feel uncomfortable. Giving a sample of saliva poses no risk. Your child may also refuse to give any of the measures listed above. In addition, there might be unusual or unknown risks. You or your child should report any problems to the interviewer.

Enhanced Protocol: Parental Permission to Participate in Research (Children Ages 3-17)

Benefits

There are no direct benefits to you or your child from taking part in this study, but the information we get will help us learn what to do in communities like yours to help prevent obesity (such as how to encourage more physical activity and eating the right kinds of foods), to reduce tobacco use and being exposed to secondhand smoke, and to control things that may put people at risk for long-term illnesses. If we learn that the life or health of you or your child is in danger, or the life or health of a child living in your home is in danger, we will inform the proper county or state agency. More information is provided in the Confidentiality section below.

Payment for Participation

Children 12-17 years old who participate in the study will receive \$10 in cash. If a child 3-11 years old participates in the study, the parent or caregiver will receive \$10 in cash.

Confidentiality

Your child's information will be put into a computer and his or her name will be replaced with a study ID number. Your child's name will not be linked to any information you or your child provide. Your contact information (name, phone number, and physical address) will be shared with trained interviewers. The interviewers are trained to carefully avoid sharing your contact information with anyone. The trained interviewers will need to call you to confirm your home visit. They will also need to know your correct address so they show up at the right place for your home visit. Your contact information will be kept in a different place than your answers to the survey. Your contact information will be permanently deleted once you have received all of your compensation. The trained interviewers have signed an agreement to keep all of your information private. Your child's information will be grouped with information of hundreds of other people. The results will only be shown for groups of people and not for individuals. No one will be able to identify you or your child from your information.

An Institutional Review Board (IRB) is a group of people who make sure that the rights of people who take part in studies are protected. A member of RTI's IRB may contact you to find out how you feel about this study. This person will be given your name, but they will not be given any of your child's private information. You don't have to answer any questions this person may ask.

All project staff involved in this study must keep your information private. In fact, they have signed a pledge to do so.

There are two important exceptions. First, if the interviewer or project staff think that your child's life or health is in danger, the proper county or state agency will be informed. Second, if they think that your life or health is in serious danger, they will contact emergency services.

Future Contacts

There are two reasons we might contact you again in the future. First, an RTI staff member may call you to make sure the field interviewer arrived at your home to collect data. Once we have confirmed the field interviewer showed up for your home visit, and you have received all of your compensation, we will permanently delete your personal information from our records. Second, there is a small chance you and your child could be invited to participate in this study or other studies going on in your community in the future.

Enhanced Protocol: Parental Permission to Participate in Research (Children Ages 3-17)

This is because participants are selected at random and by chance you may get contacted again. We may wish to contact you about other studies in the future. Whether you or your child take part in any future studies is up to you.

Your Rights

This study is completely voluntary. You or your child can refuse any part of the study, and you or your child can stop at any time. If you or your child decide to take part in the study and change your mind later, you will not be contacted again or asked for any more information.

Your Questions

If you have any questions about the study, please call Angela Blackwell, our study manager, at this toll-free number: 1-866-784-1958. If you have any questions about your rights or the rights of your child for being part of this study, or if you feel your child may have been harmed by being in this study, please call RTI's Office of Research Protection at this toll-free number: 1-866-214-2043.

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Permission to Enroll Child:

I have been told about the study and have read this form or had it read to me. I know what is expected of me and my child. I was allowed to ask questions. I had all of my questions answered. I give permission for my child to take part in this study. By signing this form, my child and I are not giving up any of our legal rights.

Date

Signature or mark of parent or legal guardian

Printed name of parent or legal guardian

Printed name of child

If the child's parent or guardian is unable to read this form, a witness must sign here:

Note: The witness should not be the person who obtains consent.

I was present when this parental permission form was read to the person named above. The person was given a chance to ask questions about this study. I believe that he or she has given permission for his or her child to take part in the research.

Date

Signature of Witness

Printed Name of Witness

Enhanced Protocol: Parental Permission to Participate in Research (Children Ages 3-17)

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this study have been explained to the above-named individual.

Date

Signature of Person Obtaining Consent

Printed Name of Person Obtaining Consent

Addendum to Parental Permission to Participate in Research: Activity Monitor

(Children 3-17)

Title of Research: Youth and Adult Biometric Study

Your child is taking part in the Youth and Adult Biometric Study. Previously, you reviewed and signed a parental permission form to let your child take part in this study.

Your child is being asked to be in another part of this study. This part involves wearing an activity monitor for 7 days beginning when your child wakes up tomorrow morning. About 125 adults and 125 children from your local area who also agreed to take part in the Youth and Adult Biometric Study will participate in the monitoring part of this study.

The activity monitor (called the Actigraph GT3XE accelerometer) is a small, very light device worn on a belt around the waist. This monitor is about the size of a small pager or cell phone and it will not get in the way of your child's normal everyday activities. It should be taken off before swimming or bathing, and it should only be worn during hours when your child is awake.

If your child is in the activity monitor part of this study, you will be asked to return the monitor to RTI International via the US Postal Service (postage pre-paid) for data processing. If we look at the data your child provides and see that it is not complete, we will ask your child to wear the monitor for another 7 days.

The activity monitor part of this study will take about 30 minutes for your child. This time includes getting instructions about using the monitor, keeping a diary of the time when your child gets up in the morning, the time your child goes to bed to sleep, and the time and reason the monitor was removed for 5 minutes or more for any activity such as swimming or showering, and mailing the monitor back to us for data processing.

Children who are in the monitor part of this study will receive a \$10 gift card after the monitor has been mailed back. The child's gift card will be sent to you as the child's parent or caregiver. If there are not at

Enhanced Protocol: Parental Permission to Participate in Research (Children Ages 3-17)

least 5 days of complete data, children will be asked to wear the accelerometer for another 7 days. Children may refuse to wear the accelerometer for a second week and still receive the \$10 gift card.

If your child agrees to wear the activity monitor, we will contact you 3 to 4 days after your home visit to make sure your child is not having problems with the monitor. We will also answer any questions you or your child have about using the monitor. And we will contact you after 7 days to see if you had any problems and to answer any questions about how to send the monitor to RTI via the US Postal Service.

Permission to Enroll Child:

I have been told about the activity monitor part of this study. I know what is expected of my child. I was allowed to ask questions. I had all my questions answered. I give permission to enroll my child in the activity monitor part of this study.

Date

Signature (of parent/legal guardian)

Printed name (of parent/legal guardian)

Printed name (of child)

If the parent or guardian is unable to read this form, a witness must sign here:

Note: The witness should not be the person who obtains consent.

I was present when this addendum was read to the above-named person. The person was given a chance to ask questions about the activity monitor part of the study. I believe that he or she has agreed for their child to participate in this part of the study.

Date

Signature of Witness

Printed Name of Witness