Consent to Participate in Research: The Community Transformation Grants Enhanced Evaluation

(Adults Only)

Title of Research: Youth and Adult Biometric Study

Introduction

Please read this form. It will explain what the study is about and what you 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 you, 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 you believe and how you behave in regard to physical activity, the food you eat, your emotional health, your 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 take part in the study, you will be asked questions by a trained interviewer who will fill out a form based on your answers. You will be asked about recent weight loss, any changes in your eating or physical activity behaviors, your tobacco use, whether you are exposed to tobacco smoke, and any recent diagnosis of high blood pressure. After finishing the survey, the interviewer will measure your height, weight, waist circumference, heart rate and blood pressure. The interviewer will also ask you to give a sample of your saliva. This will be used to find out how much secondhand tobacco smoke you've been in contact with.

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

Biospecimen Collection

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

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

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

Study Duration

Your participation in the survey and taking the measures and the saliva sample will take about 40 minutes.

Possible Risks or Discomforts

Some of the survey questions may make you feel uneasy or upset. You don't have to answer any question you don't want to answer, and you can take a break at any time. You 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 height, weight, waist circumference, heart rate, and blood pressure pose no risk, but may make you feel uncomfortable. Giving a sample of saliva poses no risk. You may also refuse to give any of the measures listed above. In addition, there might be unusual or unknown risks. You should report any problems to the interviewer.

Benefits

There are no direct benefits to you from taking part in this study, but your answers will help us learn what to do in communities like yours to help prevent obesity, 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 observe elevated blood pressure measurements,the interviewer will terminate the interview if your blood pressure is very high, and give you verbal and written information concerning the appropriate medical care if your blood pressure is high or very high. If we learn that your life or health 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

Adults who participate in this study will get $40 in cash.

Confidentiality

Your information will be put into a computer and your name will be replaced with a study ID number. Your name will not be linked to any information you 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 finished all parts of the study and have received all of your compensation. The trained interviewers have signed an agreement to keep all of your information private. Your answers will be grouped with answers 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 answers.

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 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 a child living in your home is in danger, the proper county or state agency will be informed. Also, if they think that your life or health is in serious danger, they will contact emergency services. Second, if we learn that any of your blood pressure measurements are potentially life-threatening and should be reported to a doctor, we will let you know right away and refer you to an appropriate medical care provider.

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 could be invited to participate in this study or other studies going on in your community in the future. This is because participants are selected at random and by chance you may get contacted again. Whether to take part in any future studies is up to you.

Your Rights

This study is completely voluntary. You can refuse any part of the study, and you can stop at any time. If you 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 questions about the study, please call Angela Blackwell, Project Manager, at this toll-free number: 1-866-784-1958. If you have questions about your rights for taking part in the study, or if you feel you 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.

Signing your name (or making your mark) below means that you have read (or someone read you) all of this form. It also means that you got answers to all your questions and that you have freely decided to take part in this study. By agreeing to take part in this study, you are not giving up any of your legal rights.

_____ _____

Date Signature (or Mark) of Participant

_____

Printed Name of Participant

If the participant 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 consent form was read to the person named above. This person was given a chance to ask questions about being in this study and I believe that he/she has agreed to take part in it.

_____ _____

Date Signature of Witness

_____

Printed Name of Witness

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 Consent to Participate in Research For Continuing Research Subjects (Adults Only)

Title of Research: Youth and Adult Biometric Study

You are taking part in the Youth and Adult Biometric Study. Previously you reviewed and signed an informed consent form to participate in this study.

You are now being asked to participate in another part of this study. This part of the study involves wearing an activity monitor for 7 days. The 7 days begin when you wake up tomorrow morning.

About 125 adults and 125 children from your community will participate in this part of the study. The adults and children who participate in this part of the study also agreed to participate in the Youth and Adult Biometric Study.

The activity monitor (called an Actigraph GT3XE accelerometer) is a small, lightweight device worn on a belt around the waist. This monitor will not get in the way of your normal everyday activities. It should only be worn during waking hours, and it should be removed before swimming or bathing. The activity monitor is about the size of a small pager or cell phone.

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

The activity monitor part of this study will take about 30 minutes. This time includes getting instructions about wearing the monitor. It also includes the time it will take you to keep a diary that records the time you wake up and the time you go to bed each day. You will also record the time and reason for taking off the activity monitor for 5 minutes or more for any activity like swimming or showering. And it includes the time it will take for you to mail the activity monitor back to RTI.

Adults who participate in the activity monitor part of this study can receive a $20 gift card if the data are complete. Adults will receive the gift card after the activity monitor is mailed back to RTI. When RTI receives the data you provide, if there is not at least 5 days of complete data, adults will receive a $10.00 gift card and will be asked to wear the activity monitor for another 7 days. You may refuse to wear the activity monitor again if you choose. If you wear the activity monitor for another 7 days you will receive an additional $10.00 gift card. You will not be asked to wear the activity monitor for a third week even if your data are incomplete.

If you agree to take part in the activity monitor piece of this study, we will contact you 3 to 4 days after your home visit to make sure you are not having problems with the monitor. We will also contact you after 7 days to answer any questions about how to send the monitor to RTI via the US Postal Service.

Enhanced Protocol: Consent to Participate in Research (Adults Only)

Signing your name (or making your mark) below means that you have read (or someone read you) all of this form. It also means that you got answers to all your questions and that you have freely decided to take part in this study. By agreeing to take part in this study, you are not giving up any of your legal rights.

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Date Signature (or Mark) of Participant

_____

Printed Name of Participant

If the participant 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 consent form was read to the person named above. This person was given a chance to ask questions about being in this study and I believe that he/she has agreed to take part in it.

_____ _____

Date Signature of Witness

_____

Printed Name of Witness

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
