

INFORMED CONSENT FORM FOR PARENTS OR GUARDIANS

Dear Parent or Guardian:

Your child's school is involved in a longitudinal research study called *The NEXT Generation Health Study (NEXT)* and it is funded by the National Institute of Child Health and Human Development (NICHD), the National Heart, Lung and Blood Institute (NHLBI), and the National Institute on Alcohol Abuse and Addiction (NIAAA), three of the National Institutes of Health, as well as the Health Resources and Services Administration (HRSA). Only students in 10th grade during the 2009-10 school year can be in *NEXT*. We would like your child (in 10th grade) to help us by taking part in this important study. This form explains why the research study is needed, what information we will collect during the study, how the information will be used, how the information will be protected, and what your child will receive for participating. Please read this form carefully and ask any questions that you have before you decide about letting your son or daughter be in the study. If you give permission for your child to be in the study, you will be given a copy of this form to keep.

WHAT IS THE TITLE OF THE STUDY?

The NEXT Generation Health Study (NEXT)

WHAT IS THE PURPOSE OF THE STUDY?

Sometimes teenagers develop unhealthy habits that may be related to having heart disease or other health problems later in life. Changes in their physical activity, eating habits, and sleep may contribute to teens becoming overweight. For example, teenagers, especially girls, tend to reduce the amount of exercise they get during this period. Because teens have more control over their diets, they may eat more of the types of food that are not good for them, like fast foods or unhealthy snacks. They also spend more time away from their families and with their friends, who could influence their health behaviors in either good or bad ways.

The period from early high school through the first year after high school is also important for adolescent drug and alcohol use. Problem drinking usually begins during these years (ages 15 to 18) and increases in ages 18 to 20. The year after high school is particularly important, because students often increase their alcohol use and increase problem drinking as they start working or enter their first year of college.

Motor vehicle crashes are the leading cause of injury and death among adolescents. Crash rates are higher among adolescents than among older drivers. Crash rates particularly increase during the first year they start driving, but remain high into the twenties. The major causes of crashes among young drivers include inexperience and driver error, risk taking, and distraction.

The *NEXT Generation Health Study* is designed to learn more about these important health issues for adolescents. We will ask your child questions about his or her eating, physical activity, and alcohol, tobacco, and drug use, as well as about relationships with their family and friends, and their driving behavior. What we

learn from this study will provide necessary information to improve health services and to create prevention programs that actually work for teenagers.

The main purposes of *NEXT* are:

1. To learn more about the changes in heart disease-related risk factors and behaviors in older adolescents as they become independent young adults; what causes obesity and what contributes to the risk for heart disease.
2. To understand when and why drug or alcohol use in students begins (or stops) during or after high school; what predicts that a student will be a problem drinker during the year after high school; and how families or friends influence students' drinking or drug use.
3. To learn more about teen risky driving behavior and whether their views about driving and their driving behavior change as they get older.
4. To better understand how a network of friends may influence a student's positive or negative health behaviors.
5. To learn more about teenagers' genetic predisposition to heart disease or substance use. Everyone's genes are a little different. If we can learn more about these differences we might learn how to prevent and treat certain diseases better.

We will learn about these things by asking students to complete the activities described below.

WHAT IS INVOLVED?

Your son or daughter will be asked to complete the following activities during the spring semester of his or her 10th grade year, the spring semesters of 11th and 12th grades, and the spring of the year after leaving high school.

In 10th grade students involved in the study will:

1. Fill out a 45-50 minute survey at their school about their diet, physical activity, substance use, and friends.
2. Have their height, weight, and waist circumference measured at their school.
3. Have a saliva sample collected at their school.

In 11th grade students involved in the study will:

4. Fill out a survey on-line or by phone about their diet, physical activity, substance use, and friends.
5. Have their height, weight, and waist circumference measured at their school. If they are no longer at the same school, they do not have to be measured.

In 12th grade students involved in the study will:

6. Fill out a survey on-line or by phone about their diet, physical activity, substance use, and friends.
7. Have their height, weight, and waist circumference measured at their school. If they are no longer at the same school, they do not have to be measured.

In the year after high school students involved in the study will:

8. Fill out a survey on line or by phone about their diet, physical activity, substance use, and friends.
9. NO height, weight, or waist circumference measurements will be collected.

HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

About 2,700 10th grade students in 80 schools from across the United States will be in the study.

HOW LONG WILL WE BE PART OF THE STUDY?

We will collect information from your child four times: in 10th grade, 11th grade, 12th grade, and the year after high school.

REASONS WHY YOUR CHILD MAY NOT BE ALLOWED TO BE INVOLVED:

Your child will not take part in the study if he or she has:

- No signed informed consent from parent(s) (this form),
- No informed assent from the student (the attached form),
- If he or she cannot read and understand the questions on the survey, which will be written in English, or
- Developmental limitations that affect your child's ability to understand or provide age appropriate responses to the questions.

EXPECTED RISKS AND DISCOMFORTS:

We will ask questions that deal with sensitive health issues, such as what is the student's weight and whether he or she smokes or drinks alcohol. Some students may not feel at ease answering these types of questions. However, most questions on the survey are not highly sensitive and those that are somewhat sensitive are commonly included in many US surveys. The staff involved in this study is trained to help limit the amount of discomfort caused by these questions.

Also, students may not feel at ease with someone measuring their weight, height, and waist circumference. A student can refuse to participate in any of the assessments. These measurements will be conducted in private by trained and certified survey staff.

The only potential risk to students participating in NEXT is a breach of confidentiality. The survey and measurements are confidential; student responses and measurements are identified only by a numeric ID. The only link between student information and their names is kept in a separate, password protected (tracking) database at the home office. This information is needed so we may contact students during the study. A Certificate of Confidentiality has been obtained to assure that individual student information can never be accessed by parents or school personnel. This Certificate is issued to the study by the National Institutes of Health to protect the privacy of research subjects. The researchers never have to release any "identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, State, or local level" (OER NIH Website, 2008).

In addition, methods we will use to protect your child’s privacy and confidentiality are to provide very careful and thorough training of the data collectors, and to monitor their performance closely. All Survey staff sign confidentiality pledges, stating they will not share information with unauthorized persons. Other than this informed consent form, none of the questionnaires, interview records, or other paper records kept for this study will show your name or your child’s name or other identifying information like a social security number or home address. Your child’s study ID code number will be put on all of these items rather than his or her name. All study data will be sent by the data collectors by overnight delivery to the home office data entry staff right after it is collected and then entered or scanned into a password-protected computerized data file and stored for analysis. The hard copies will be stored in locked areas and only authorized staff will have access to the computer files. If any of these items are lost, it will not be possible for anyone who finds them to identify your child. Copies of informed consent forms and families' contact information will be sent to our office and stored separately from the other study data, which will not contain names or other identifying information.

WHAT ARE THE POSSIBLE BENEFITS FOR BEING IN THE STUDY?

The results of *NEXT* will advance our knowledge of the risk of obesity, heart disease, and substance use of older adolescents and young adults. This information can be used to improve health services and create prevention programs to help older adolescents and young adults, as well as set national priorities for school and youth programs. Youth may benefit from the diagnostic aspects of the no-risk in-school height, weight, and waist circumference measurements.

WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?

It is highly unlikely that your child will be injured by being in this study. In the unlikely event that an injury occurs during the measurement, we will follow routine school procedures. If an injury should occur, you will not be paid for the injury and neither The CDM Group nor the sponsors of the survey, NICHD, NHLBI, NIAAA, or HRSA, will pay for treatment.

WHAT WILL MY SON OR DAUGHTER RECEIVE FOR BEING IN THE STUDY?

Your son or daughter will receive the following for completing the survey and the physical measurements:

Year of Participation	Completing Survey	Completing Weight, Height, and Waist Circumference Measurements	Providing a Saliva Sample	Total by Year
10 th grade	\$ 10 gift card	\$25 gift card	\$20 gift card	\$55 value
11 th grade	\$25 gift card	\$25 gift card		\$40 value
12 th grade	\$30 gift card	\$25 gift card		\$45 value
After high school	\$40 gift card	No measurement conducted		\$25 value
Overall Total	\$105 value	\$75 value	\$20 value	\$200 value

It is very important that we are able to contact your child each year to complete the survey and measurements. We will ask each student to update his or her contact

information on our website every three months so we do not lose touch with anyone. All students who update or confirm their contact information will be entered in a lottery drawing to win prizes. There will be nine total lottery drawings. Of the students who update their information, ten students will be randomly selected (by chance) each time to win a prize valued at \$250. The students will be able to select from a menu of gifts items such as a gift card to their favorite store, a pre-paid Visa Card, an IPOD, or movie gift certificates.

IS THIS STUDY VOLUNTARY?

Whether your son or daughter takes part in the study is your choice. Also, your son or daughter may choose not to take part in any or all of the measures at any time or for any reason. If after giving your consent, you decide to withdraw your son or daughter from the study, this will not hurt your or your child's future relations with your son's or daughter's school.

IS THIS STUDY CONFIDENTIAL?

During the study, all of your son's or daughter's data, including address and phone number, will be kept private and will not be shared with others outside the *NEXT* study. All data will be stored safely in locked files. An ID number will be assigned to each child at the start of the study and this number will be used for record keeping and data analysis. Please note that we are required to inform you, in writing, if your son's or daughter's height or body weight falls below the growth standards for boys or girls their age. For these reasons, it is very important that you provide your mailing address, email address (if applicable) and phone number(s) on the last page of the consent form. After the study is completed, the data will be available to other researchers. However, we will never share any information that could be linked to your son or daughter. His or her name will never appear in any reports or published papers.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

You may ask questions about the study or anything you do not understand. If you do not have questions now, you may ask later. During the study, you will be told any new facts that could affect whether you want your child to stay in the study. For more information about the research, you may contact Mary Ann D'Elio, *NEXT* Project Director, at toll-free 1-866-864-9972 or NEXT@cdmgroup.com; or Dr. Ronald J. Iannotti, Principal Investigator, at 301-435-6951 or iannottr@mail.nih.gov.

Please complete the following:

If you sign your name below, that means that you have read this consent form and have had a chance to ask any questions. Also, your son's or daughter's signature on the attached *Child Assent Form* means that he or she has agreed to take part in *NEXT*. If you agree to allow your son or daughter to be involved, you may change your mind and withdraw your consent at any time. As mentioned before, your son or daughter should not take part if he or she cannot read and understand the questions on the survey, which will be written in English.

Please mark ONE of the choices below:

- Yes**, I do consent to have my son/daughter take part in **ALL** aspects of the study.
- Yes**, I do consent to have my son/daughter take part in **ONLY** the survey and the measurement of height, weight, and waist circumference.
- Yes**, I do consent to have my son/daughter take part in **the survey only**.
- No**, I do not consent to have my son/daughter take part in *NEXT*.

Name of child

Last Name																						
-----------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

First Name																						
------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Child Date of Birth: _____ / _____ / _____
Month Day Year

My child is a _____ boy _____ girl.

Name of parent/guardian

Last Name																						
-----------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

First Name																						
------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Parent/Guardian Signature

Date

If you selected "Yes", please complete the information on the attached form, place this form in the envelope provided, and seal the envelope. Ask your child to return the sealed envelope along with the signed consent form to his or her classroom. We have given clear instructions to your child's school that this sealed envelope should not be opened by any of the school staff; only by the data management staff in the NEXT project office.

ID: _[preprinted]__

- 1.** Will your child be able to read and understand questions written in English?
 Yes No

- 2.** Are you employed?
 Yes No (if no, skip to question 3).

a. Where do you work, for example, at a hospital, bank, or restaurant?

b. Please write down exactly what job you do there (for example, are you a teacher, bus driver, or doctor, etc).

- 3.** What is the highest grade of regular school you have completed?

1. Less than high school diploma
2. High school diploma
3. GED
4. Some college or technical school
5. Associate's degree
6. Bachelor's degree
7. Graduate degree

- 4.** Does another parent or guardian for your child live in your household?

Yes No (if no, skip to question 7).

*

- 5.** Is he or she employed?

Yes No (if no, skip to question 6).

a. Where does he or she work, for example, at a hospital, bank, restaurant)?

b. Please write down exactly what job he/she does there (for example: teacher, bus driver, doctor).

6. What is the highest grade of regular school he or she has completed?

1. Less than high school diploma
2. High school diploma
3. GED
4. Some college or technical school
5. Associate's degree
6. Bachelor's degree
7. Graduate degree

7. Is there a parent or guardian for your child who does NOT live in your household but contributes to your child's well-being?

Yes No (if no, skip to question 10).

8. Is he or she employed?

Yes No (if no, skip to question 9).

a. Where does he or she work, for example, at a hospital, bank, restaurant)?

b. Please write down exactly what job he or she does there (for example: teacher, bus driver, doctor).

9. What is the highest grade of regular school he or she has completed?

1. Less than high school diploma
2. High school diploma
3. GED
4. Some college or technical school
5. Associate's degree
6. Bachelor's degree
7. Graduate degree

10. What is the current address of your child? **NOTE: We will NOT share your child's address, phone number, or email with anyone outside of the NEXT study.**

Street Address _____ Apt #

City _____ State _____ Zipcode _____

Home telephone: _____

Cell phone: _____

Email: _____

11. What is your current address? **NOTE: We will NOT share your address, phone number, or email with anyone outside of the NEXT study.**

Street Address _____ Apt # _____

City _____ State _____ Zipcode _____
Home telephone: _____
Cell phone: _____
Email: _____

12. Who might know where you are should you move from your current address? Please provide contact information for two people who are not living with you now who are most likely to know how we can get in touch with you should you move from your current address? **NOTE: We will NOT share the contact person's address, phone number, or email with anyone outside of the NEXT study.**

13. Alternate contact person 1:

Name: (please print) _____
Street Address _____ Apt # _____

City _____ State _____ Zipcode _____
Home telephone: _____
Cell phone: _____
Email: _____
Relationship to you (example: sister, father, friend) _____

14. Alternate contact person 2:

Name: (please print) _____
Street Address _____ Apt # _____

City _____ State _____ Zipcode _____
Home telephone: _____
Cell phone: _____
Email: _____
Relationship to you (example: sister, father, friend) _____

Thank you for providing this information. Please place this form in the envelope provided and seal the envelope. Ask your child to return the envelope to his or her classroom. We have given clear instructions to your child's school that this envelope

should not be opened by any of the school staff; only by the data management staff in the NEXT project office.