

## **NEXT PLUS INFORMED CONSENT FORM FOR PARENTS OR GUARDIANS**

### ***Dear Parent or Guardian:***

Your child is participating in a research study called the *NEXT Generation Health Study* (NEXT) and it is funded by the National Institute of Child Health and Human Development (NICHD) and the National Heart, Lung and Blood Institute (NHLBI), two of the National Institutes of Health. We would like your child to be one of 750 students randomly selected from the 2,700 students participating in NEXT to also participate in a smaller “substudy” called *NEXT Plus*. *NEXT Plus* is designed to learn even more about the factors associated with heart disease. This form explains why *NEXT Plus* 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 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?**

*NEXT Generation Health Study Plus (NEXT Plus)*

### **WHAT IS THE PURPOSE OF THE STUDY?**

As we explained for NEXT, sometimes teenagers develop unhealthy habits that may be related to having heart disease and 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 unhealthful 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.

NEXT will help us learn lots of important things about risk factors for heart disease. Yet there are limits to what can be learned in a survey conducted one time each year. *NEXT Plus* is designed to learn much more about these important health issues. We will ask your child to report what he or she eats on three days each year so we know exactly what and how much he or she is eating each day and how much of that food is made up of fat or sugar or protein. We will ask your child to wear small monitors which will show your child’s physical activity and sleep for a week, and check his or her blood pressure. Also, using a simple blood test (collected by a finger prick), we will check for things that may show a risk for heart disease, like cholesterol and blood sugar levels. What we learn from *NEXT Plus* (along with what we learn from NEXT) will provide important information to improve health services and to create prevention programs that actually work for teenagers.

The main goals of *NEXT Plus* are:

1. To learn more about whether teenagers’ diets meet the guidelines for a heart-healthy diet and how diet influences their risk for heart disease.
2. To understand what things influence whether a teenager is overweight or not.

3. To learn more about how physical activity and sleep increase or decrease as teenagers become young adults and how their physical activity and sleep influence their risk for heart disease.
4. To understand how biological markers, such as cholesterol and blood sugar levels, change with physical activity and diet and how they influence teenagers' risk for heart disease.

### **WHAT IS INVOLVED?**

A trained health researcher will come to your home, at your convenience, to complete two sets of activities with your child. First, the health researcher will show your child how to do the following:

1. Complete an on-line dietary questionnaire listing all that he or she eats or drinks for three days.
2. Wear a small activity monitor all day for seven days in a row. The activity monitor will measure your child's physical activity levels.
3. Wear a watch on his or her wrist that measures physical activity and sleep patterns for seven days in a row.
4. Fill out a survey for seven days to report what activities he or she did during the time the activity monitor and sleep watch were worn.

Second, the health researcher will work with your child to do the following:

1. Measure his or her height, weight, and waist circumference.
2. Take his or her blood pressure.
3. Have your child arrive at school on a specified day without eating breakfast so the health researcher can collect a small amount of blood from his or her finger after it is pricked to test for the biological markers listed below. These markers are important measures of risk for obesity, diabetes, and heart disease. Your child will then be given breakfast.
  - a. Fasting blood glucose.
  - b. HbA1c.
  - c. Total cholesterol
  - d. Triglycerides
  - e. LDL-C, HDL
  - f. C-reactive protein
  - g. Uric acid
  - h. Cotinine
4. Complete a brief survey asking about the prescription or over-the-counter medicines he or she takes on a regular basis and details about the neighborhood where you live.

The following is a schedule of when the above activities will occur:

During *10<sup>th</sup> grade and the year after high school*, students involved in *NEXT Plus* will:

1. Complete an on-line dietary survey for three days listing what they have eaten each day.
2. Have height, weight, waist circumference measured and blood pressure taken, provide a small amount of blood from a finger stick before eating breakfast, and complete a brief survey asking about the prescription or over-the-

- counter medicines he or she takes on a regular basis and details about the neighborhood where you live.
3. Wear a small activity monitor and sleep watch for seven days to measure physical activity and sleep.
  4. Complete a brief diary each day to report on physical activity.

During *11<sup>th</sup> and 12<sup>th</sup> grade* students involved in the study will:

1. Complete an on-line dietary survey for three days listing what has been eaten each day.
2. Wear a small activity monitor and sleep watch for seven days to measure physical activity and sleep.
3. Complete a brief diary each day to report on physical activity.

### **WILL PARENTS BE ASKED TO DO ANYTHING?**

Parents or guardians will be asked to agree to a home visit and to answer a short survey about your child's health. If any of your child's test results are outside of normal values we will alert you promptly and recommend that you discuss the results with your health care provider. 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.

### **HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?**

About 750 10<sup>th</sup> grade students from 54 schools from across the United States will be in the study.

### **HOW LONG WILL WE BE PART OF THE STUDY?**

Just as in NEXT, we will collect information from your child four times: in 10<sup>th</sup> grade, 11<sup>th</sup> grade, 12<sup>th</sup> grade, and the year after high school.

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

Your child cannot 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,
- Developmental limitations that affect your child's ability to understand or provide age appropriate responses to the questions, or
- A blood condition that will not let them stop bleeding after the fingerstick.

### **EXPECTED RISKS AND DISCOMFORTS:**

Some students may not feel at ease with someone measuring their weight, height, and waist circumference or taking their blood pressure. The activity monitor will be attached to an elastic belt and worn around the waist over your child's clothing. The small size of the activity monitor makes it highly unlikely that your child will feel any discomfort when wearing it. The sleep watches will be worn around the wrist like a regular watch and should not cause any discomfort. Blood samples will be taken by finger-stick. This will require enough blood for the tests listed above. It may sometimes be necessary to do a second finger-stick to get enough blood. It is usually possible to get enough blood with one stick. Some teenagers find giving a blood sample to be unpleasant, as it carries the risk of brief pain, stinging, and

bruising, and a very slight risk of infection. We carefully clean the finger and wear sterile gloves to prevent the risk of infection. A student can refuse to participate in any of the assessments. These assessments will be conducted by trained health researchers.

Another potential risk to students participating in NEXT *Plus* is a breach of confidentiality. This risk is minimized because all information is kept confidential.

### **YOU SAY THIS STUDY IS CONFIDENTIAL. HOW DO YOU PROTECT MY CHILD'S PRIVACY?**

Responses, measurements, and blood test results 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, 2009).

All of the procedures we use to protect confidentiality have been used with great success in previous studies of children and adults. For example, one method we use to protect your child's privacy and confidentiality is to provide very careful and thorough training of the health researchers, and to monitor their performance closely. All our staff sign confidentiality pledges, stating they will not share information with unauthorized persons. Other than this NEXT *Plus* 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 home address. Only your child's study ID code number will be put on all of these items rather than his or her name. All study data (without your child's name) will be sent by the health researchers by overnight delivery to the home office data entry staff right after it is collected and then entered 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. You or your teen will send the activity monitor and sleep watch via overnight delivery in a self-addressed, prepaid Federal Express envelope to the home office where all data from the activity and sleep monitor will be downloaded into a secured data base. All lab results will be entered into a secured data base. All dietary recall data will be uploaded to a secured data base. If any of these items are lost, it will not be possible for anyone who finds them to identify your child. None of these databases will contain names or other identifying information. A copy of this informed consent form and your family's contact information will be sent to our office separately and stored separately from the other study data.

After the study is completed, the data without identifying information will be available to other researchers. 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.

### **WHAT ARE THE POSSIBLE BENEFITS FOR BEING IN THE STUDY?**

The results of *NEXT Plus* will advance our knowledge of the risk of obesity and heart disease among 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. In addition, parents and students will receive a copy of the height, weight, waist circumference, blood pressure, and laboratory results.

**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. However, 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 or NHLBI, 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 participating in *NEXT Plus*. This is in addition to the gift cards he or she will receive for participating in *NEXT*.

Year of Participation	Completing dietary recalls for three days	Completing home visit: weight, height, waist circumference and blood draw	Wearing activity monitor and sleep watch for seven days	Completing activity diary for seven days	Total by Year
10 <sup>th</sup> grade	\$30 gift card	\$50 gift card	\$35 gift card	\$35 gift card	\$150 value
11 <sup>th</sup> grade	\$30 gift card	No visit	\$35 gift card	\$35 gift card	\$100 value
12 <sup>th</sup> grade	\$30 gift card	No visit	\$35 gift card	\$35 gift card	\$100 value
After high school	\$30 gift card	\$50 gift card	\$35 gift card	\$35 gift card	\$150 value
Overall Total	\$120 value	\$100 value	\$140 value	\$140 value	\$500 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 month so we do not lose touch with anyone. Students who update or confirm their contact information will receive a free music download for that month.

**IS THIS STUDY VOLUNTARY?**

Whether your son or daughter takes part in *NEXT Plus* is your choice. Also, your child 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 child from the study, this will not hurt your or your child’s future relations with your son’s or daughter’s school.

**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 *Plus* Project Director, at toll-free 866-864-9972 or [NEXT@cdmgroup.com](mailto:NEXT@cdmgroup.com); or Dr. Ronald J. Iannotti, NEXT *Plus* Principal Investigator, at 301-435-6951 or [iannottr@mail.nih.gov](mailto:iannottr@mail.nih.gov).

