**INFORMED CONSENT FORM FOR NEXT CURRENT PARTICIPANTS WHO TURN 18**

***Dear NEXT Participant***

You are currently involved in a four-year research study called *The NEXT Generation Health Study (NEXT)*. Now that you have turned 18, we need your consent for you to continue participating in this study. This form explains why the research study is needed, what information we will collect during the study, how the information will be used and kept private, and what you will receive for participating. Please read this form carefully. This study is paid for by the *Eunice Kennedy* Shriver National Institute of Child Health and Human Development (NICHD), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the Health Resources and Services Administration (HRSA). If you have any questions, e-mail us or call toll-free 866-864-9972. If you give your consent to continue in the study, you can print this page, or request a copy be sent to you by e-mailing [NEXT@cdmgroup.com](mailto:NEXT@cdmgroup.com).

**WHAT IS THE TITLE OF THE STUDY?**

*The NEXT Generation Health Study (NEXT)*

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

Sometimes young adults develop lifestyle habits that may be related health problems later in life. These may include changes in their physical activity, eating and sleep habits, and alcohol and drug use. Motor vehicle crashes are also a concern, because they are the leading cause of injury and death among teens and a high risk among young adults.

The *NEXT Generation Health Study* wants to learn more about these important health issues for teens and young adults. We will continue to ask you questions about your eating, physical activity, romantic relationships, driving, and alcohol, tobacco, and drug use, as well as about your family and friends. What we learn from this study will help improve health services and create programs that actually work for teenagers and young adults.

The main purposes of *NEXT* are:

* To learn more about the changes in heart disease and related behaviors in older teens as they become independent young adults.
* To learn about what influences body size and what makes some young adults at greater risk for heart disease and other health problems.
* To learn more about participants' family history with heart disease.
* To understand when and why drug or alcohol use in teenagers and young adults begins or stops; what could predict that a young adult’s drinking behavior after high school; and how families or friends influence drinking or drug use.
* To learn more about driving behavior and about changes in how young adults drive as they get older.
* To better understand how a group of friends may influence health behaviors.

Everyone is 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 you to do the activities described below.

**WHAT IS INVOLVED?**

You will be asked to fill out the NEXT on-line or written survey about your diet, physical activity, substance use, and friends’ behaviors during the spring of 2014 through 2016.

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

About 2,770 students from 81 schools from across the United States are in the study.

**HOW LONG WILL I BE PART OF THE STUDY?**

We will collect information from you four more times: in 2013, 2014, 2015 and 2016.

**EXPECTED RISKS AND DISCOMFORTS:**

We will ask questions that deal with lifestyle issues, such as what is your weight and whether you smoke or drink alcohol. You may not feel at ease answering these types of questions. However, most questions on the survey are not highly personal and those that are somewhat personal are often included in many US surveys.

Also, you may not feel at ease with someone measuring your weight, height, and waist. These measurements will be conducted in private by trained and certified survey staff. You can refuse to do anything at anytime.

The only possible risk to you is if someone accidently saw your answers or measurements. The survey and measurements are confidential; your answers and measurements are identified only by a number ID. The only link between your information and your name is kept in a separate, password protected database at the home office that we use when we need to contact you during the study. A Certificate of Confidentiality has been received from the United States Department of Health and Human Services (DHHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to give anyone information that may name you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from volunteering to give information about you or your participation in this study. Note however, that if an insurer or employer learns you are participating in NEXT, **and gets your consent to receive research information**, then we may not use the Certificate of Confidentiality to keep this information away from them. This means that you and your family must also protect your own privacy. Finally, you should understand that we will in all cases do what is necessary, including reporting to authorities, to prevent serious harm to yourself or others such as in cases of child abuse or neglect.

We will protect your privacy

* **By carefully training the people who will work with you**. We will watch them carefully to make sure they are doing their job well. All people who work with you sign forms saying they will not share information about your family with any other people.
* **Using an ID code rather than your name on all forms**. Other than this consent form, none of the questionnaires, interview records, or other paper records kept for this study will show your name or other information like a social security number or home address. In the unlikely even any items are lost, it will not be possible for anyone who finds them to identify you.
* **Storing data safely and properly**. All study data will be sent by the people who work with you by overnight delivery to the home office staff right after it is collected for processing. Data are 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 special staff will be able to see the computer files.
* **Copies of informed consent forms and your contact information will be stored separately from the other study data**.

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

The results of NEXT will help us learn more about why older teens and young adults **get heart disease, or develop certain lifestyle behaviors**. This information can be used to improve health services and create programs to help young adults, as well as set national priorities for school and youth programs. You may benefit from the no-risk in-school height, weight, and waist measurements.

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

It is highly unlikely that you 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, NIDA, NIAAA, or HRSA, will pay for treatment.

**WHAT WILL YOU RECEIVE FOR BEING IN THE STUDY?**

You will receive the following for completing the survey and the physical measurements:

|  |  |
| --- | --- |
| **Year of Participation** | **Completing Survey** |
| 2014 | $40 |
| 2015 | $45 |
| 2016 | $50 |
| Overall Total | $135 |

**IS THIS STUDY VOLUNTARY?**

Whether you continue to take part in the study is your choice. Also, you may choose not to take part in any or all of the surveys at any time or for any reason. If after giving your permission, you decide you should not be in the study anymore, this will not hurt your relationship with your school.

**IS THIS STUDY CONFIDENTIAL?**

During the study, all of your information, including your address and phone number, will be kept private and will not be shared with others outside the *NEXT* study. All information will be stored safely in locked files. An ID number was assigned to you 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 height or body weight falls below what is normal for adolescents your 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 you. Your name will never appear in any reports or published papers.

**WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THIS 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 to stay in the study. For more information about the research, you may contact Mary Ann D’Elio, *NEXT* Project Director, at toll-free 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. If you agree to continue to be involved, you may change your mind and withdraw your consent at any time.

**Please complete ONE box below**

🞎 **YES**, I agree to continue to be in the NEXT Generation Health Study.

🞎 **NO**, I do not want to continue to take part in the NEXT Generation Health Study.

**Your name**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Last Name |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | First Name |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Your Date of Birth: \_\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_\_\_ Your gender is \_\_\_\_\_\_male \_\_\_\_\_\_ female.**

**Month Day Year**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Your Signature**  **Date**

\_\_\_\_ I have received a copy of this consent document.