

INFORMED CONSENT FORM (Peer Survey)

Dear NEXT Participant:

You are invited to be involved in a research study called *The NEXT Generation Health Study (NEXT)*. 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 and ask any questions that you have before you decide to participate in the study. This study is paid for by the National Institute of Child Health and Human Development (NICHD), the National Heart, Lung and Blood Institute (NHLBI), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Addiction (NIAAA), four of the National Institutes of Health, as well as the Health Resources and Services Administration (HRSA). We would like you to help us by taking part in this important study. If you decide to participate 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 young adults develop unhealthy 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 ask you questions about your eating, physical activity, driving, romantic relationships, relationships with friends, and alcohol, tobacco, and drug use. 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:

1. To learn more about health behaviors in teens; for example, what causes obesity and what makes them more likely to be at risk for heart disease.
2. To better understand drug or alcohol use in teenagers; and how families or friends influence students' drinking or drug use.
3. To learn more about teen risky driving behavior.
4. To learn more about teenage dating relationships and the presence of abusive behaviors in relationships.
5. To better understand how a group of friends may influence a student's good or bad 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.

WHAT IS INVOLVED?

You will be asked to fill out a 30-40 minute one-time questionnaire, either on-line or a paper copy. The questionnaire will ask about eating habits, physical activity, driving, romantic relationships, and alcohol, tobacco, and drug use, as well as relationships with friends.

HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

About 2,800 teens and young adults from across the United States will complete the questionnaire.

HOW LONG WILL WE BE PART OF THE STUDY?

We will collect information from you one-time (in 2013).

EXPECTED RISKS AND DISCOMFORTS:

We will ask questions that deal with health 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

The only possible risk to you is if someone accidentally saw your answers while completing the questionnaire on the computer or on paper. The questionnaire is confidential; answers 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. This information is needed so we may provide you with the monetary incentive for completing the questionnaire. 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 you tell an insurer or employer that you are participating in NEXT, **and you give your consent for them to receive research information**, then we may not use the Certificate of Confidentiality to keep this information away from them. This means that you 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 work on the study.** We will watch them carefully to make sure they are doing their job well. All people who work on the study sign forms that say they will not share information about your family with any other people.
- **Using an ID number rather than your name on all forms.** Other than this consent form, none of the questionnaires 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.** If you complete the questionnaire online, the data will be uploaded to a secured database. If you complete a paper version of the questionnaire, it will be scanned into a password-protected computerized data file and stored for analysis. The hard copy will be stored in locked areas and only authorized staff will have access to 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 **become obese, get heart disease, or use drugs or alcohol.** 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.

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, you will not be paid for the injury and neither The CDM Group nor the sponsors of the study, NICHD, NHLBI, NIDA, NIAAA, or HRSA, will pay for treatment.

WHAT WILL YOU RECEIVE FOR BEING IN THE STUDY?

You will receive a \$25 gift card for completing the questionnaire.

IS THIS STUDY VOLUNTARY?

Whether you take part in the study is your choice. If after giving your permission, you decide you do not be in the study anymore, you can withdraw your consent at any time.

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 will be assigned to each participant and this number will be used for record keeping and data analysis. 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.

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 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.

