

INFORMED CONSENT FORM FOR PARENTS OR GUARDIANS (Peer Survey)

Dear Parent or Guardian:

Your child has been asked to participate 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, 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. 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 your child to help us by taking part in this important 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 get less exercise during this period. Because teens have more say 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 have an effect on their health behaviors in either good or bad ways.

The teen years are also important for drug and alcohol use. Problem drinking usually begins sometime between ages 15 to 18 and increases in ages 18 to 20.

Motor vehicle crashes are the leading cause of injury and death among teens. Crash rates are higher among teens than among older drivers. The major causes of crashes among young drivers include inexperience and driver error, risk taking, and distraction.

The *NEXT Generation Health Study* wants to learn more about these important health issues for teens. We will ask your teenager questions about his or her eating, physical activity, driving, relationships with friends, including romantic relationships, 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.

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 understand more about 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.

WHAT IS INVOLVED?

Your son or daughter will be asked to fill out a 30-40 minute questionnaire, either on-line or a paper copy. The questionnaire will ask about eating habits, physical activity, driving, experiences with dating 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 YOUR CHILD BE PART OF THE STUDY?

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

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 your child (the attached form),
- If he or she cannot read and understand the questions on the questionnaire, which will be written in English, or
- Your child is not able to understand or provide age appropriate responses to the questions.

EXPECTED RISKS AND DISCOMFORTS:

We will ask questions that deal with health issues, such as what is your child's weight and whether he or she smokes or drinks alcohol. Some teenagers may not feel at ease answering these types of questions. However, most questions on the questionnaire are not highly personal and those that are somewhat personal are often included in many US questionnaire.

The only possible risk to your child is if someone accidentally saw his/her 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 child's information and his/her name is kept in a separate, password protected (tracking) database at the home office. This information is needed so we may provide your child 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 or your child 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 yourself or your child 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, your child or others such as in cases of child abuse or neglect.

In addition, we will protect your child's privacy by carefully training the people who work on the study and 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. No other forms other than this consent form will show your name or your child's name or other information like a social security number or home address. Your child's study ID number will be put on his or her survey rather than his or her name. If your child completes the questionnaire online, the data will be uploaded to a secured database. If your child completes 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. 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 stored separately from the other study data, which will not contain names or other information that could be traced back to your family.

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, engage in risky driving, use drugs or alcohol, and how friendships and romantic relationships influence teen behavior. This information can be used to improve health services and create programs to help older adolescents and 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 your child will be injured by being in this study. In the unlikely event that an injury should occur, 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 MY SON OR DAUGHTER RECEIVE FOR BEING IN THE STUDY?

Your son or daughter will receive a \$25 gift card for completing the questionnaire.

IS THIS STUDY VOLUNTARY?

Whether your son or daughter takes part in the study is your choice. If after giving your permission, you decide to your son or daughter should not be in the study anymore, you can withdraw your consent at any time.

IS THIS STUDY CONFIDENTIAL?

During the study, all of your son's or daughter's information, including 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 child at the start of the study 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 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 866-864-9972 or NEXT@cdmgroup.com; or Dr. Ronald J. Iannotti, Principal Investigator, at 301-435-6951 or iannottr@mail.nih.gov.

