

**Permission for Your Child to be Part of a Study
SMARTOOL STUDY**

Project Title: SMARTool Study

Project Director: Dr. Heather Kane (RTI International)

Study Sponsor: U.S. Department of Health and Human Services

Invitation to be Part of a Study

Your child is invited to participate in a study about programs that teach youth how to have healthy relationships and avoid sexual risks. The [Curriculum Name] program is part of this study at your child's school. Taking part in this study is voluntary. To identify which students are invited to participate, we have requested demographic data for students from the school; these data include student name and/or ID number, date of birth, sex, race/ethnicity, English Language Learner status, and (if available) Individualized Education Plan (IEP) status, GPA, and homeroom teacher. Your child's name and school ID will be removed from any data collected as part of the study.

Please take time to read this entire form and ask questions before deciding whether your child can take part in this study.

What is the study about and why are we doing it?

The purpose of the study is to evaluate programs that teach youth how to have healthy relationships and avoid sexual risks.

What will my child be asked to do in the study?

If you agree that your child can participate in the study, your child will be asked to take part in the [Curriculum Name] program and complete two surveys to help us evaluate the impact of the program. Survey questions ask about things like romantic relationships, feelings about marriage and sex, sexual behavior, and contraception. The surveys also ask about tobacco, alcohol, and other drug use. Youth do not have to be sexually active to be in the study. Your child would spend approximately 30-40 minutes completing each survey during school in the fall 2019. A member of the study team may also visit your child's class to observe the teacher's instruction and take notes. Your child will not be asked to do anything outside of normal class activities during the observation. Your child's survey responses will be linked to demographic information provided by the school, such as gender, race/ethnicity, and GPA.

What are the benefits of this study?

Benefits of the study include helping communities better serve youth and their families by understanding how programs like this are helpful to youth. In the [Curriculum Name] program, your child will also learn more about healthy relationships and how to avoid sexual risks. About 2,400 youth from 14 schools from across the country are participating.

What risks might result from being in this study?

The study team takes steps to reduce the chance that your child will experience unintended problems because of the study. Even so, it is possible that some youth may feel embarrassed or upset by some of the questions. We will tell youth to reach out to a trusted adult if they want to talk about their feelings after taking the survey. They will also get a list of hotline numbers they can call. RTI will work with the school to identify a point person (e.g., counselor, social worker, etc.) at the school who students can be directly referred to if they need to talk to someone.

How will we protect your child's information?

We will keep all information collected about your child **confidential**. We will not share information collected about your child with your child's teachers, you, or anyone else outside the study team. We will use study identification numbers instead of youth names to track your child's survey responses in the final dataset. We will also store and transmit your child's survey responses separately from any forms or data that list your child's name (for example, attendance logs or assent forms). Your child's survey responses will be stored and handled on secure servers that only the study team can access. No audio or video recordings of your child will be taken during the study.

Before you agree to give permission for your child to be in this study, it is important that you know that there is an exception to our promise of confidentiality. We may share your child's information with appropriate personnel or authorities if we learn that someone's life or health could be in danger, or that someone is being abused or neglected. However, we are not seeking this type of information and youth will not be asked questions about these issues.

What will happen to the information we collect about your child after the study is over?

Your child's name will be deleted from the data collected as part of the project. We may share your child's data with other investigators without asking for your permission again, but it will not contain information that could directly identify your child. We may also share the data with the U.S. Department of Health and Human Services (HHS). We will keep your child's survey response data for three years after the project ends and will then destroy the data in accordance with HHS regulations. We will destroy our copies of your child's demographic school records when the project ends.

What other choices does my child have if they don't take part in this study?

Your child's school will provide an alternative activity if you do not agree for your child to participate in the study.

Your Child's Participation in this Study is Voluntary

It is totally up to you to decide whether your child can be part of the study. Participating in this study is voluntary. Even if you decide your child can be part of the study now, you may change your mind and withdraw your child from the study at any time. Your child can choose not to take part in the survey or to skip any questions in the survey. They can also quit at any time. Your child can continue to be in the [Curriculum Name] program even if they do not want to fill out the surveys. If your child does not participate, it will not affect his/her grades or anything else at school. You may withdraw your permission at any time by contacting the school Principal, and your child's responses will be removed from the data if you or your child withdraw from the study. Your child will not be penalized or lose any benefits to which he/she is otherwise entitled if your child does not participate in the study. You may also review the blank questionnaires in the Principal's office at any time.

Contact Information for the Study Team and Questions about the Study

If you have questions about this study, please contact Dr. Heather Kane, toll-free at 1-800-334-8571 ext. 26738, or by email at hkane@rti.org.

Parent or Legally Authorized Representative Permission

Please read the information below and check one box. A legal parent/guardian must sign and return this form **within 3 days or with other start-of-school paperwork** so that your child may take part in the study. Make sure you understand what the study is about before you sign. Please keep the top portion of this letter. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

[PLEASE PRINT] Child's Name: _____ Grade: _____

I have read this form and understand what the study is about and my questions so far have been answered.

- I **GIVE** PERMISSION for my child to take part in the [**[Curriculum Name]** program and // **SMARTool study**]
- I **DO NOT GIVE** PERMISSION for my child to take part in the [**[Curriculum Name]** program and // **SMARTool study**]

[PLEASE PRINT] Legal Parent/Guardian name: _____

Legal Parent/Guardian signature: _____

Date: _____

Phone number: _____

