

Assent to be Part of a 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

You are 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 school. Taking part in this study is voluntary. The study team identified you from a list of eligible students obtained from your school. Your 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 you will 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 I be asked to do in the study?

If you agree to participate in the study, you will be asked to take part in the [Curriculum Name] program and complete two surveys to help us find out how the programs are helping youth. We are not evaluating you, and the surveys are not a test. 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. You would spend about 30-40 minutes completing each survey during school in the fall 2019. You would take one survey now, and the other survey about one or two weeks from now. A member of the study team may also visit your class to observe the teacher's instruction and take notes. You will not be asked to do anything outside of normal class activities during the observation. Your survey responses will be linked to demographic information provided by the school, such as your 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, you may 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 you 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 encourage you to reach out to a trusted adult if you want to talk about your feelings after taking the survey. You will also get a list of hotline numbers you can call. RTI will work with the school to identify a point person (e.g., counselor, social worker, etc.) at the school who you can speak with if you need to talk to someone.

How will we protect your information?

We will keep all information collected about you **confidential**. We will not share information collected about you with your teachers, parents, or anyone else outside the study team. There is an exception to our promise of confidentiality that we want to make sure you understand before you agree to participate in the study. The exception is that if you tell us that someone's life or health could be in danger, or that you or another child is being hurt or not taken care of. If that happens, we may tell someone whose job it is to keep you or others safe. We will use study identification numbers instead of youth names to track your survey responses in the final dataset. We will also store and transmit your survey responses separately

from any forms or data that list your name (for example, attendance logs or assent forms). Your survey responses will be stored and handled on secure servers that only the study team can access. No audio or video recordings of you will be taken during the study.

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

Your name will be deleted from the data collected as part of the project. We may share your study data with other investigators without asking for your permission again, but it will not contain information that could directly identify you. We may also share the data with the U.S. Department of Health and Human Services (HHS). We will keep your 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 the eligibility list when the project ends.

What other choices do I have if I don't take part in this study?

Your school will provide an alternative activity if you do not agree to participate in the study.

Your Participation in this Study is Voluntary

Your parent has signed a permission form saying it is okay for you to take part in the study. It is totally up to you to decide whether you will be part of the study. Participating in this study is voluntary. You will **not** be in trouble if you choose not to participate. Even if you decide to be part of the study now, you may change your mind and withdraw from the study at any time. You can choose not to take part in the survey or to skip any questions in the survey. You can also quit at any time. You can continue to be in the [Curriculum Name] program even if you do not want to fill out the surveys. If you do not participate, it will not affect your grades or anything else at school. You can withdraw yourself from the study at any time by telling your parent, teacher, or the survey helper, and you will not be in trouble for withdrawing. If you withdraw, we will remove your responses from the data for the study.

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.

Your Permission

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Printed Participant Name

Signature

Date
