



Parent/Guardian Permission Form for Young Women's Participation in the Teen Health Empowerment Study Safer Sex Intervention

We would like your daughter to take part in an important study. The study will find out how health care providers and communities can help young women like your daughter make healthy decisions and avoid risky behaviors. This form gives information about the study. At the end of the form, you can tell us whether or not you would like your daughter to take part in the study. **It is really important that you read and return this form.**

What is the study about? The goal of the study is to find out if a program called the Safer Sex Intervention does a good job helping young women like your daughter understand the risks of unprotected sex, learn how to avoid risks, and make healthy choices about having sex. In the program, young women meet one-on-one with a highly trained health educator who can give them medically accurate information and work with them on ways to keep themselves safe and healthy.

Will all young women in the study get the Safer Sex program? No. **Some** of the young women whose parents/guardians give consent and who agree to be in the study will get the program and **some will not**. Who gets the program is decided by chance, like flipping a coin. If your daughter is not selected for the program, she will receive the usual care or services offered by the provider.

Who is doing the study? The study is being run by a company named Abt Associates. Abt has been doing research for more than 45 years and is well-known for its work in finding out what programs help people live healthy lives. Abt is partnering with Decision Information Research (DIR) and CiviCore as the study team. The study is paid for by the US Department of Health and Human Services (HHS).

What will my daughter be asked to do if she takes part in the study? The study lasts for 18 months. If you agree that your daughter can be in the study, she will be asked to complete three

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-XXXX. The time required to complete this information collection is estimated to average 5 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.

on-line surveys. For each survey, she will be asked some questions, and the questions will take about 30 minutes to answer. Each time she finishes a survey, she will get a gift card worth \$25. So, over the 18 months, she can get \$75 in gift cards.

The first survey will be completed on a computer at the health clinic or health center. For the second and third surveys, the study team will send your daughter a link to the survey website, so that she can take the survey in a private place that she chooses, like at home or at the library. As part of the study, your daughter may also be invited to join a small group of young women to talk about her experiences in the study.

What kinds of questions do the surveys ask? The surveys will have questions about your daughter's experiences in school and community activities, about your family, and about sexual activity. Your daughter will only be asked questions about things she has already done; the computer will skip questions if they do not apply to her.

How will you contact my daughter about the surveys? When you give consent and she agrees to be in the study, the health educator will ask her for her name and contact information. They will also ask her how she would like to be contacted. When she takes the first survey, she can also give us the names and contact information of relatives or friends who can help us contact her if she moves. The study team will keep in touch with her to update her contact information and to remind her of upcoming surveys. We may invite her to join the Teen Health Empowerment Study page on Facebook. If she does so, other study participants may see that she is also a study participant. She doesn't have to join the Facebook page – it is her choice.

What are the potential benefits and risks if I agree to allow my daughter to be in the study? There are no direct benefits to you or your daughter. However, your daughter's participation will help us learn more about effective ways to prevent teen pregnancy. There is very little risk for your daughter to participate in this study. She may feel uncomfortable answering some personal questions on the survey. **She can decide not to answer survey questions. She can decide to stop being in the study at any time.**

Your daughter does not have to be in the study to receive health care or other services at the clinic or provider setting. If you decide not to have her take part in the study or if she decides to leave the study it is OK. Saying no to the study or leaving the study will not negatively affect you or your daughter, or hurt your or her relationship to the clinic or service provider.

Privacy. We will keep your daughter's answers to the survey private, as much as the law allows us to. Only the health educator, the people doing the study at the Knox County Health Department, and the research team at Abt will know her name and contact information. Only the researchers at Abt and their partners doing the study can see her answers to the survey. We keep all personal information like her name and contact information separate from her survey answers.

We train all the people who work on the study to follow strict rules to protect your daughter's confidentiality. Family members, including parents and legal guardians, will **not** see her survey answers or get information with her name attached. There is little risk of her survey answers and personal information being seen by people who don't have permission, but we have many safety measures in place to prevent this from happening.

The researchers doing this study will never identify people in the study or people at the clinic or provider setting in their reports. When we write a report, the information your daughter gives us will be combined and reported with information from all the people in the study. We will share the survey data – that means all the answers from all the surveys – with the funder, authorized researchers, and the program. But we will exclude names and contact information, so no one can tell what your daughter's survey answers are.

To further help protect the research, we have a special certificate from the U.S. Department of Health and Human Services. This certificate adds special protection for the information that identifies her, like her name, address, or phone number. It says that we do not have to tell anyone who she is. It says that we do not have to tell anyone that she is in the study. Even if a judge asks us to, we can say no. The only time that we may have to tell someone is if we find out that your daughter or someone else could be hurt or in danger.

We will do everything we can to protect your daughter's privacy. But it is important that you and she protect her privacy too. If she wants other people to learn about her participation in the study and she asks us to share her information, we will do that – **but only if she asks**.

Can my daughter be in the program but not be in the study? It is possible for her to be in the program but not the study. At the end of this form, you can agree that your daughter can be in the study and have the chance to receive the Safer Sex Intervention or you can decide not to allow her to be in the study but agree that she can have the chance to receive the Safer Sex Intervention. In either case, whether she receives the program will be decided by chance.

If you have any questions about the study, please contact Meredith Kelsey, Abt Associates Study Director, at 617-520-2422 (toll call). For questions about your rights or your child's rights in the study, please call Teresa Doksum, at Abt Associates at 877-520-6835 (toll-free call).

Please print her name, print your name, sign your name and write the date on the form below. Please have your daughter sign and date below in the space provided. Please keep one copy of the completed form for your records. Thank you for your cooperation in this important study.

Parent/Guardian Permission/Youth Assent.

Below, you have three options: 1) agree to allow your daughter to participate in the study, with a chance of receiving the program; 2) refuse the study but allow your daughter to have a chance to participate in the program; or 3) refuse the study and any opportunity to receive the program.

Permission to Participate in Study

I have read and understood the description of the study being conducted by Abt Associates/DIR. I understand that the information will be used ONLY for the purpose of the study and will be kept strictly confidential, to the extent provided for by law.

- **Yes, I agree** to allow my daughter to participate in the study and have a chance to receive the program. I allow the researchers conducting this study to collect three surveys from my daughter, and to ask my daughter to update her contact information periodically during the course of the study.
- **No, I do NOT** allow my daughter to participate in the study, **but I do allow** my daughter to have a chance to receive the program. I do not allow researchers conducting this study to collect survey information from my daughter.
- **No, I do NOT** allow my daughter to participate in the study. I **do NOT** allow her to participate in the program.

Print YOUR CHILD'S Name:

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First Last

Print YOUR Name:

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First Last

Your Signature: _____ **Date:** _____

YOUTH ASSENT

By signing, I agree to take part in the study described above.