



Teen  
Health  
Empowerment  
Study

## Youth Consent Form for Participation in the Teen Health Empowerment Study Safer Sex Intervention

The Teen Health Empowerment Study will find out how health care providers and communities can help young women like you 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 to participate 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 you 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 Intervention?** No. **Some** of the young women 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 you are not selected for the program, you will still receive care as usual at the health clinic.

**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 working with its research partners Decision Information Research (DIR) and CiviCore. The study is paid for by the US Department of Health and Human Services.

**What will I be asked to do if I am in the study?** The study lasts for 18 months. In that time, **everyone** who agrees to be in the study will be asked to take three online surveys. For each survey, you are asked some questions, and the questions will take about 30 minutes to answer. Each time you finish a survey, you will get a gift card. Over the 18 months, you can get \$75 in gift cards.

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.

The first time you take the survey will be right after you agree to be in the study. You will do it on a computer in the health clinic. For the second and third surveys, the study team will send you a link to the survey website, so you can take the survey in a place that you choose, like at home on your own computer or in a library. As part of the study, you may also be invited to join a small group of young women to talk about your experiences in the study.

**What kinds of questions do the surveys ask?** The surveys will have questions about your experiences in school and community activities. They will have questions about your family. They will also have questions about sexual activity. You will only be asked questions about things you have already done; the computer will skip questions if they do not apply to you.

**How will you contact me about the surveys?** When you agree to be in the study, your health educator will ask you for your name and contact information. They will also ask you how you would like us to contact you. When you take the first survey, you can also give us the names and contact information of relatives or friends who can help us contact you if you move. The people doing the study at Abt and DIR will keep in touch with you to update your contact information and to remind you of upcoming surveys. We may invite you to join the Teen Health Empowerment Study page on Facebook. If you do so, other study participants may see that you are also a study participant. You don't have to join the Facebook page – it is your choice.

**What are the possible benefits and risks if I agree?** There are no direct benefits to you. But you will help us learn more about ways to prevent teen pregnancy. There is very little risk for you to participate in this study. You may feel uncomfortable answering some personal questions on the survey. **You can decide not to answer survey questions. You can decide to stop being in the study at any time.** All your answers to the survey will be kept private. Your name will never be attached to your answers.

You do not have to be in the study in order to receive health care at the clinic. If you decide not to participate or if you decide to leave the study now or in the future, it is OK. Not being in the study or leaving the study will not negatively affect you or hurt your relationship to the clinic.

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

We train all the people who work on the study to follow strict rules to protect your privacy. Your family members, including parents and legal guardians, will not see your survey answers or get information with your name. There is little risk of your 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 in their reports. When we write a report, the information you give 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 survey answers are.

To further protect the research project, we have a special certificate from the U.S. Department of Health and Human Services. It is called a Certificate of Confidentiality. It adds special protection for the information that identifies you, like your name, address, or phone number. It says that we do not have to tell anyone who you are. It says that we do not have to tell anyone that you are 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 you or someone else could be hurt or in danger.

We will do everything we can to protect your privacy and confidentiality. But it is important that you and your family protect your privacy too. If you want other people to learn about your participation in the study and you ask us to share your information, we will do that – **but only if you ask.**

**Can I be in the program but not be in the study?** It is possible for you to be in the program but not the study. At the end of this form, you can agree to be in the study and have the chance to receive the Safer Sex Intervention or you can decide not to be in the study but still agree to have the chance to receive the Safer Sex Intervention. In either case, whether you receive the program will be decided by chance.

**Who should I contact if I have any questions about the study?** 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 in the study, please call Teresa Doksum, at Abt Associates at 877-520-6835 (toll-free call).

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

**Youth Consent. Below, you have three options: 1) agree to be in the study, with a chance to get the program; 2) decide not to be in the study but still have a chance to be in the program; or 3) decide not to be in the study and not to have any chance to get the program.**

**Permission to be in the 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 be in the study and have a chance to get the program. I allow the researchers conducting this study to collect three surveys from me, and to contact me occasionally during the study.
- **No, I do NOT agree** to be in the study, **but I do agree** to have a chance of getting the program. I do not allow researchers conducting this study to collect survey information from me.
- **No, I do NOT agree** to be in the study. I **do NOT** want a chance to get the program.

**Print YOUR Name:**

\_\_\_\_\_

—

First

Last

**Your Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_