

## **Appendix B. Consent Form- Comparison Group Consent for Your Child to Join a Study**

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

### **Your child is invited to join a study.**

This study is about the sexual and reproductive health of young people.

Next Steps: 1<sup>st</sup>: Read the details below. 2<sup>nd</sup>: Ask any questions you have. 3<sup>rd</sup>: Decide if you permit your child to join the study.

### **What is a study? What is this study about?**

A study is a way to learn about a specific part of life. In this research study, we aim to gather generalizable knowledge about the sexual and reproductive health of young people. This study will provide knowledge to the field about the replicability of adolescent pregnancy prevention programs in new populations.

### **What will my child do in the study?**

In the study, your child will complete 3 surveys. Your child's responses will help the study team learn from and about your child. These surveys are not for testing or judging your child. You may view a copy of the survey questions by reaching out to the study team. The study team's contact information is listed on the other side of this paper. The survey questions were made for young people 12 to 16 years of age. We will only share your child's survey answers with the study team. We will not share their answers with you or with anybody else outside of the study team. This way, only your child and the study team will know how they answered the questions.

**Survey Details:** Survey questions are about your child, your family, and your child's behaviors. Some questions are about sexual health. They are about romantic relationships, pregnancy, and sexually transmitted infections. If your child joins the study, they will take 3 surveys. Each takes about 50 minutes to finish, and all 3 surveys are ask the same questions. We are interested in learning how your child's answers change while going through the program. The first survey will be delivered just prior to the beginning of the program, the second survey will be delivered upon completion of the program, and the 3<sup>rd</sup> and final survey will occur 3 months after the completion of the program . Each child will answer their survey on a separate computer or tablet.

### **What are the benefits of this study for my child?**

The surveys will help us learn what youth your child's age think, feel, and do. Your child may like sharing their experiences.

### **What are the risks of this study for my child?**

The surveys ask questions that may make your child feel embarrassed or uneasy. If your child feels this way, we can help them find a trusted adult to talk to about how they feel.

### **How we you protect my child's information?**

We will keep all information we get about and from your child private. Only study team members will see this information. We will not share this information with you or with anybody outside of the study team. The only time this rule will change is if your child tells us someone is in danger. Then we have to tell someone whose job it is to keep your child or others safe.

Surveys will not ask for your child's name or address. We will use special numbers instead of their name to keep your child's identity private. We will do this to keep the survey information private.

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Your child's information will be stored in safe data system that only the study team can access. If we need to share your child's information with each other, we will take extra steps to protect it. These steps will involve using a code for the data and extra passwords only the study team will know.

### **What will happen to my child's information after the study is ends?**

When the study ends, the study team will delete your child's name, birthdate, and address from our records. The rest of their information will be considered "de-identified." This means it cannot be linked to your child. We may use this de-identified information for future analyses and publications. When we use or share your child's de-identified data, it will be combined with other people's data. This also helps to make sure that no one will be able to know your child's answers to the survey questions.

We will also share de-identified data with the U.S. Department of Health and Human Services.

### **Can my child say "no" to joining the study?**

You get to decide if it is okay for your child to join the study. Your child also gets to decide if they want to join the study. Even if you say "yes" now, you may change your mind and have your child stop at any time. Your child can also stop at any time. Your child can stop by telling any adult on the study team. If your child says "yes" to the study now, they can also skip any questions in the surveys. Please note: If you or your child choose to stop participating, any data we have collected up until this point will still be a part of our analyses because we won't know whose responses are whose, as we are separating identifying information from specific question responses.

### **Who can I contact to ask questions about the study?**

If you have questions about this study or a question about your child's rights, please contact the study coordinator at MITRE, <<insert name>>. Call <<insert name>> at 1-800-334-8571 ext. [XXXX] or email <<insert name>> at <<insert email address>>.

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### Consent for Your Child to Join a Study

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

#### **Your child is invited to join a study.**

The [Name] program is a program in your community. You are receiving this form because you have enrolled your child in this program. The [Name] program is also part of a study about sexual and reproductive health of young people involved in health programs.

Next Steps: 1<sup>st</sup>: Read the details below. 2<sup>nd</sup>: Ask any questions you have. 3<sup>rd</sup>: Decide if you permit your child to join the study.

#### **What is a study? What is this study about?**

A study is a way to learn about a specific part of life. In this research study, we aim to gather generalizable knowledge about the sexual and reproductive health of young people. This study will provide knowledge to the field about the replicability of adolescent pregnancy prevention programs in new populations.

#### **What will my child do in the study?**

In the study, your child will complete 3 surveys and join 1 meeting called a focus group, in addition to their involvement in the [Name] program. During the [Name] program, sessions will be audio-recorded.

The surveys and focus groups will help us learn how the [Name] program affects youth, and the recordings will help us learn about the [Name] program. The surveys and focus groups give us a chance to learn from your child, and are not for testing or judging your child. You may view a copy of the questions from the surveys and the focus group by reaching out to the study team. The study team's contact information is listed on the other side of this paper. The questions in the surveys and focus group were made for young people 12 to 16 years of age. We will only share recordings and your child's survey and focus group answers with the study team. We will not share their voices or answers with you or with people in the [Name] program. This way, only your child and the study team will know how they answered the questions.

**Survey Details:** Survey questions are about your child, your family, and your child's behaviors. Some questions are about sexual health. They are about romantic relationships, pregnancy, and sexually transmitted infections. It takes about 50 minutes to finish each survey. If your child joins the study, the first survey will be delivered just prior to the beginning of the program, the second survey will be delivered upon completion of the program, and the 3<sup>rd</sup> and final survey will occur 3 months after the completion of the program. Each child will answer their survey on a separate computer or tablet.

**Focus Group Details:** The focus group is different from the surveys. Focus group questions are about your child's experience in the [Name] program. The focus group will take about 90 minutes. The focus group will take place in a nearby location that is private and quiet. The focus group will be audio recorded so the study team can remember what each person says. If your child decides to join the focus group, they will join other youth in the focus group about 1 to 2 weeks after the [Name] program ends. The study team will lead the focus groups. Up to 10 youth in the program will join the focus group. Everyone in the focus group will hear everyone's answers. The youth will receive instructions for

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keeping others' answers private if they need to talk with a trusted adult about the focus group.

### **What are the benefits of this study for my child?**

The surveys will help us learn what youth your child's age think, feel, and do. The focus groups will also help us learn about the thoughts, feelings, and actions youth experienced while in the [Name] program. Your child may like sharing their experiences.

### **What are the risks of this study for my child?**

Your child may feel embarrassed by some of the questions. Your child does not have to answer any questions they do not want to answer, and they do not need to talk during the class if they do not want to. Your child can go to the health educator(s) of the [Name] program <<insert name, insert details>> for support and additional resources. The study team can also help your child find a trusted adult to talk to about how they feel at any point in the study. There is a risk that other people might know that your child participated in the surveys or focus groups. There is a risk that youth in the focus group could share information they hear. Youth will receive instructions for keeping others' answers private if they need to talk with a trusted adult about the focus group.

### **How will you protect my child's information?**

We will keep all information we get about and from your child private. Only study team members will see this information. We will not share this information with you or with people in the [Name] program. The only time this rule will change is if your child tells us someone is in danger. Then we have to tell someone whose job it is to keep your child or others safe.

Surveys will not ask for your child's name or address. We will use special numbers instead of their name to keep your child's identity private. We will also do this for the information the [Name] program gives us if your child joins the study.

Your child's information will be stored in safe data system that only the study team can access. If we need to share your child's information with each other, we will take extra steps to protect it. These steps will involve using a code for the data and extra passwords only the study team will know.

### **What will happen to my child's information after the study is ends?**

When the study ends, the study team will delete your child's name, birthdate, and address from our records. The rest of their information will be considered "de-identified." This means it cannot be linked to your child. We may use this de-identified information for future studies and publications.

We will also share the de-identified data with the U.S. Department of Health and Human Services.

### **Can my child say "no" to joining the study?**

You get to decide if it is okay with you for your child to join the study. Your child also gets to decide if they want to join the study. Even if you say "yes" now, you may change your mind and have your child quit at any time. Your child can also quit at any time. Your child can quit by telling any adult involved with the [Name] program or on the study team. If your child says "yes" to the study now, they can also skip any questions in the surveys or focus group.

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Remember that the [Name] program is separate from the study. Your child can participate only in the [Name] program. Or, they can participate in the [Name] program and the study. Your child is still part of the program even if they do not join the study.

### **Who can I contact to ask questions about the study?**

If you have questions about this study or a question about your child's rights, please contact the study coordinator at MITRE, <<insert name>>. Call <<insert name>> at 1-800-334-8571 ext. [XXXX] or email <<insert name>> at <<insert email address>>.

## Appendix B. Consent Form- Program Group Parent/Guardian Consent

Please read the information below. Be sure you understand what the study is about. Ask the study team any remaining questions you may have. Then, check the boxes that match your decisions. Lastly, sign your name. You must be a legal parent/guardian of your child to sign this form.

We will give you a copy of this document for you to keep. We will also keep a copy with the study records.

Today's Date: \_\_\_\_\_

Please print your child's name: \_\_\_\_\_

Please check each box if you agree:

I understand what the study is about and my questions have been answered.

I understand my child can stop being a part of the study at any time.

I understand my child can stop taking the surveys and/or leave the focus group at any time.

Please check one box in column **A**, one box in column **B**, and one box in column **C**

Please sign your name: \_\_\_\_\_

Please provide your phone number: \_\_\_\_\_

