Official Title: Prevention of Substance Use in At-Risk Students: A Family-Centered Web Program

NCT Number: NCT03060291

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Informed Consent Document and Child Assent Document



University of Oregon Child and Family Center The Middle School Success Online Study (MS-SOS)

Parent Consent Form

- You are being asked to participate in the Middle School Success Online Study (MS-SOS!) because you are the parent of a 6th or 7th grade student at one of the middle schools that are participating in this project.
- This study is funded by the National Institute on Drug Abuse (NIDA).
- The purpose of this study is to test the effectiveness of a web-based parenting curriculum for parents of middle school-aged youth. This curriculum provides parents with information and support to improve their child's chances of academic and behavioral success in middle school.
- For this study, we will ask you and your child to complete surveys. We may also invite you to use our website and resources.
- We expect a total of about 700 participants (including parents and children) to enroll in this study.

Carefully read each section below to learn about the parts of the study, the risks and benefits, and your rights as a research participant.

THE PARTS OF THE STUDY:

- Baseline surveys: You and your child will each be asked to complete a survey that takes about 30 minutes to complete and can be returned by mail. Your survey asks questions about your child and your family. Your child's survey asks questions about his/ her personality, health, family life, and school life. You are asked not to view your child's answers in order to maintain his/ her privacy.
- **Group selection:** After completing surveys, your family will be randomly selected to be in one of 3 groups. This process is like drawing names out of a hat.
 - <u>Web/ mobile-only</u>: Parents in this group will be asked to log-in and explore a website that offers an online parenting program. This website includes an additional survey, similar to the paper one completed by mail. Once the online survey is completed, the website provides feedback and parenting resources. This parenting program includes parenting tips, videos, and interactive tools.
 - Web/ mobile + coach: Parents in this group will be offered the same online program <u>plus</u> the opportunity to discuss parenting with a family coach. These meetings will occur over the phone, and there will be a minimum of two meetings.
 - Waitlist web/ mobile-only: Parents in this group will be given the same opportunities and resources as the web/mobile only group starting 12 months after completion of the initial paper survey.
- Follow up surveys: To help researchers understand how children and families may change after using parenting resources, you and your child will each be asked to complete paper surveys identical to the baseline (paper) surveys 3 times over the next year. You will be asked to complete these surveys 3 months, 6 months, and 12 months from now. These surveys will also take about 30 min. to complete and can be returned by mail.

COMPENSATION:

- Your family can earn up to \$450 for participating in this research study.
 - o \$100 at Baseline: Your family will receive \$100 after you complete the parent and child surveys.
 - \$100 after 3-month Follow-up: Your family will receive \$100 after you complete the parent and child surveys at the 3-month follow-up.
 - o \$100 after 6-month Follow-up: Your family will receive \$100 after you complete the parent and child surveys at the 6-month follow-up.
 - o \$100 after 12-month Follow-up: Your family will receive \$100 after you complete the parent and

- child surveys at the 12-month follow-up.
- \$50 Bonus: Your family will receive a \$50 bonus if you complete parent and child surveys at all 4 time points.

POSSIBLE RISKS INVOLVED IN THIS STUDY:

- You may feel some discomfort while completing the forms or while talking with study staff members.
- You will be asked for some personal information and there is always the possibility that someone who is not authorized might see it.

HOW RESEARCHERS PROTECT YOUR PRIVACY:

- Access to surveys will be limited to the project staff members.
- All surveys will be kept in locked files.
- All electronic information is coded & secured using a password protected file on a secure server.
- Your name will be removed from all information you give us (except your name on this consent form). We will replace your name with a unique Study ID number.
- Only authorized staff will have access to the key that links your name to your Study ID number.
- When researchers report the results of the study they will describe group results without identifying the results of any individual study participants.
- The only reason research staff would share your name with anyone is if we think someone is being abused or plans to harm themselves. Research staff members are required by the State of Oregon to report this information.
- The Department of Health and Human Services (DHHS) will issue a Certificate of Confidentiality to our project through the University of Oregon. This Certificate will protect the project staff from being forced to release any research data about you. This protects you and our participating families from being identified in any civil, criminal, administrative, legislative, or other proceedings whether federal, state, or local. This protection, however, is not absolute. For example, the investigators will report child abuse as stated above to the appropriate authorities. Because this research is sponsored by the National Institute on Drug Abuse, their staff may review records that identify you. However, it is the policy of these agencies and of the project staff that every attempt will be made to resist demands to release information that identifies you. When results of this project are published, your name will not be used. The Certificate of Confidentiality does not represent an endorsement of this research project by the Secretary of Health and Human Services.
- Part of this project involves data collected through a website. All information sent over the internet is at risk for security breaches.
 - To reduce the chances that any information you send will be seen by an unauthorized person, researchers will use an industry-standard encryption tool called Secure Socket Layers (SSL).
 - The research team may send you emails or text messages. These items are also not completely secure.
 To reduce the chances of other people seeing messages intended for you, it is important for you to use your own personal email and text message accounts.

BENEFITS OF TAKING PART IN THIS STUDY:

- You may enjoy thinking about the research process and knowing that you am contributing to a project that will help many families of middle school-aged youth.
- You may learn helpful tips that enhance your parenting and help your child be more successful in school.

YOUR RIGHTS AS A RESEARCH PARTICIPANT:

- You are a volunteer in this study and you may stop participating at any time. You may choose to not answer any questions or complete any parts of the study that you don't want to do.
- If you have any questions or concerns about your participation, or if you wish to drop out of the study for any reason, you can contact the Project Coordinator, Dr. Allison Caruthers, at 503-412-3770 or ascaru@uoregon.edu.
- If you have any questions about your rights as a research subject, you may contact the Research Compliance Services Office, University of Oregon at (541-346-2510) or ResearchCompliance@uoregon.edu

I agree to participate in the Mid I have been given a copy of this		ly.
Parent Name (please print clearl	y):	
Child's name (please print clearly	y):	
Parent Signature:		Date:
families grow and change during move before the study ends, mait much easier for us to find faminumbers in a database to obtain project staff, this information widestroyed no later than 5 years at lagree to provide my Driver's Li	Is that time. From our work on conking it difficult to locate them for the state of	ear and collect information about how children and other studies like this, we know that families may for follow-up data collection and services. It makes r's License number. We are able to use these bers. Like all other information you provide to password-protected files on a secure server and staff more easily relocate my family if we become information will be kept private and stored in
Parent Signature:		Date:
Driver's License Information:		
State:	Number:	
No, I do not want to provid	de my Driver's License number	at this time.

University of Oregon Child and Family Center

The Middle School Success Online Study (MS-SOS)
Student Assent Form

- You are being asked to participate in the Middle School Success Online Study (MS-SOS!) because you are a student at one of the middle schools that are participating in this project.
- This study is funded by the National Institute on Drug Abuse (NIDA).
- The purpose of this study is to look at different ways that parents can help their kids succeed in middle school.
- We will ask you to answer a set of questions 4 times over the next 12 months. Each time it will take you about 30 min. to complete. These questions ask about your personality, health, family, and school life. Your parents will not have access to your answers.
- We expect about 700 participants (parents and children) to enroll in this study.

As a participant in this study...

- I understand that I may feel some discomfort while completing the forms or while talking with study staff members.
- I understand that I will be asked for some personal information and there is always the possibility that someone who is not authorized might see it.
- I understand that all of the information I give to the researchers on the project will be kept private.
 - Access to all surveys is limited to the project staff members.
 - All surveys are kept in locked files.
 - All electronic information is coded and secured using a password protected file on a secure server.
 - Other than my signature on this assent form, my name will be removed from all information I give them and I will be assigned a unique ID number.
 - Only authorized staff will have access to link my name to my ID number.
- I understand that the only reason research staff would share my name with anyone is if they think someone is being abused or plans to harm themselves. Research staff members are required by the State of Oregon to report this information.
- I understand that I may be helping my family and other families by participating in this project.
- I understand that I am a volunteer in this project and I may stop at any time.
- If I have any questions or concerns about my participation, or if I wish to drop out of the study for any reason, I can contact the Project Coordinator, Dr. Allison Caruthers, at 503-412-3770 or ascaru@uoregon.edu.
- If I have any questions about my rights as a research subject, I may contact the Research Compliance Services Office, University of Oregon at (541-346-2510) or ResearchCompliance@uoregon.edu
 - ✓ I agree to participate in the Middle School Success Online Study.
 - ✓ I have been given a copy of this assent form.

Student Name (please print clearly):		
Student Signature:	Date:	