

INFORMED CONSENT

The Rewire Study (Mindfulness Mobile App to Reduce Adolescent Substance Use)

Grant Number/Protocol ID: 1R43DA043288-01

Clinical Trials.gov ID: NCT03533491

Federal Award Date: 4/17/2017

Rewire Study
at Influents Innovation
 (a partner of Oregon Research Institute)
Statement of Informed Consent

Your teen is invited to take part in a research study which will test an app (a software program used on a phone or tablet) that helps teens reduce stress and make healthy decisions about behavior and avoiding substance use. This study is being conducted by Dana K. Smith, PhD at Influents Innovation in Eugene, Oregon and is funded by the National Institute for Drug Abuse (NIDA). We want everyone in the study to understand what it is about. Please read this form and ask any questions you may have before agreeing to let your teen participate in the study.

What will your teen be asked to do if s/he chooses to be in the project?

Your teen will be asked to complete 3 surveys for the Rewire Study. For the first survey, your teen will come to Oregon Research Institute for about an hour. Your teen will complete some questionnaires about his or her behavior and use of alcohol and drugs. A staff member will help your teen load the mobile app onto his or her phone and provide instructions for how to use it. Your child will receive text message reminders about using the app. After 2 weeks, your son or daughter will receive an emailed link to the second survey. This survey will be completed on a computer, tablet, phone or other mobile device by your teen and will take about 20 or 30 minutes. It will also ask questions about behavior, emotions and substance use, and feedback on potential modifications to the app. After another 6 weeks, your teen will receive the link to the third and final survey, which will ask similar questions and will also take 20 or 30 minutes. We ask that these surveys be completed within 3 days of receiving the link.

The study will also collect a urine sample from your daughter or son during the visit to Oregon Research Institute. The urine will be checked for the presence of drugs. The results will never be shared with anyone, including you, your daughter or son, or anyone else. The urine samples will be destroyed after testing. Your teen may be randomly selected and asked for a second urine sample during the two months that s/he is involved in the study. Teens who complete a random UA will receive an additional gift card.

All participants will receive checks or gift cards of \$20 for completing each survey. Teens will have a choice of gift cards (e.g., iTunes, Amazon, Subway or Target). A bonus gift card of \$25 is given after the final survey.

Activity	Description	How long	Received
First Assessment	Meet at ORI to complete first survey and install app on phone	About 1 hour	\$20
Using the App	Complete all 4 modules on 4 different days Complete daily check-ins	About 5-10 minutes per day	
2 Week Assessment	Complete second survey using computer or mobile device	About 20-30 minutes	\$20
2 Month Assessment	Complete final survey using computer or mobile device	About 20-30 minutes	\$20
Bonus	Given after completing third and final assessment		\$25
	TOTAL		\$85

As a participant in this project, there are a few risks to your teen:

- We will be getting personal information from your teen. There is always the possibility that someone who is not authorized may see some personal information, even though we strive to protect it. We take the following precautions to prevent any unauthorized person from having any access to the information your teen gives us: Any information you or your child gives us will be kept strictly confidential, even from other members of your own family. Parents will not have access to their children's information. We will remove all names from all the information we get (except this consent form). We assign an ID# to the information your teen gives us, and only authorized staff will have access to the key that links your teen's name to her/his ID#. All information will be kept in locked filing cabinets and password-protected computer files.
- ORI will be asking your teen some personal questions about her/his feelings and experiences. Your teen might feel a little embarrassed or uncomfortable because of the personal nature of some of the questions. Remember, your teen is free to say 'No' to any questions or activities.
- ORI staff will do all we can to protect your confidentiality. However, because your teen is a client of DYS, others in DYS might be able to figure out that you are in this study.

If you feel uncomfortable or you want to talk to someone about any of these risks, please let us know or contact project staff at 541-484-2123.

How will your privacy (or confidentiality) be protected?

Confidentiality means that we will do all we can to keep everything about you and your family completely private. In order to protect your privacy:

- We use numbers instead of names on all of the information we collect so that no one can tell who it is about.
- We allow only a small number of project staff members to have access to records that identify you. In some cases, The National Institute of Drug Abuse, the agency responsible for and funding this project, might see information about you as part of their review of our project. They are also required to protect your confidentiality.
- We train all staff members to protect your privacy.
- We store all information in safe, locked areas.
- We will not give any of the information we get about you to anyone without your permission and we will not tell you anything about others in the project, including your family members.
- We write papers, make presentations, and work with other education or research centers using the information from the project for scientific purposes only, but ORI will never use names or other information that could identify anyone in the project.
- We have received a "Certificate of Confidentiality", a legal assurance from the federal government, which will help us protect your privacy even if the records are subpoenaed. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

Are there any times when your information might be shared with others?

Yes. There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse reported by the researcher
- if the investigator reports cases of contagious disease (such as HIV) to the state."

What are the benefits to your teen as a participant?

ORI research is well respected and well known in the U.S. as well as in other countries. The studies we do improve our knowledge about people's health and behavior. The information gained from this project might help us understand more about teens in the juvenile justice system and the tools that help them feel confident and make choices that promote their success.

What if your teen starts the project but does not finish it?

Your teen's participation is entirely voluntary. You can decide not to participate at any time without penalty.

How do I find more information?

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call Holly or Erika at 541-484-2123. If you have questions about your rights as a research subject, please call the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900. You will be given a copy of this form to keep.

Your signature below indicates that you:

- have read and understand the information provided in the Statement of Informed Consent for the Rewire Study at Influents Innovation/Oregon Research Institute
- willingly agree to allow your child to participate
- understand that you may withdraw your consent and stop your child's participation at any time without penalty
- have received a copy of this consent form

I have the legal authority to give consent for my child to take part in this program because I am her/his biological or adoptive parent or legal guardian and I have sole or joint legal custody of her/him.

Teen's Full Name

Teen's Birthday

Parent/Guardian Signature

Parent/Guardian Name (Please Print)

Date

Parent/Guardian Phone Number

Parent/Guardian Email

I understand the research project as described above and I agree to participate.

Teen Signature

Teen Name (Please Print)

Date

Teen Phone Number

Teen Email

Teen Facebook

Gift Card preference